FRAMEWORK AGREEMENT AND TERMS AND CONDITIONS

The Authority	The NHS Commissioning Board (Operating Under the Name of NHS England) whose principal office is at Quarry House, Leeds.
The Supplier	**Shire Pharmaceuticals Limited** Whose registered office is at: 1 Kingdom Street, London, W2 6BD ('the Supplier')
Commencement Date	
Type of Goods	**Products for the treatment of Haemophilia A**
Contract Reference	**CM/PHS/17/5564**

The Authority placed a contract notice 2020/S 040-095840 on 26 February 2020 in the Official Journal of the European Union inviting potential service providers (including the Supplier) to tender for the provision of Products for the treatment of Haemophilia A (divided into Lots) to Participating Authorities identified in the contract notice under framework agreements.

On the basis of the Supplier's Offer, the Authority selected the Supplier to enter a framework agreement(s) to provide goods to those Participating Authorities who place Orders for Products for the treatment of Haemophilia A in accordance with this Framework Agreement.

This Framework Agreement is made on the date set out above subject to the terms set out in the schedules and appendix listed below ("**Schedules**"). The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of this Framework Agreement.

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

Schedules

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Information and Data Provisions
Schedule 4	Definitions and Interpretations
Schedule 5	Specification
Schedule 6	Award Schedule
Schedule 7	Ordering Procedure

Schedule 8	Participating Authorities
Appendix A	Call-off Terms and Conditions for the Supply of Goods

Schedule 1

Key Provisions

Standard Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 7 of this Schedule 1 shall apply to this Framework Agreement.

1.2 The optional Key Provisions at Clauses 8 to 10 of this Schedule 1 shall only apply to this Framework Agreement where they have been checked and information completed as applicable.

1.3 Extra Key Provisions shall only apply to this Framework Agreement where such provisions are set out at the end of this Schedule 1.

2 Duration and scope

2.1 In relation to each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule, the terms of this Framework Agreement shall:

2.1.1 apply with effect from the effective date specified in the Award Schedule for that Good in Lot 1, Lot 2, Lot, 3 and Lot 4 ("the **Effective Date**"); and

2.1.2 unless terminated earlier in accordance with the terms of this Framework Agreement or the general law, shall continue to apply until the expiry date specified in the Award Schedule for that Good in Lot 1, Lot 2, Lot 3 and Lot 4 ("the **Expiry Date**") unless the Authority elects to exercise its option to extend in accordance with Clause 15.2 of Schedule 2.

2.2 Insofar as the terms of this Framework Agreement apply to each Good Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule (as described in Clause 2.1 of this Schedule 1), the Parties agree that:

2.2.1 each set of terms as they apply to each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule shall be a framework agreement within the meaning of Regulation 33(2) of the Regulations; and

2.2.2 for the purposes of Regulation 33 of the Regulations, the term of each such framework agreement shall be the period commencing on the Effective Date and ending on the Expiry Date for that Good in Lot 1, Lot 2, Lot 3 and Lot 4, unless the framework agreement is terminated

earlier or unless the Authority elects to exercise its option to extend the framework agreement.

2.3 In relation to each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule, the Supplier shall ensure that it is able to fulfil Orders placed at any time on or after the Effective Date.

3 Contract Managers

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

3.1.1 for the Authority:

Karen Bell – Senior Operations Advisor and Commercial Practitioner

3.1.2 for the Supplier:

Sam Williams – Tender and Pricing Manager

4 Names and addresses for notices

4.1 Notices served under this Framework Agreement are to be delivered to:

4.1.1 for the Authority:

Karen Bell, Senior Operations Advisor and Commercial Practitioner, Commercial Medicines Unit, 2nd Floor, Rutland House, Runcorn, Cheshire, WA7 2ES

4.1.2 for the Supplier:

Sam Williams, Tender and Pricing Manager, Shire Pharmaceuticals Ltd, 1 Kingdom Street, London, W2 6BD

5 Management levels for escalation and dispute resolution

5.1 The management levels at which a dispute will be dealt with are as follows:

Level	Authority representative	Supplier representative
1	Contract Manager	Tender & Pricing Manager
2	Category Manager	Business Unit Director

3	**Lead Category Manager**	**Managing Director**

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 Framework Agreement the order of priority for construction purposes shall be:

6.1.1 the provisions on the front page (page 1) of this Framework Agreement for the Supply of Goods;

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 5: Specification;

6.1.4 Schedule 2: General Terms and Conditions;

6.1.5 Schedule 6: Award Schedule;

6.1.6 Schedule 3: Information and Data 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 Framework Agreement 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.

7 Participating Authorities

7.1 The Contracting Authorities referred to in Schedule 8 are entitled to place Orders.

Optional Key Provisions

8 Quality assurance standards ☐ (only applicable to the Framework Agreement if this box is checked and the standards are listed)

8.1 The following quality assurance standards shall apply, as appropriate, to the manufacture, supply, and/or installation of the Goods:

9 Different levels and/or types of insurance ☐ (only applicable to the Framework Agreement if this box is checked and the table sets out the requirements. If this box is not checked then the insurance provisions at Clause 14 of Schedule 2 will apply)

9.1 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

10 Guarantee ☐ (only applicable to the Framework Agreement if this box is checked)

10.1 Promptly following the execution of this Framework Agreement, and if required by the Authority, 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 Framework Agreement.

Extra Key Provisions

11 Price Variations

11.1 For each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule, on the expiry of the Price Firm Period for such Good the Authority may review the Contract Price payable for the Good:

11.1.1 at its own instigation; or

11.1.2 following a request from the Supplier no later than thirty (30) Business Days before the expiry of the Price Firm Period (as defined in Clause 11.8 of this Schedule 1), provided that the Supplier can demonstrate to the satisfaction of the Authority that there have been changes to the market, supplier's manufacturing, distribution and supply costs in connection with the provision of the Good since the previous Review (if any)

(each such review being a "**Review**" for the purposes of this Clause 11 of this Schedule 1).

11.2 The Authority shall be entitled to increase or decrease the price of the Good in the event that the Contract Price does not in the sole opinion of the Authority (acting reasonably) reflect the principal underlying costs (including, but not limited to, wage costs, fuel costs and energy costs) necessarily and properly incurred by the Supplier in connection with the manufacture and distribution of such Good(s). For the avoidance of doubt the Parties accept and acknowledge

that any changes to the Contract Price shall not have the effect of altering the overall nature of this Framework Agreement.

11.3 In reviewing the Contract Price pursuant to Clause 11.1 of this Schedule 1, and subject always to Clause 11.4 of this Schedule 1, the Authority may have regard to the following factors:

11.3.1 any changes to the Supplier's manufacturing, distribution and supply costs, to the extent that such costs are necessary and properly incurred by the Supplier in the provision of the Good;

11.3.2 the prices at which goods which are reasonably equivalent to the Good are supplied by other suppliers in the open market;

11.3.3 prices payable by other health authorities and NHS Trusts for goods which are reasonably equivalent to the Good; and/or

11.3.4 the volumes of the Good ordered by, and supplied to, the Participating Authorities.

11.4 The Supplier shall provide all such evidence to the Authority as the Authority may reasonably request. Such evidence shall be provided by the Supplier to the Authority on a transparent basis, reference publicly available sources of evidence where appropriate, and shall be sufficient to enable the Authority to verify and substantiate any changes to the costs of the Supplier in connection with the provision of the Good. In addition, the Supplier shall, on request, allow the Authority to inspect and take copies of (or extracts from) all relevant records and materials of the Supplier relating to the supply of the Good as may be reasonably required.

11.5 The Authority shall endeavour (but shall not be obliged to) to complete the Review within thirty (30) days from the commencement of the Review. Upon completion of the Review by the Authority, the Authority may elect to:

11.5.1 increase the price of the Good by giving the Supplier not less than three (3) months' written notice of such increase; or

11.5.2 decrease the price of the Good by giving the Supplier not less than one (1) month's written notice of such decrease

(in both cases the relevant notice being "the **Review Notice**") and the Review Notice shall stipulate the new prices as varied pursuant to the Review ("the **Revised Contract Price**") and the reasons for this. The Supplier shall be entitled to supply the Good at the Revised Contract Price upon expiry of the Review Notice (unless the Supplier serves notice to terminate under Clause 11.6 of this Schedule 1 in which case Clause 11.7 of this Schedule 1 shall apply).

11.6 The Supplier may terminate this Framework Agreement by giving to the Authority not less than four (4) months' notice in writing, such notice to be given within fourteen (14) days of its receipt of a Review Notice under Clause 11.5 of this Schedule 1.

11.7 For the avoidance of doubt, if the Supplier serves notice to terminate under Clause 11.6 of this Schedule 1:

11.7.1 until such notice expires, the prices shall remain fixed at the price payable immediately preceding the Review; and

11.7.2 the Supplier shall be obliged to supply the Goods in accordance with the terms of this Framework Agreement and any order that may be placed prior to the date of termination.

11.8 For the purpose of this Clause 11 of this Schedule 1, for each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule, the "**Price Firm Period**" means:

11.8.1 in the case of the first Review to be carried out by the Authority, the period commencing on the Commencement Date and ending on the initial framework period for that Good; or,

11.8.2 in the case of the second or any subsequent Review to be carried out by the Authority, a consecutive period of no less than six (6) months following the last Review and at six (6) monthly intervals thereafter.

11.9 For the avoidance of doubt, the second and any subsequent Review thereafter may be conducted (in accordance with this Clause 11 of this Schedule 1) irrespective of whether the first Review was conducted.

12 Additional Goods

12.1 Subject to Clauses 12.2 to 12.4 of this Schedule 1, additional goods may be added to this Framework Agreement by the Supplier during the Term if they are within the same product range as any existing Goods supplied from time to time under this Framework Agreement. Additional goods will be deemed to be within such product range if they are made with the same active ingredient(s) and the Supplier is the sole source of supply of such additional goods.

12.2 If the Supplier wishes to add additional goods to this Framework Agreement, it shall submit a proposal to the Authority in writing stating the identity and Contract Price of the additional goods.

12.3 The Authority shall inform the Supplier in writing if the additional goods (being the subject matter of the notice given by the Supplier under Clause 12.2 of this Schedule 1) are to be added to the Framework Agreement and the date of such addition. The Authority reserves the right not to add the additional goods to this Framework Agreement for any reason whatsoever.

12.4 The Contract Price of the additional goods shall be the price offered by the Supplier under Clause 12.2 of this Schedule 1.

12.5 Where additional goods are added to this Framework Agreement such additional goods shall be deemed to form part of the Goods for the purposes of interpretation of this Framework Agreement and the Call-off Terms and Conditions.

13 Price Guarantee Provisions

13.1 The Supplier acknowledges and agrees that the Authority has entered into this Framework Agreement on the basis of the pricing information supplied to and accepted by the Authority as specified in the Award Schedule. The Supplier shall not charge for Goods the subject of this Framework Agreement to Participating Authorities at a lower price than has been accepted by the Authority as specified by the Supplier in the Award Schedule unless it is in accordance with Clause 12 of this Schedule 1.

13.2 If the Supplier charges for Goods the subject of this Framework Agreement to a Participating Authority at a lower price than that specified in the Award Schedule, in breach of Clause 13.1 of this Schedule 1, this breach shall be deemed to be a material breach of this Framework Agreement, and shall entitle the Authority to terminate this Framework Agreement in accordance with Clause 15.4 of Schedule 2 of this Framework Agreement.

13.3 The right to terminate this Framework Agreement given by Clause 13.2 of this Schedule 1 shall be without prejudice to any other right or remedy of the Authority in respect of the breach concerned or any other breach.

13.4 The Authority may, at its sole discretion, decide to accept the Supplier's breach of Clause 13.1 of this Schedule 1 and instead of terminating this Framework Agreement the Authority shall substitute the lower price offered by the Supplier in breach of Clause 13.1 of this Schedule 1 for the original price specified in the Award Schedule.

13.5 Any waiver by the Authority of Clause 13.2 of this Schedule 1, pursuant to Clause 13.4 of this Schedule 1, shall not be considered as a waiver of any subsequent breach of the same or any other provision of this Framework Agreement.

13.6 Where the Contract Price is or may become subject to any pricing requirements of any voluntary scheme agreed with government and/or statutory pricing regulation, the Parties shall comply with such 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.

14 Further Termination Rights

14.1 The Supplier may terminate this Framework Agreement in whole (in relation to all of the Goods) or in part (in relation to any particular Good(s)) by giving one hundred and twenty (120) days' written notice to the Authority to such effect.

14.2 The Authority may terminate this Framework Agreement in whole (in relation to all of the Goods) or in part (in relation to any particular Good(s)) by giving ninety (90) days' written notice to the Supplier to such effect.

14.3 For the avoidance of doubt, in the event that either party gives notice to terminate this Framework Agreement in whole or part under Clause 14.1 or Clause 14.2 of this Schedule 1, the Supplier shall supply the Goods in accordance with the terms of this Framework Agreement pursuant to any Order that may be placed by, or on behalf of, Participating Bodies, prior to the expiry of such termination notice.

15 Additional warranties

15.1 In addition to the warranties set out at Clause 10 of Schedule 2 of this Framework Agreement, the Supplier warrants and undertakes that the Goods will pass any reasonable and proportionate tests and trials required by the Authority (whether carried out by the Authority or by a third party on behalf of the Authority) to satisfy the Authority that the Goods are not injurious to health and/or meet the specifications or any samples of the Goods provided to the Authority during the procurement process leading to the establishment of this Framework Agreement.

Schedule 2

General Terms and Conditions

Contents

1 Supplier's appointment

1.1 The Authority appoints the Supplier as a potential supplier of the Goods and the Supplier shall be eligible to be considered for the award of Orders during the Term.

1.2 In consideration of the Authority agreeing to appoint the Supplier to this Framework Agreement in accordance with Clause 1.1 of this Schedule 2 and the mutual exchange of promises and obligations under this Framework Agreement, the Supplier undertakes to supply Goods under Orders placed with the Supplier:

1.2.1 of the exact quality, type and as otherwise specified in the Specification;

1.2.2 at the Contract Price calculated in accordance with the Award Schedule; and

1.2.3 in such quantities, at such times and to such locations as may be specified in an Order.

1.3 The Supplier agrees that the Call-Off Terms and Conditions for the Supply of Goods shall apply to all supplies of Goods made by the Supplier to a Participating Authority pursuant to this Framework Agreement. The Supplier agrees that it will not in its dealings with a Participating Authority seek to impose or rely on any other contractual terms which in any way vary or contradict the relevant Contract.

1.4 The Supplier shall comply fully with its obligations set out in this Framework Agreement, the Specification, the Call-off Terms and Conditions for the Supply of Goods and any other provisions of Contracts entered into under and in accordance with this Framework Agreement (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery and installation and training in relation to use of the Goods).

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

1.6 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.5 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.

1.7 In complying with its obligations under this Framework Agreement, 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.

2 Authority commitments

2.1 Unless otherwise set out in the Award Schedule, the Supplier acknowledges that:

2.1.1 there is no obligation on the Authority or on any other Participating Authority to purchase any Goods from the Supplier during the Term;

2.1.2 no undertaking or any form of statement, promise, representation or obligation has been made by the Authority and/or any other Participating Authority in respect of the total quantities or value of the Goods to be ordered by them pursuant to this Framework Agreement and the Supplier acknowledges and agrees that it has not entered into this Framework Agreement on the basis of any such undertaking, statement, promise or representation;

2.1.3 in entering this Framework Agreement, no form of exclusivity has been granted by the Authority and/or other Participating Authority;

2.1.4 the Authority and/or other Participating Authorities are at all times (including during the Term of this Framework Agreement) entitled to enter into other contracts and framework agreements with other suppliers and/or the Supplier for the provision of any or all goods which are the same as, equivalent, partially equivalent or similar to the Goods; and

2.1.5 the Authority shall have no liability to it in respect of or arising out of the volume of Orders received by the Supplier during the continuance of this Framework Agreement.

3 Ordering procedure

3.1 Any Participating Authority may enter into Contracts by placing an Order in accordance with the Ordering Procedure.

4 Reasonable assistance

4.1 Upon the written request of any Participating Authority, the Supplier shall provide such Participating Authority with any reasonable and proportionate information that it holds about the Goods it supplies under this Framework Agreement including, without limitation, the compatibility and interoperability of such Goods with other products, to enable the Participating Authority to complete any necessary due diligence before purchasing such Goods.

5 Supplier performance

5.1 The Supplier shall perform all Contracts entered into under this Framework Agreement by the Authority or any other Participating Authority in accordance with:

5.1.1 the requirements of this Framework Agreement; and

5.1.2 the provisions of the respective Contracts.

6 Business continuity

6.1 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:

6.1.1 the criticality of the procurement of medicines to the Participating Authorities; and

6.1.2 the impact of and any disruption caused by EU exit;

6.1.3 any reasonably foreseeable risks; and

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

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

6.2 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 Framework Agreement to Participating Authorities 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 6.2 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.

6.3 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.

6.4 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.

6.5 During and following a Business Continuity Event, the Supplier shall use reasonable endeavours to continue to fulfil its obligations in accordance with this Framework Agreement.

7 The Authority's obligations

7.1 The Authority shall provide reasonable cooperation to the Supplier and shall, as appropriate, provide copies of or give the Supplier access to such of the Policies that are relevant to the Supplier complying with its obligations under this Framework Agreement.

7.2 The Authority shall comply with the Authority's Obligations, if any.

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 Framework Agreement. 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 this Framework Agreement. 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 to review the performance of the Supplier under this Framework Agreement and to discuss matters arising generally under this Framework Agreement. Each Party shall ensure that those attending such meetings have the authority to make decisions regarding the day to day operation of the Framework Agreement. Review meetings shall take place at the frequency specified in the Specification or (should the Specification not state the frequency) whenever deemed necessary by the Authority and agreed in writing between the Parties.

8.3 Two weeks prior to any review meeting (or at such time and frequency as may be specified in the Specification) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods and the operation of this Framework Agreement. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:

8.3.1 details of the performance of the Supplier under this Framework Agreement and any Contracts when assessed in accordance with the KPIs, as relevant to the Framework Agreement and any Contracts, since the last such performance report;

8.3.2 details of any complaints by Participating Authorities 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 Specification as being relevant to the operation of this Framework Agreement;

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, the Authority may (at its sole discretion) take minutes of each review meeting and circulate draft minutes to the Supplier within a reasonable time following such review meeting. If the Authority elects to take minutes of the review meeting and circulate them to the Supplier, 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 Parties will each produce minutes of the review meeting and shall retain a copy of such minutes for its own records.

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 ordered and any payments made under this Framework Agreement or any Contracts and any other information relevant to the operation of this Framework Agreement.

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 Framework Agreement 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

9.1 The Contract Price for all Contracts shall be calculated as set out in the Award Schedule and the payment provisions for all Contracts shall be as set out in the Call-off Terms and Conditions for the Supply of Goods.

9.2 Where any payments are to be made under this Framework Agreement by either Party in addition to any payments to be made by Participating Authorities under any Contracts, the details of such payments and the invoicing arrangements shall be set out in the Award Schedule.

10 Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 it will comply with the terms of all Contracts entered into by Participating Authorities under this Framework Agreement;

10.1.2 it will promptly respond to all requests for information regarding this Framework Agreement, the Goods and any Contracts at the frequency and in the format that the Authority may reasonably require;

10.1.3 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 Framework Agreement (to include, without limitation, as referred to in the Specification and Terms of Offer) and all accompanying materials is accurate;

10.1.4 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations required to enter into and comply with its obligations under this Framework Agreement;

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

10.1.6 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 Framework Agreement and the documents referred to in this Framework Agreement;

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

10.1.8 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;

10.1.9 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Framework Agreement;

10.1.10 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Framework Agreement;

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

10.1.12 it has satisfied itself as to the nature and extent of the risks assumed by it under this Framework Agreement and has gathered all information necessary to perform its obligations under this Framework Agreement and all other obligations assumed by it;

10.1.13 it shall:

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

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

10.1.14 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 10.1.14 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

10.2 The Supplier warrants that all information, data and other records and documents required by the Authority as set out in the Specification and Terms of Offer shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Terms of Offer.

10.3 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.

10.4 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:

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

10.4.2 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.

10.5 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.

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

11 Statutory compliance

11.1 The Supplier shall comply with all Law and Guidance relevant to its obligations under this Framework Agreement and any Contracts.

11.2 Without limitation to Clause 11.1 of this Schedule 2, the Supplier shall be responsible for obtaining any statutory licences, authorisations, consents or permits required in connection with its performance of its obligations under this Framework Agreement and any Contracts.

12 Independence of Participating Authorities

12.1 The Authority has established this Framework Agreement as a central purchasing body for and on behalf of such Participating Authorities as may from time to time be Participating Authorities.

12.2 The supply contracts resulting from any Orders will be between the Supplier and the Participating Authorities concerned and the Authority shall not be a party to such supply contracts. The Supplier acknowledges that each

Participating Authority is independently responsible for the conduct of its award of Contracts under this Framework Agreement and that the Authority is not responsible or accountable for and shall have no liability whatsoever in relation to:

12.2.1 the conduct of Participating Authorities other than the Authority in relation to the operation of this Framework Agreement; or

12.2.2 the performance or non-performance of any Participating Authorities other than the Authority under any Contracts between the Supplier and such other Participating Authorities entered into under this Framework Agreement.

13 Limitation of liability

13.1 Nothing in this Framework Agreement 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;

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

13.1.4 to make any payments agreed in accordance with Clause 9.2 of this Schedule 2; or

13.1.5 under Clause 2.5 of Schedule 3.

13.2 Subject to Clause 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 Framework Agreement whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to five hundred thousand GBP (£500,000).

13.3 There shall be no right to claim losses, damages and/or other costs and expenses under or in connection with this Framework Agreement 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.

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 Framework Agreement.

13.5 The liability of the Supplier and any Participating Authorities under any Contracts entered into pursuant to this Framework Agreement shall be as set

out in the Call-off Terms and Conditions for the Supply of Goods forming part of such Contracts.

14 Insurance

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 (in each case) 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.

14.4 The amount of any indemnity cover and/or self insurance arrangements shall not relieve the Supplier of any liabilities under this Framework Agreement. 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 Framework Agreement. 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 Framework Agreement, the Supplier shall ensure that any on-going liability it has or may have arising out

of this Framework Agreement shall continue to be the subject of appropriate indemnity arrangements for the period of twenty one (21) years from termination or expiry of this Framework Agreement or until such earlier date as that liability may reasonably be considered to have ceased to exist.

15 Term and termination

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

15.2 The Authority shall be entitled to extend this Framework Agreement for a further period of up to a total of 24 months (either by way of a single extension or a series of multiple extensions) by giving the Supplier written notice no less than three (3) months prior to the specified expiry date. The Authority shall be entitled to extend the Framework Agreement in relation to all or any of the Goods and any extension shall apply to all or any of the Goods as the Authority may specify in the notice given pursuant to this Clause 15.2. For the avoidance of doubt, in the event that this Framework Agreement is extended, the Contract Price of the Goods subject to any extension shall remain fixed at the price payable (for such Goods) immediately preceding the extension subject always to any price variation made in accordance with Clause 11 of Schedule 1.

15.3 In the case of a breach of any of the terms of this Framework Agreement by either Party that is capable of remedy (including any failure to pay sums due under this Framework Agreement), the non-breaching Party shall, without prejudice to its other rights and remedies under this Framework Agreement, issue notice of the breach and 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 Framework Agreement in accordance with Clause 15.4.2 of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

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 15.4.2 of this Schedule 2, a material breach of this Framework Agreement by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

15.4 Either Party may terminate this Framework Agreement forthwith by notice in writing to the other Party if such other Party commits a material breach of any of the terms of this Framework Agreement which is:

15.4.1 not capable of remedy; or

15.4.2 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 Framework Agreement forthwith by notice in writing to the Supplier:

15.5.1 if the Supplier, or any third party guaranteeing the obligations of the Supplier under this Framework Agreement, 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 if 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 Framework Agreement or the reputation of the Authority;

15.5.3 if the Supplier purports to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Framework Agreement in breach of Clause 29.1 of this Schedule 2 ;

15.5.4 pursuant to and in accordance with the Key Provisions and Clauses 15.6, 24.8, 26.2, 26.4, 27.2 and 30.2 of this Schedule 2;

15.5.5 if the warranty given by the Supplier pursuant to Clause 10.4 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 10.4 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.4 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable;

15.5.6 where a court (or other competent authority) or the Authority (acting reasonably) makes a finding or determination that any of the Intellectual Property Rights required for the purposes of supplying the Goods is invalid or unenforceable for whatever reason;

15.5.7 on the occurrence of, or at any time following, any NHSE Event; or

15.5.8 if any marketing authorisation in relation to the Goods is withdrawn, suspended and/or not renewed by the Licensing Authority at any time during the Term.

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 Framework Agreement 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 Framework Agreement 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 Framework Agreement 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 Framework Agreement 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 (as set out in Clause 23.3 of this Schedule 2) shall entitle, but

shall not compel, the Authority to terminate this Framework Agreement in accordance with Clause 15.4.1 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 Framework Agreement forthwith by notice in writing to the Supplier where:

15.7.1 the Framework Agreement has been substantially amended to the extent that the Regulations 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 Regulations from the procurement procedure leading to the award of the Framework Agreement;

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

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 Framework Agreement under this Clause 15.7.4.

15.8 If the Authority novates this Framework Agreement to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Framework Agreement 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 Framework Agreement forthwith by notice in writing 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.

15.9 The Supplier agrees and acknowledges that the Authority is entitled to recover any costs the Authority and/or any Participating Authorities may incur in consequence of the Authority terminating this Framework Agreement pursuant to this Clause 15.

15.10 The Supplier agrees that upon termination for any reason or expiry of this Framework Agreement it shall not be entitled to make a claim against the Authority in relation to costs incurred by the Supplier in providing the Goods or costs incurred in acquiring equipment and/or materials used in the provision of the Goods or in engaging third parties in connection with the Goods the subject of this Framework Agreement.

15.11 For the avoidance of doubt, the Authority shall be entitled to terminate the Framework Agreement pursuant to this Clause 15 of this Schedule 2 in whole (in relation to all of the Goods) or in part (in relation to any particular Good(s)) and any termination shall apply to all of the Goods or particular Goods as the Authority may specify in any notice given under Clause 15 of this Schedule 2.

16 Consequences of expiry or earlier termination of this Framework Agreement

16.1 Upon expiry or earlier termination of this Framework Agreement, the Authority and the Supplier agree that all Contracts entered into under this Framework Agreement will continue in full force and effect unless otherwise terminated under the terms and conditions of such Contracts. The expiry or earlier termination of this Framework Agreement for whatever reason shall not in any way affect the validity of any Order raised by a Participating Authority prior to the date of such expiry or termination.

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 Framework Agreement. This cooperation shall extend to providing access to all information relevant to the operation of this Framework Agreement, 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.

16.3 The expiry or earlier termination of this Framework Agreement 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 Framework Agreement 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 Suspension of Supplier's appointment

17.1 Without prejudice to the Authority's rights to terminate this Framework Agreement, if a right for the Authority to terminate this Framework Agreement arises (irrespective of whether the circumstances leading to such right are capable of remedy) in accordance with Clause 15 of this Schedule 2, the Authority may suspend the Supplier's appointment to receive new Orders under this Framework Agreement by giving notice in writing to the Supplier and all Participating Authorities.

17.2 If the Authority provides notice to the Supplier in accordance with Clause 17.1 of this Schedule 2, the Supplier's appointment shall be suspended for the period set out in the notice or such other period notified to the Supplier by the Authority in writing from time to time provided that such suspension shall be lifted where:

17.2.1 the circumstances leading to the Authority's right to terminate this Framework Agreement have been remedied;

17.2.2 the Authority has satisfied itself that the risk and/or impact of the circumstances giving rise to the Authority's right to terminate this Framework Agreement no longer requires such suspension; or

17.2.3 the Authority exercises its rights to terminate this Framework Agreement in accordance with Clause 15 of this Schedule 2.

18 Complaints

18.1 The Supplier shall notify the Authority of any formal written complaints made by other Participating Authorities relating to the Supplier's noncompliance with any of its obligations under any Contract within two (2) Business Days of the Supplier becoming aware of such complaints.

18.2 Without prejudice to any rights and remedies that the Participating Authority may have under the relevant Contract and/or the Authority may have under this Framework Agreement, the Supplier shall use its reasonable endeavours to resolve such complaint within ten (10) Business Days and in so doing, shall deal with the complaint fully, expeditiously and fairly.

18.3 Within two (2) Business Days of a written request by the Authority, the Supplier shall provide further reasonable details of the complaint to the Authority, including details of the steps being taken to progress its resolution and, following its resolution, details of how and when the complaint was resolved.

19 Sustainable development

19.1 The Supplier shall comply in all material respects with applicable environmental, 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 Terms of Offer. 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 Terms of Offer in relation to any stated environmental, 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 Framework Agreement.

20.7 The Supplier shall indemnify the Authority from against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with the Product Information save for where this is a result of the Authority's wilful or negligent misrepresentation of the Product Information.

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

21 Sales Information

21.1 If requested by the Authority, the Supplier shall provide the Authority with statements giving accurate and complete details of the quantity and value of the Goods supplied by the Supplier to Participating Authorities pursuant to this Framework Agreement. The frequency, format and level of detail to be included in such statements shall be as specified by the Authority in the Invitation to Offer, or as otherwise agreed between the Authority and the Supplier.

21.2 The Supplier shall keep at its normal place of business detailed, accurate and up to date records of the quantity and value of the Goods sold by it to any Participating Authority pursuant to this Framework Agreement, together with accurate details of the identity of the Participating Authority to which such Goods were sold. Subject to any other auditing process being agreed between the Authority and the Supplier in writing, the Authority shall be entitled by prior appointment to enter the Supplier's normal place of business during normal office hours and to inspect such records in order to verify whether any statement supplied by the Supplier to the Authority pursuant to Clause 21.1 of this Schedule 2 is accurate and complete.

22 Change management

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

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

23 Dispute resolution

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

23.2 In the case of a dispute arising out of or in connection with this Framework Agreement 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 23.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

23.3 If any dispute arises out of the Framework Agreement 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 services 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.

23.4 If the procedure set out in Clause 23.3 of this Schedule 2 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 exhaustion of all levels of the escalation procedure at Clause 23.3 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

23.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 23.4 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.

23.6 Nothing in this Framework Agreement shall prevent:

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

23.6.2 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.

23.7 Clause 23 of this Schedule 2 shall survive the expiry of or earlier termination of this Framework Agreement for any reason.

24 Force majeure

24.1 Subject to Clause 24.2 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 Framework Agreement 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.

24.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 24 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Framework Agreement if:

24.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2;

24.2.2 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

24.2.3 the Supplier has complied with the procedural requirements set out in Clause 24 of this Schedule 2.

24.3 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 Framework Agreement and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.

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

24.5 If either Party is prevented or delayed in the performance of its obligations under this Framework Agreement 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.

24.6 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.

24.7 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.

24.8 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 Framework Agreement on service of written notice on the Supplier.

24.9 Following such termination in accordance with Clause 24.8 of this Schedule 2 and subject to Clause 24.10 of this Schedule 2, neither Party shall have any liability to the other.

24.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 24.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Framework Agreement.

25 Records retention and right of audit

25.1 Subject to any statutory requirement and Clause 25.2 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 Framework Agreement.

25.2 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 Framework Agreement.

25.3 The Authority shall have the right to audit the Supplier's compliance with this Framework Agreement. 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 Framework Agreement.

25.4 Should the Supplier sub-contract any of its obligations under this Framework Agreement, 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 Framework Agreement 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.

25.5 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 Framework Agreement for the purposes of:

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

25.5.2 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.

25.6 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 25 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.

25.7 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 Framework Agreement.

25.8 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 Framework Agreement.

26 Conflicts of interest and the prevention of fraud

26.1 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 Framework Agreement. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

26.2 The Authority reserves the right to terminate this Framework Agreement 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 Framework Agreement. The actions of the Authority pursuant to this Clause 26.2 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.

26.3 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.

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

27 Equality and human rights

27.1 The Supplier shall:

27.1.1 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;

27.1.2 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

27.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 27 of this Schedule 2.

27.2 If the Supplier fails to comply with the provisions of Clause 27.1 and/or contravenes the Equality Legislation, the Authority may terminate this Framework Agreement and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

27.3 The Supplier shall also indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under the Equality Legislation due directly or indirectly to any act or omission by the Supplier, its agents, employees or sub-contractors.

27.4 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 27 of this Schedule 2.

28 Notice

28.1 Subject to Clause 23.5 of this Schedule 2, any notice required to be given by either Party under this Framework Agreement shall be in writing quoting the date of the Framework Agreement 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.

28.2 A notice shall be treated as having been received:

28.2.1 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

28.2.2 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

28.2.3 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.

29 Assignment, novation and sub-contracting

29.1 The Supplier shall not assign, sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Framework Agreement 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 Framework Agreement, every act or omission of the Sub-contractor shall for the purposes of this Framework Agreement 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.

29.2 Any authority given by the Authority for the Supplier to sub-contract any of its obligations under this Framework Agreement 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 Framework Agreement.

29.3 Where the Authority considers the grounds for exclusion under Regulation 57 of the Regulations apply to any Sub-contractor then:

29.3.1 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

29.3.2 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.

29.4 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.

29.5 The Authority may at any time transfer, assign, novate, sub-contract or otherwise dispose of its rights and obligations under this Framework Agreement or any part of this Framework Agreement 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 Framework Agreement 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 Framework Agreement or any part of this Framework Agreement without the prior written consent of the Supplier, such consent not to be unreasonably withheld or delayed by the Supplier.

30 Prohibited Acts

30.1 The Supplier warrants and represents that:

30.1.1 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 any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

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

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

30.2 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:

30.2.1 the Authority shall be entitled:

(i) to terminate this Framework Agreement 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;

30.2.2 any termination under Clause 30.2.1 of this Schedule 2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

30.2.3 notwithstanding Clause 23 of this Schedule 2, any dispute relating to:

(i) the interpretation of Clause 30 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.

31 General

31.1 Each of the Parties is independent of the other and nothing contained in this Framework Agreement 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 Framework Agreement.

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

31.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Framework Agreement 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.

31.4 Any provision of this Framework Agreement 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 Framework Agreement and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

31.5 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 Framework Agreement 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 Framework Agreement or unless such representation, undertaking or warranty was made fraudulently.

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

31.7 The rights and remedies provided in this Framework Agreement are cumulative and not exclusive of any rights or remedies provided by general law, or by any other contract or document. In this Clause 31.7 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.

31.8 A person who is not a party to this Framework Agreement 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 Framework Agreement.

31.9 This Framework Agreement, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this Framework Agreement or any variation to this Framework Agreement, contain the entire understanding between the Supplier and the Authority relating to the operation of this Framework Agreement 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 Framework Agreement. Nothing in this Framework Agreement 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 Framework Agreement shall form part of this Framework Agreement.

31.10 This Framework Agreement, 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.

31.11 Subject to Clause 23 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Framework Agreement or its subject matter.

31.12 All written and oral communications and all written material referred to under this Framework Agreement 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 Framework Agreement 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 The Recipient shall be entitled to disclose the Confidential Information of the Discloser where:

1.2.1 the Recipient is required to disclose the Confidential Information by Law, provided that Clause 3 of this Schedule 3 shall apply to disclosures required under the FOIA or the Environmental Regulations;

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

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

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

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

(iv) the Recipient has reasonable grounds to believe that the Discloser is involved in activity that may constitute a criminal offence under the Bribery Act 2010 and the disclosure is being made to the Serious Fraud Office.

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

1.3.1 on a confidential basis to any Central Government Body or other Contracting Authority for any proper purpose of the Authority or of the relevant Central Government Body or other 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 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;

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

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

1.3.5 on a confidential basis for the purpose of the exercise of its rights under this Framework Agreement; or

1.3.6 on a confidential basis to a proposed transferee, assignee or novatee of, or successor in title to the Authority,

and for the purposes of the foregoing, 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 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 the operation of this Framework Agreement, 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 Framework Agreement. 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 Framework Agreement.

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 Framework Agreement and/or that it has been appointed as a Supplier to the Authority and/or make any other announcements about this Framework Agreement.

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 Framework Agreement 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 To the extent that the nature of this Framework Agreement means that the Parties are acting both as Controllers, each Party undertakes to comply at all times with its obligations under the Data Protection Legislation and shall:

2.2.1 implement such measures and perform its obligations (as applicable) in compliance with the Data Protection Legislation;

2.2.2 be responsible for determining its data security obligations taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of the Processing as well as the risk of varying likelihood and severity for the rights and freedoms of the Data Subjects, and implement appropriate technical and organisational measures to protect the Personal Data against unauthorised or unlawful Processing and accidental destruction or loss and ensure the protection of the rights of the Data Subject, in such a manner that Processing will meet the requirements of the Data Protection Legislation where Personal Data has been transmitted by it, or while the Personal Data is in its possession or control;

2.2.3 where appropriate, promptly refer to the other Party any requests, from (i) Data Subjects in regards to the right of access to Personal Data by that Data Subject in accordance with the Data Protection Legislation; (ii) the Information Commissioner; or (iii) any other law enforcement authority and to the extent it is reasonable and practical to do so consult with the other Party (for the avoidance of doubt at no additional cost) before responding to such request.

2.3 Where Personal Data is shared between the Parties, each acting as Controller:

2.3.1 the Data Transferor warrants and undertakes to the Data Recipient that such Personal Data has been collected, Processed and transferred in accordance with the Data Protection Legislation and this Clause 2 of this Schedule 3;

2.3.2 the Data Recipient will Process the Personal Data in accordance with the Data Protection Legislation and this Clause 2 of this Schedule 3; and

2.3.3 where the Data Recipient is in breach of its obligations under this Schedule 3 and the Data Protection Legislation, the Data Transferor may temporarily suspend the transfer of the Personal Data to the Data Recipient until the breach is repaired.

2.4 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).

2.5 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 Framework Agreement.

3 Freedom of Information and Transparency

3.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA 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 and Environmental Regulations. The Supplier agrees:

3.2.1 that this Framework Agreement and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Framework Agreement are subject to the obligations and commitments of the Authority under the FOIA 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 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 and Environmental Regulations and the Supplier itself is subject to the FOIA 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 and Environmental Regulations and the Supplier is not itself subject to the FOIA 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 Framework Agreement; 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 and Environmental Regulations, the content of this Framework Agreement is not Confidential Information.

3.4 Notwithstanding any other term of this Framework Agreement, the Supplier consents to the publication of this Framework Agreement 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 and Environmental Regulations.

3.5 In preparing a copy of this Framework Agreement 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 Framework Agreement.

3.7 Where any information is held by any Sub-contractor of the Supplier in connection with this Framework Agreement, 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.

Schedule 4

Definitions and Interpretations

1 Definitions

1.1 In this Framework Agreement the following words shall have the following meanings unless the context requires otherwise, other than in relation to the Call-off Terms and Conditions for the Supply of Goods at Appendix A of this Framework Agreement. The definitions and Interpretations that apply to the Call-off Terms and Conditions for the Supply of Goods are as set out at Appendix A of this Framework Agreement.

"Authority"	means the authority named on the front page of the Framework Agreement at page 1;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Specification;
"Award Schedule"	means the document set out at Schedule 6;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to fulfil its obligations under this Framework Agreement including an influenza pandemic, EU Exit and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods during a Business Continuity Event;
"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Call-off Terms and Conditions for the Supply of Goods"	means the call-off terms and conditions for Contracts as set out at Appendix A of this Framework Agreement forming part of the Contract(s) placed under this Framework Agreement;
"Central Government Body"	means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);

	(c) Non-Ministerial Department; or (d) Executive Agency
"Commencement Date"	means the date of this Framework Agreement;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Framework Agreement including any procurement process which is: (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; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"Contract"	means any contract entered into under this Framework Agreement with the Supplier by any Participating Authority as further defined in the Call-off Terms and Conditions for the Supply of Goods;
"Contracting Authority"	means any contracting authority as defined in Regulation 2 of the Regulations, other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by a Participating Authority under any Contract for the full and proper performance by the Supplier of its obligations under such Contracts (as calculated in accordance with the provisions of the Award Schedule) and as confirmed in the relevant Order Form relating to the particular Contract;
"Controller"	shall have the same meaning as set out in the GDPR;
"Data Protection Legislation"	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;

"**Data Recipient**"	means the Controller who agrees to receive Personal Data from the Data Transferor for further Processing in accordance with Schedule 3;
"Data Subject"	shall have the same meaning as set out in the GDPR;
"**Data Transferor**"	means that Controller who transfers the relevant Personal Data;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 23 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Effective Date"	has the meaning given under Clause 2.1.1 of Schedule 1;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"Environmental Regulations"	the Environmental Information Regulations 2004, together with any guidance and/or codes of practice issued by the Information Commissioner or any Central Government Body in relation to such Regulations;
"eProcurement Guidance"	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement as amended from time to time, together with any further Guidance issued by the Department of Health and Social Care in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000,

	the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034), the Human Rights Act 1998 and the National Minimum Wage Regulations 2015 (as amended by the National Minimum Wage (Amendment) Regulations 2016);
"EU Exit"	means the process of the UK leaving the EU pursuant to Article 50 of the Treaty on the Functioning of the European Union and any resulting changes in Law, customs duties and/or tariffs, and/or import/export rules or restrictions;
"Expiry Date"	has the meaning given under Clause 2.1.2 of Schedule 1;
"FOIA"	means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time, together with any guidance and/or codes of practice issued by the Information Commissioner or any relevant Central Government Body in relation to such Act;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Framework Agreement; (b) acts of terrorism (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and

	(i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but, for the avoidance of doubt, not including EU Exit unless and to the extent that a consequence of EU Exit falls within one of the above defined circumstances;
"Framework Agreement"	means the form of agreement at the front of this document and all schedules and appendices attached to the form of agreement;
"Framework Providers"	means the Supplier and other suppliers appointed as framework providers under this Framework Agreement;
"Fraud"	means any offence under any law in respect of fraud in relation to this Framework Agreement or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"GDPR"	means the General Data Protection Regulation (Regulation (EU) 2016/679);
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Framework Agreement, including in accordance with any codes of practice published by relevant trade associations;
"Goods"	means any and all goods, materials or items that the Supplier is required to supply to Participating Authorities under Contracts placed under this Framework Agreement, details of such Goods, materials or other items being set out in the Specification, the Award Schedule and any Order;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the

	Department of Health and Social Care, Monitor, NHSE, the MHRA, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Invitation to Offer"	means the invitation to offer issued by the Authority comprising: Document No.01 This covering letter Document No.02 Terms of offer Document No.03 Framework Agreement and Terms and Conditions Document No.04a Contract Specifics Document No.04b Management Information Schedule Document No.04c Management Information Schedule - Template Document No.04d Participating Authorities Document No.05a Offer Schedule Document No.05b Scoring Methodology Document No.06 Form of Offer Document No.07a Quality control technical sheet Document No.07b Guidance for performing a risk assessment of licensed medicines for the NHS Document No.08 Confidential Information Schedule
"Key Provisions"	means the key provisions set out in Schedule 1;
"KPI"	means the key performance indicators as set out in Schedule 5;
"Law"	means any applicable legal requirements including without limitation: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation as applicable in England and Wales; (b) (subject to EU Exit) any applicable European Union directive, regulation, decision or law; (c) (subject to EU Exit) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;

	(e) requirements set by any regulatory body as applicable in England and Wales; (f) any applicable code of practice as applicable in England and Wales; and (g) any relevant collective agreement and/or international law provisions (to include without limitation as referred to in (a) to (f) above).
"Licensing Authority"	means the MHRA or the EMA or such other licensing authority as the Authority shall determine;
"Lot(s)"	shall have the meaning ascribed in the Terms of Offer;
"MHRA"	means the Medicines and Healthcare products Regulatory Agency;
"Mid-Point Date"	for each Good in Lot 1, Lot 2, Lot 3 and Lot 4 specified in the Award Schedule, means the date falling half way between the Commencement Date and the expiry date specified in the Award Schedule for that Good;
"NHS"	means the National Health Service;
"**NHSE**"	means the Authority;
"**NHSE Event**"	means any event by which NHSE procures or seeks to procure goods and/or services which are the same as or similar to the Goods/Services that are the subject of this Framework Agreement, which shall include (without limitation) the following such events: (a) the award of a contract by NHSE to the Supplier (and/or any other supplier(s)) for the provision of any or all goods and/or services which are the same as or similar to the Goods/Services that are the subject of this Framework Agreement; (b) the conclusion of a framework agreement with the Supplier (and/or any other supplier(s)) for the provision of any or all goods and/or services which are the same as or similar to the Goods/Services that are the subject of this Framework Agreement; (c) the entering into a contract(s) or framework agreement(s) with the Supplier (and/or any other supplier(s)) for the provision of any or all goods and/or services which are the same as or similar to the Goods/Services that are the subject of this Framework Agreement; or (d) the commencement of delivery of goods and/or services by the Supplier (and/or any other supplier(s) to NHSE (or any bodies

	nominated by NHSE) pursuant to the contract or framework agreement specified in (c) above (as the case may be).
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: (i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; (ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion;
"Offer"	means the offer submitted by the Supplier to the Authority in response to the Invitation to Offer;
"Order Form"	means the order form on which Orders are to be placed (such order form being in such form as the Participating Authority and the Supplier shall agree from time to time);
"Ordering Procedure"	means the procedure enabling Participating Authorities to call-off Goods and enter into Contracts under this Framework Agreement, as set out in Schedule 7;
"Orders"	means orders for Goods placed under this Framework Agreement by Participating Authorities;
"Participating Authority"	means a Contracting Authority entitled to place Orders under this Framework Agreement including the Authority and any other Contracting Authority as set out in the Key Provisions;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in the GDPR;

"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Price Firm Period"	has the meaning given under Clause 11 of Schedule 1;
"Process"	shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's product catalogue from time to time;
"Prohibited Acts"	has the meaning given under Clause 30.1.1 of Schedule 2;
"Regulations"	means the Public Contracts Regulations 2015 (SI 2015/102) as amended;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"Remedial Proposal"	has the meaning given under Clause 15.3 of Schedule 2;
"Review"	has the meaning given under Clause 11 of Schedule 1;
"Review Notice"	has the meaning given under Clause 11 of Schedule 1;
"Revised Contract Price"	means the new Contract Price for the Goods as established pursuant to a Review;
"Specification"	means the document set out in Schedule 5 (including the Quality Control Technical Sheet) as amended and/or updated in accordance with this Framework Agreement;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Framework Agreement including any Sub-contractors and person employed or engaged by such Sub-contractors;
"Sub-contract"	means a contract between two or more suppliers at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Framework Agreement;
"Sub-contractor"	means a party to a Sub-contract other than the Supplier;

"Supplier"	means the supplier named on the front page of Framework Agreement at page 1;
"Supplier Lot(s)"	means the Lots to which the Supplier has been appointed under this Framework Agreement as specified in the Award Schedule;
"Term"	means the period commencing on the Commencement Date and ending on the latest of the Expiry Dates specified in the Award Schedule;
"Terms of Offer"	means the document entitled 'Terms of Offer' issued by the Authority as part of the Invitation to Offer;
"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2; and
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

1.2 References to any statute or order shall include any statutory extension, modification or re-enactment, and any order, regulation, bye-law or other subordinate legislation.

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 Framework Agreement to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Framework Agreement.

1.5 References in this Framework Agreement 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 Award Schedule as a chargeable item and subject to Clause 31.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Framework Agreement.

1.7 The headings are for convenience only and shall not affect the interpretation of this Framework Agreement.

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

1.9 Where a term of this Framework Agreement provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as 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 and any other part of this Framework Agreement, such other part of this Framework Agreement shall prevail.

1.11 Where a document is required under this Framework Agreement, 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 Framework Agreement.

Schedule 5

Specification

Document No. 04a - Contract Specifics
NHS National Framework Agreement for the supply of products for the treatment of Haemophilia A
Offer reference number: CM/PHS/17/5564
Period of contract: 1 July 2020 to 30 June 2022 with options to extend up to a further 24 months. The total maximum framework period including any extensions will be no more than 48 months

1 Terms of the Framework and Product Specification

1.1 The framework will cover the supply of products for the treatment of Haemophilia A.

1.2 The framework agreement will cover England, Northern Ireland, Scotland and Wales.

1.3 The length of this framework is 24 months with options to extend up to a further 24 months. The total maximum framework agreement period including extensions will be no more than 48 months.

1.4 This framework is split into four lots. Volumes and patient numbers for Lot 1, 2 and 3 have been taken from the UKHCDO Annual Report 2019[1]. For Lot 4 the annual forecasted figures have been predicted. See Table 1 below for details.

Table 1:

Lot	Product Area	Unit of Measure	Apr 2018 – Mar 2019 Volume	Apr 2018 – Mar 2019 Patient Numbers
1	Plasma Derived Factor VIII	IU	12,887,380	31
2	Standard Half-life Recombinant Factor VIII	IU	487,248,114	2376
3	Enhanced Half-life Recombinant Factor VIII	IU	93,965,778	408
	Forecasted Annual Figure (Haemophilia A Non-Inhibitor Patients)			
4	Emdicizumab	Mg	2,500,000	550

(a) _____

[1] UKHCDO Annual Report 2019 & Bleeding Disorder Statistics for 208/2019, Data table for Figure 13, page 50

1.5 Any volume estimates provided to Offerors by Authority staff are statements of opinion, provided in good faith and based on past experience and market knowledge, but they should not be relied upon by Offerors in formulating their offers. No commitment is made by the Commercial Medicines Unit (CMU) on its own behalf or on behalf of Participating Authorities as to the volume of goods which may be purchased by Participating Authorities pursuant to the Framework Agreement.

1.6 Each lot is defined as follows:

Table 2:

Lot	Product Area	Definition:
1	Plasma Derived Factor VIII	Any plasma derived FVIII product
2	Standard Half-life Recombinant Factor VIII	Recombinant human FVIII which is expected to have the same pharmacokinetics as native human FVIII
3	Enhanced Half-life Recombinant Factor VIII	Recombinant human FVIII which has been modified in a manner specifically and proven to extend or enhance the elimination half-life compared with native human FVIII
4	Emicizumab	Humanised bispecific antibody

1.7 Products may be submitted in respect of one lot only.

1.8 All products must be supplied complete with appropriate diluents and devices for administration.

1.9 Additional products to those specified above will only be considered by CMU where additional products are new SKUs; i.e. different presentation size, or where one product replaces another, i.e. the new product holds the same Marketing Authorisation as the product it is replacing, or it is a direct replacement. Any such additional product must be price linked to the product submitted as a tender; i.e. the same pro-rata price for a different vial/syringe size or an identical price where one product replaces another. CMU will not consider any additional products offered at an unrelated price to the offer price nor any “enhanced” products. For more detail on ADDITIONAL GOODS refer to Document No.03 – Framework Agreement and Terms and Conditions, Schedule 1 (section 12).

1.10 If more than one product is awarded a place on a lot, Participating Authorities will initially be recommended to purchase the product ranked first in that lot. If the product ranked first is unsuitable to meet the requirements of the patient, then Participating Authorities may purchase the product ranked second in that lot. If this product is also unsuitable to meet the requirements of the patient, then Participating Authorities may purchase the product ranked third in that lot and so on.

2 Outline

2.1 As part of this ITT Offerors are required to complete Document No. 05a – Haemophilia A - Offer Schedule.

2.2 Offerors must provide 20 product demonstration kits for reconstitution AND any other equipment needed to reconstitute or mix vials to give a 750IU dose. All samples must be delivered by Tuesday 24 March 2020 using the address label provided at the end of this document.

2.3 Failure to provide samples will result in a score of zero (0) out of a possible combined maximum score of 7.44 for sub-criteria points; 10, 11, 12, 13, 14, 15, 16, 17, 18 and 19, within the Ease of Use evaluation criteria.

2.4 Prices are to be submitted using Document No. 05a – Haemophilia A - Offer Schedule.

2.5 Prices will be fixed for 24 months. If the framework is extended, then prices may be reviewed at this point.

2.6 Offerors are required to provide their offer price(s) per unit of issue (excluding VAT) to four decimal places i.e. 0.1111.

2.7 Lots 1, 2 and 4 will be evaluated within their respective groups on a 1:1 unit basis. ie. one unit of a product is therapeutically equivalent to one unit of another product [within that group].

2.8 Lot 3 will be evaluated based on an annual cost for prophylaxis per patient (aged 12 year+) and will be calculated on the following basis:

Mean patient weight has been confirmed as 80Kg based on patients in the National Haemophilia Database (NHD) with a weight recorded and meeting the following criteria:

- Diagnosis of severe congenital haemophilia A
- No current or active inhibitor
- Aged 12 years and older.

The prophylaxis dose and administration regimen of product will be obtained from the UK Summary of Product Characteristics (SPC). Where the SPC stipulates a range (either in terms of units per kg, or dose interval in days) the mid-point of the normal or standard range will be used.

Brand	Drug	Manufacturer	Smallest Vial	IU/Kg	Frequency (days)	Units per Dose (abs) 80kg	Units per Dose (Rounded)	Doses per annum (abs)	Doses per annum (Rounded)	Units Per Annum (Rounded)
Jivi	Damoctocog	Bayer	250	35	3.5	2800.0	3000.0	104.3	104.0	312000
Esperoct	Turoctocog	Novo Nordisk	500	50	4.0	4000.0	4000.0	91.3	91.0	364000
Adynovi	Rurioctocog	Takeda	250	45	3.5	3600.0	3750.0	104.3	104.0	390000
Elocta	Efmoroctocog	SOBI	250	50	4.0	4000.0	4000.0	91.3	91.0	364000

Using the mean patient weight obtained as stated, an absolute total dose (units) will be calculated using the selected dose regimen. This will then be rounded UP to the nearest whole vial to give a rounded dose in units.

The rounded dose will then be scaled up (multiplied) for administration over 365 days, or 52 weeks. The dose interval as per the regimen defined for comparison will result in the following number of doses per 365 days or 52 weeks

- Twice per week = 104 doses
- Once every four days = 91 doses

The resulting rounded dose per units per kg multiplied by the respective dose interval will result in a total number of units per annum.

Offerors must provide a cost per international unit (IU). This will be used with the calculated total number of units per annum (rounded) for the respective product. The sum of this calculation will be the total cost to treat the patient for the year and will be used for the cost evaluation in Lot 3.

2.9 Offerors are required to provide the minimum annual volume that will be made available for this framework in Document No. 05a – Haemophilia A - Offer Schedule.

3 Award Criteria

3.1 The award of this framework will be based on the most economically advantageous tender (MEAT).

3.2 Award criteria for this framework are:

Criteria	Weighting
Eligibility	Pass / Fail
Price / Cost to Treat	75%
Security of Supply	10%
Ease of Use	15%

3.3 For information about howeach of the award criteria will be evaluated and scored please see the table below and see Document No. 05b – Haemophilia A - Scoring Methodology.

Award Criteria	Description	Weighting
1. Eligibility	Mandatory Requirements of Framework: **1** Technical merit/safety as set out in 4.1 below	**Pass or Fail**

<table>
<tr><td></td><td>2 Terms and conditions accepted in full without amendment as set out in Section 4.2 below
3 Service levels as set out in Section 4.3 below</td><td></td></tr>
<tr><td>2. Price / Cost to Treat</td><td>4 The lowest price will score a maximum of 10 with the following price brackets being scored as follows:

<table><tr><th></th><th>Score</th></tr><tr><td>Offer price more than 0.0001% higher and equal to/less than 5% higher</td><td>9</td></tr><tr><td>Offer price more than 5.0001% higher and equal to/less than 10% higher</td><td>8</td></tr><tr><td>Offer price more than 10.0001% higher and equal to/less than 15% higher</td><td>7</td></tr><tr><td>Offer price more than 15.0001% higher and equal to/less than 20% higher</td><td>6</td></tr><tr><td>Offer price more than 20.0001% higher and equal to/less than 25% higher</td><td>5</td></tr><tr><td>Offer price more than 25.0001% higher and equal to/less than 30% higher</td><td>4</td></tr><tr><td>Offer price more than 30.0001% higher and equal to/less than 35% higher</td><td>3</td></tr><tr><td>Offer price more than 35.0001% higher and equal to/less than 40% higher</td><td>2</td></tr><tr><td>Offer price more than 40.0001% higher than lowest offer price</td><td>1</td></tr><tr><td>No bid</td><td>0</td></tr></table></td><td>75%</td></tr>
<tr><td>3. Security of Supply</td><td>Offerors will be evaluated on the capacity of supply for the product being offered:
If requested suppliers must provide evidence supporting their answer for this section

5 Minimum annual volume of product available to the UK market (as a percentage of the volume stated for the relevant Lot in Table 1 of this document)

Score</td><td>10%</td></tr>
</table>

>100%	**10**
>75%-100%	**7**
>50-75%	**5**
>25%-50%	**3**
= or <25%	**1**

6 Drug substance manufacture (*preparation of substances to be used in the manufacture of the final drug)*

	Score
Multiple (>2) geographic locations with facilities	**5**
Two geographic locations with facilities	**4**
One geographic location with two or more facilities	**2**
One facility at one geographic location	**1**

7 Production of drug (*the manufacture of the final drug)*

	Score
Multiple (>2) geographic locations with facilities	**5**
Two geographic locations with facilities	**4**
One geographic location with two or more facilities	**2**
One facility at one geographic location	**1**

8 Packaging and labelling *(enclosing and labelling products for distribution, storage, sale and safe use)*

	Score
Multiple (>2) geographic locations with facilities	**5**
Two geographic locations with facilities	**4**
One geographic location with two or more facilities	**2**
One facility at one geographic location	**1**

<table>
<tr>
<td></td>
<td>
9 Stock holding facility/warehouse (facility for storing finished product which is ready for distribution to end user)
<table>
<tr><th></th><th>Score</th></tr>
<tr><td>Multiple (>2) geographic locations with facilities</td><td>5</td></tr>
<tr><td>Two geographic locations with facilities</td><td>4</td></tr>
<tr><td>One geographic location with two or more facilities</td><td>2</td></tr>
<tr><td>One facility at one geographic location</td><td>1</td></tr>
</table>
</td>
<td></td>
</tr>
<tr>
<td>4. Ease of Use</td>
<td>
Offerors will be evaluated on the following:

10 Does ancillary pack allow for sterile administrations via portacath with a syringe which is 10ml or greater?
<table>
<tr><th></th><th>Score</th></tr>
<tr><td>Yes</td><td>4</td></tr>
<tr><td>No</td><td>0</td></tr>
</table>
11 Does ancillary pack allow for administration of multiple vials with one syringe?
<table>
<tr><th></th><th>Score</th></tr>
<tr><td>Yes</td><td>2</td></tr>
<tr><td>No but extra syringe can be provided</td><td>1</td></tr>
<tr><td>No</td><td>0</td></tr>
</table>
12 Is there an option to add an ancillary pack to the purchase order without packs automatically being supplied?
<table>
<tr><th></th><th>Score</th></tr>
<tr><td>Yes</td><td>1</td></tr>
<tr><td>No</td><td>0</td></tr>
</table>
13 Does packaging contain bar-code?
</td>
<td>15%</td>
</tr>
</table>

	Score
Yes	**5**
No	**0**

14 Size of pack – in relation to storage at patient's home

	Score
< or = 200 cubic cm	**8**
>200 – 400 cubic cm	**5**
>400 – 500 cubic cm	**2**
>500 cubic cm	**0**

15 Are all required items in one box or are items supplied in additional packs?

	Score
Yes - all required items are received in one box	**5**
No - some items are supplied separately	**0**

16 How environmentally friendly is packaging i.e. amount of packaging, plastic v cardboard, bulkiness of packaging?

	Score
Least amount of waste all of which is recyclable	**8**
Bulky waste which includes all recyclable material	**5**
Bulky waste which includes some non-recycling material	**2**
Bulky waste which includes all non-recycling material	**0**

17 How many steps are required to prepare product for administration?

FOR EXAMPLE: 1-open box / **2**-take individual components out of box / **3**-taking bottle tops off / **4**-

open the swabs / **5**-clean the top(s) / **6**-taking off the syringe lid / **7**-screw the pre-filled syringe plunger into barrel of syringe device (if applicable) OR connect water and factor devices / **8**-fit syringe into transfer device / **9**-draw factor into syringe / **10**-remove factor vial / **11**-open butterfly needle / **12**-remove needle cap / **13**-put needle on syringe / **14**-remove needle sheath

	Score
1 to 10	**10**
11 to 15	**8**
16 to 20	**6**
21 to 25	**4**
26 to 30	**3**
31 to 35	**2**
36 to 40	**1**
>40	**0**

18 Is dose reusable if reconstitution set fails or does whole set get wasted?

	Score
Yes	**10**
No	**0**

19 How easily can a 750 IU dose be prepared and infused

	Score
Very Easy	**10**
Easy	**5**
Difficult	**1**
Very Difficult	**0**

20 Diluent volume supplied with 250 - 1000 IU vial

	Score
<3ml	**7**
3-4ml	**5**
5ml	**3**
>5ml	**1**

21 Diluent volume supplied with 1500 - 3000 IU vial

	Score
<3ml	**7**
3-4ml	**5**
5ml	**3**
>5ml	**1**

22 Can unconstituted product be stored at room temperature?

	Score
Yes	**5**
No	**0**

23 How long can unconstituted product be stored at room temperature?

	Score
>12 months	**5**
>9 - 12 months	**4**
>6 - 9 months	**3**
>3 - 6 months	**2**
<3 months	**1**
Cannot be stored at room temperature	**0**

24 Age range of license indication

	Score
< 2 years 2 – 12 years >12 years	**10**
2 – 12 years > 12 years	**6**
> 12 years only	**3**

25 Total number of infusions required per week per adult with severe Haemophilia A as per SmPC

	Score

Once or less per week	**10**
1 – 2 per week	**7**
2 – 3 per week	**5**
More than three times a week	**1**

26 Route of Administration

	Score
Sub-cut	**10**
IV	**1**

27 Number of vials available:

	Score
All vial options	**10**
Five vial options which include: (Lots 1-3) 250 & 500 IU vials (Lot 4) 30 & 60mg vial	**9**
Five vial options which include: (Lots 1-3) either a 250 or 500 IU vial (Lot 4) either a 30 or 60mg via	**8**
Four vial options which include: (Lot 1-3) 250 & 500 IU vials (Lot 4) 30 & 60mg vial	**7**
Four vial options which include: (Lot 1-3) either a 250 or 500 IU vial (Lot 4) either a 30 or 60mg vial **OR** Three vial options which include: (Lot 1-3) 250 & 500 IU vials (Lot 4) 30 & 60mg vials	**6**
Four vial options <u>not</u> including: (Lot 1-3) 250 or 500 IU vials or (Lot 4) 30 or 60mg vials **OR** Three vial options which include: (Lot 1-3) either a 250 or 500 IU vial (Lot 4) either a 30 or 60mg vial **OR** Two vial options which include: (Lot 1-3) 250 & 500 IU vials (Lot 4) 30 & 60mg vials	**5**

	Three vial options <u>not</u> including: (Lot 1-3) 250 or 500 IU vials (Lot 4) 30 or 60mg vials **OR** Two vial options which include: (Lot 1-3) either a 250 or 500 IU vial (Lot 4) either a 30 or 60mg vial	**4**	
	Two vial options <u>not</u> including: (Lot 1-3) 250 or 500 IU vials (Lot 4) 30 or 60mg vials **OR** One vial option which includes: (Lot1-3) either a 250 or 500 IU vial (Lot 4) either a 30 or 60mg vial	**3**	
	One vial option <u>not</u> including: (Lot 1-3) 250 or 500 IU vial (Lot 4) 30 or 60mg vials	**2**	

4 Eligibility

All the points listed within section 4 of this document are mandatory requirements. Any tender failing to meet any one or more of these requirements will be disqualified.

4.1 Technical Merit/Safety

4.1.1 All products must have a valid UK Marketing Authorisation awarded by the MHRA or EMA applicable to all categories of products offered at the award date of the framework which is anticipated to be 1 June 2020.

4.1.2 Offerors must have product available for delivery to Participating Authorities at the framework go-live date which is 1 July 2020.

4.2 Terms and Conditions

4.1.1 Full acceptance of the CMU terms and conditions must be confirmed by signing Document No. 03 – Framework Agreement and Terms and Conditions. No legal or commercial alterations or substitutions can be proposed.

4.2 Service Levels

The following service levels will become legally-binding obligations if the Offeror becomes a supplier under the framework agreement.

4.2.1 The Offeror must commit to maintain a level of stock holding enough to meet 12 weeks' anticipated demand with effect from the commencement of the framework. The stock holding figure will be calculated using indicative annual volumes obtained from treatment centres. The CMU will monitor monthly volumes and adjust the required stock holding figure in line with actual volumes. Any amendments will be done on a quarterly basis. in conjunction with the supplier and in accordance with the terms of the framework agreement.

4.2.2 The Offeror must commit to supply products with a shelf life of not less than 12 months. Where any products are supplied under this framework, the period between the date of supply of these goods to the Participating Authority and the expiry date shown on the goods ("shelf life") must not be less than 12 months. Supply of any product with a shelf life of less than 12 months must be agreed with the Participating Authority prior to delivery. In the event that the supplier supplies product with a shelf life of less than 12 months (or such other period as agreed with the Participating Authority), the Supplier must, upon request by the Participating Authority and at no cost to the Participating Authority, replace any product the Participating Authority is unable to use within the product's remaining shelf life period. Any replacement product must have a shelf life greater than 12 months unless otherwise agreed with the Participating Authority prior to delivery. Failure to comply with the shelf life service level or any of the other obligations outlined above may lead to CMU terminating the framework agreement with the relevant supplier, in accordance with the terms of the framework agreement.

4.2.3 The Offeror must commit to ensuring security of delivery to the appropriate delivery point.

4.2.4 The Offeror must not propose (and no supplier may impose) any delivery charges for standard deliveries within this framework agreement.

4.2.5 The Offeror must commit to notify CMU of any disruptions to supply and of the contingency arrangements being employed to mitigate and resolve the supply restriction. Notification must be given by contacting the Specialised Pharmaceuticals team by email – specialisedpharma@cmu.nhs.uk **and** the relevant CMU Contract Manager.

4.2.6 The Offeror must commit to deliver to third party homecare suppliers on current and any future national framework agreements for the home delivery of products covered in this framework. Any orders placed by third party homecare suppliers as of 1 July 2020 will be subject to the framework awarded prices.

5 Contract Pricing

5.1 Offerors are required to submit prices in Document No. 05a – Haemophilia A - Offer Schedule - Product Information; these prices will be fixed for the framework length of 24 months unless stated otherwise. If the framework is extended, then prices may be reviewed at this point. Any price reviews will be made in line with the Framework Agreement Price Variation Clause which can be found in Document No. 03 – Framework Agreement and Terms and Conditions, Schedule 1 (section 11).

5.2 Prices submitted must be exclusive of VAT.

6 General Requirements – Products, Packaging and Stock Holding

6.1 Offerors are required to provide details of their contingency arrangements with their offer i.e. details of any business continuity accreditation or procedure e.g. ISO 22301 in Document No. 05a – Haemophilia A - Offer Schedule - Additional Information.

6.2 “Stock holding” refers to product held in the UK and available for despatch within 24 hours, to meet fluctuation in demand, stocks held elsewhere may be used providing delivery is made in line with the stated delivery lead-time given in Doc No. 5a – Haemophilia A - Offer Schedule - Additional Information.

6.3 If awarded a place as a supplier on the framework, the Offeror must meet the following stockholding obligations under the framework agreement -

6.3.1 The supplier must notify CMU within 24 hours if the stock holding drops below 12 weeks’ average sales.

6.3.2 The supplier must notify CMU within 4 hours if the stock holding drops below eight weeks average sales.

6.3.3 The supplier must notify CMU of any stock holding issues by contacting the Specialised Pharmaceuticals team by emailing specialisedpharma@cmu.nhs.uk and the CMU Contract Manager responsible for this framework.

6.3.4 If stock levels fall below the required minimum level, the supplier must take action to rectify the issue. Failure to do so may lead to termination of the framework agreement with the supplier.

6.3.5 Where a supplier is unable to meet the delivery requirements of locally agreed contractual arrangements, the supplier shall be liable for any incurred or additional costs incurred by the customer resulting from the requirement to source a suitable product from an alternative supplier.

6.3.6 The supplier shall on request by CMU provide without delay certificates of analysis (including, without limitation, certificates confirming B.P, E.P. or B.P.C. conformity) in such form as CMU may reasonably require) for such products as CMU may specify.

6.4 The framework agreement (and therefore any future orders placed under it) may be suspended unless and until the supplier can demonstrate to CMU satisfaction that:

6.4.1 the products have a valid UK Marketing Authorisation awarded by the MHRA or EMEA applicable to all categories of the products at the award date of the framework which is anticipated to be 1 June 2020 and have product available for delivery to Participating Authorities at the framework go-live date which is the 1 July 2020;

6.4.2 the goods have been supplied in accordance with current legislation and if such goods are medical devices that they are CE marked; and

6.4.3 should the appropriate Marketing Authorisation not have been obtained by the award date of the framework which is anticipated to be 1 June 2020 or product be unavailable for delivery to Participating Authorities on 1 July 2020, CMU will disregard any offer or terminate any subsequent awarded framework and re-distribute the award accordingly.

6.5 In the event of the goods being recalled, initiated by the manufacturer of the goods, the Secretary of State for Health or the MHRA (or any such similar regulatory body), the supplier must, without delay and at its own expense, arrange for the collection of such goods and credit the Participating Authority for any goods delivered but unused by the Participating Authority including part used packs.

6.6 Offerors are required to upload information onto PharmaQC no later than the go live date of 1 July 2020 (see Document No. 05a – Haemophilia A - Offer Schedule - Additional Information, Document No. 07a - Quality control technical sheet and Document No. 07b - Guidance for performing a risk assessment of licensed medicines for the NHS for further information). If an Offeror have already supplied product information on PharmaQC it is essential that the Offeror ensures the information contained on PharmaQC for its product(s) is up to date.

7 Local Issues

7.1 Certain issues will need to be considered at a local level and have therefore been excluded from this framework agreement. Successful Offerors will be required to discuss and agree with individual Participating Authorities protocols on areas such as the following:

- Training associated with the supply and use of the product by patients or healthcare professionals
- Delivery requirements, delivery notes, times, etc.
- Research and clinical trials
- The provision of Quality Assurance / Quality Control procedures, certificates, analyses, etc.
- KPIs
- Compliance with the appropriate Authority policies
- Home delivery of product in accordance with Participating Authority's home delivery arrangements. From the go-live date of the framework agreement (1 July

2020), the awarded framework prices will be the prices that apply to the product element of any Participating Authority's home delivery arrangement.

8 Homecare and Extension of NHS Terms and Conditions and Pricing to Defined Beneficiaries

8.1 Where the NHS has delegated to defined beneficiaries certain responsibilities, such as delivery of products to patients' homes, the CMU framework agreement terms and pricing are to be extended to the defined beneficiaries.

8.2 The suppliers awarded a place on this framework agreement are expected to work with the home delivery providers appointed to the CMU NHS National Framework Agreement for the Homecare Delivery Service of products for the treatment of bleeding disorders in England, Wales and Northern Ireland (CM/MSR/15/5480) and with suppliers appointed to any future CMU Home Delivery Service framework agreements for products for the treatment of bleeding disorders.

8.3 In preparation for the transition of the new framework the supplier awarded a place on this framework are responsible for ensuring that the home delivery providers are aware of the new framework prices well in advance of the framework go-live date of 1 July 2020. Up to date details for home delivery providers appointed to the CMU NHS National Framework Agreement for the Homecare Delivery Service of products for the treatment of bleeding disorders in England, Wales and Northern Ireland (CM/MSR/15/5480) can be obtained from lynne.newell@nhs.net

8.4 Suppliers awarded a place on this framework agreement are responsible for ensuring that home delivery providers have updated framework prices throughout the duration of this framework. Where relevant, the suppliers must inform the home delivery provider well in advance of any start dates of new prices.

8.5 Home delivery providers are responsible for updating their pricing information accordingly. The home delivery provider will invoice the Participating Authority at the agreed framework prices for products and medicines from 1 July 2020.

9 Improving Patient Care and Lifestyle

9.1 Successful Offerors will be required to attend regular meetings to discuss and review proposals for innovative delivery of products covered by this framework. Parties present at such meetings may include representatives from CMU, the UKHCDO, Blood Disorders CRG and NHS England Commissioning. The purpose of such meetings will be to provide an opportunity for discussion about such things as new prescribing regimes and improving patient care and lifestyle in a cost-effective way. Frequency and dates for meetings will be agreed with the successful Offerors.

10 Framework Monitoring including Management Information

10.1 The Offeror (if appointed to the framework) will comply with all ad-hoc requests by the DHSC, NHS England, the UKHCDO and CMU for management data to be provided in respect of the products supplied under this framework agreement. This information is to be provided within 10 working days for ad hoc requests.

10.2 Offerors are required to provide a named contact in Document No. 05a – Haemophilia A - Offer Schedule - Supplier Information who will be responsible for the provision of management information.

10.3 Management information must be submitted in accordance with Document No. 04b – Management Information Schedule.

11 Supplier Performance Management

11.1 CMU will continually monitor the successful suppliers' performance for this framework during the contract period. As a minimum, CMU will use a supplier scorecard process which will monitor:

- Volume of product supplied
- Quantity of stock held
- Number of complaints received in relation to number of orders received
- Receipt of monthly MI by the required date and in the required format.

11.1.1 Each of these areas will be given a score on a monthly basis and these scores are used to obtain a quarterly score for the supplier.

11.1.2 Suppliers are required to score above a minimum score of 80% for each area. Suppliers' scores will be discussed in supplier review meetings which will be held on a regular basis throughout the term of the framework.

11.1.3 Further details on the supplier scorecard can be viewed in the Excel spreadsheet attached below.

	2018_2019	SUPPLIER NAME											
1	Allocated Volume	100,000											
		Q1			Q2			Q3			Q4		
		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	Target volume	8,333	8,333	8,333	8,333	8,333	8,333	8,333	8,333	8,333	8,333	8,333	8,333
	Actual Volume												
	Q total target volume			25,000			25,000			25,000			25,000
	Q total actual volume			-			-			-			-
2	Innovation	Comment											
	Q1												
	Q2												
	Q3												
	Q4												
3	Management Information	Q1			Q2			Q3			Q4		
		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	Correct data received at the right time												
	Score												
	Score Q			0			0			0			0
4	Continuity of Supply		3 month stock figure		25,000	Product allocation	100,000						
		Q1			Q2			Q3			Q4		
		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	Stock level												
	Above 3 month	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000	- 25,000
	Score												
	Score Q			-			-			-			-
	Stock out												
	Score												
	Score Q			-			-			-			-
5	Customer Satisfaction	Q1			Q2			Q3			Q4		
		Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
	Number of complaints received	0	0	0	0	0	0	0	0	1			
	Number of orders												
	Percentage	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
	Score												
	Score Q			0			0			0			0

SUPPLIER NAME:	SUPPLIER NAME

Q1 - DATE:	

Evaluation fields	Evaluation items	0	1	2	3	Weight	Your score	Max Score	Comments
Management Information	1) Correct data received at the right time					27.5	0	83	
Continuity of Supply	2) Stock held equal to three months supply					19.5	0	59	
	3) Stock out					25.5	0	77	
Customer Satisfaction	4) Complaint about supplier received					27.5	0	83	
						TOTAL	0	300	Total score:
		Recommendation:					NOT APPROVED		0%

Q2 - DATE:	

Evaluation fields	Evaluation items	0	1	2	3	Weight	Your score	Max Score	Comments
Management Information	1) Correct data received at the right time					27.5	0	83	
Continuity of Supply	2) Stock held equal to three months supply					19.5	0	59	
	3) Stock out					25.5	0	77	
Customer Satisfaction	4) Complaint about supplier received					27.5	0	83	
						TOTAL	0	300	Total score:
		Recommendation:					NOT APPROVED		0%

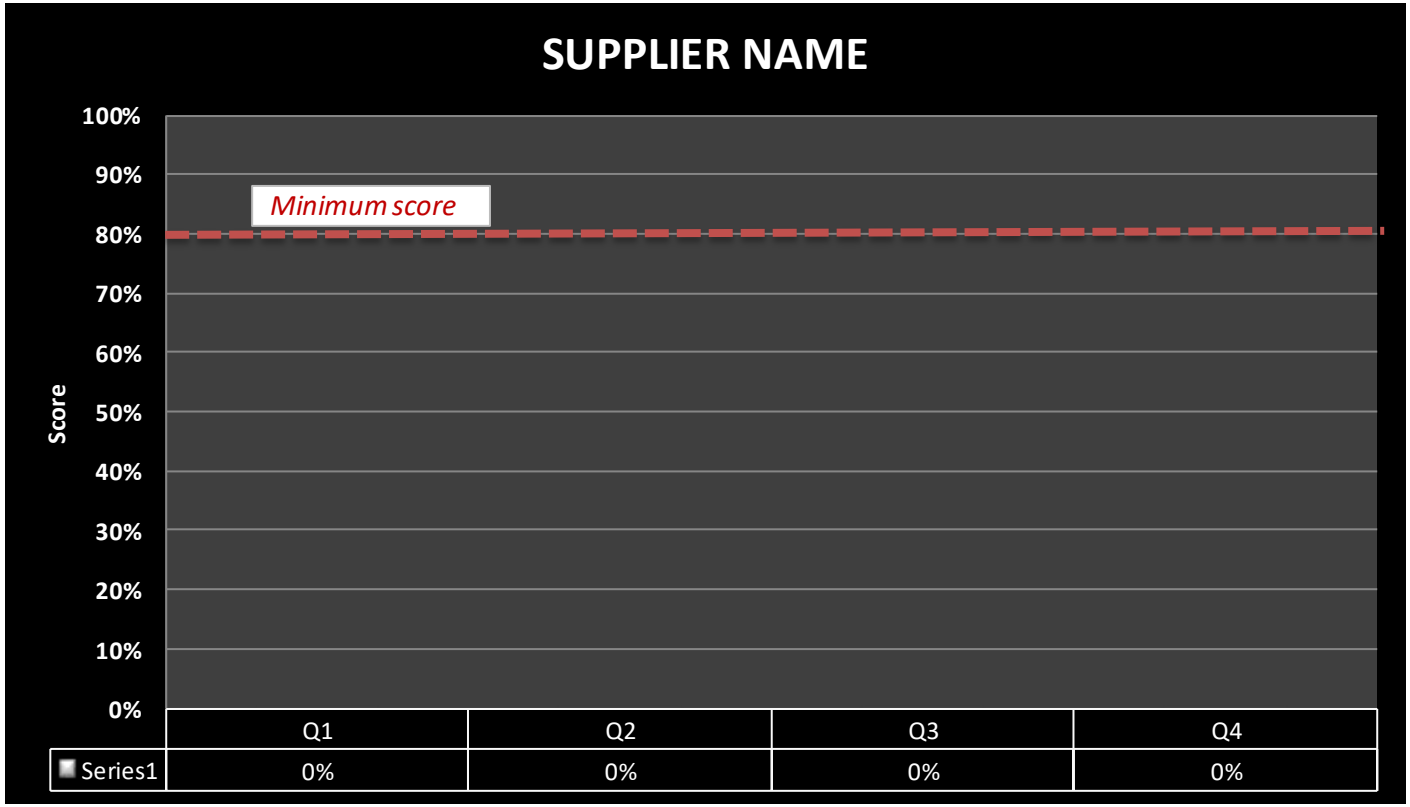
Q3 - DATE:	

Evaluation fields	Evaluation items	0	1	2	3	Weight	Your score	Max Score	Comments
Management Information	1) Correct data received at the right time					27.5	0	83	
Continuity of Supply	2) Stock held equal to three months supply					19.5	0	59	
	3) Stock out					25.5	0	77	
Customer Satisfaction	4) Complaint about supplier received					27.5	0	83	
						TOTAL	0	300	Total score:
		Recommendation:					NOT APPROVED		0%

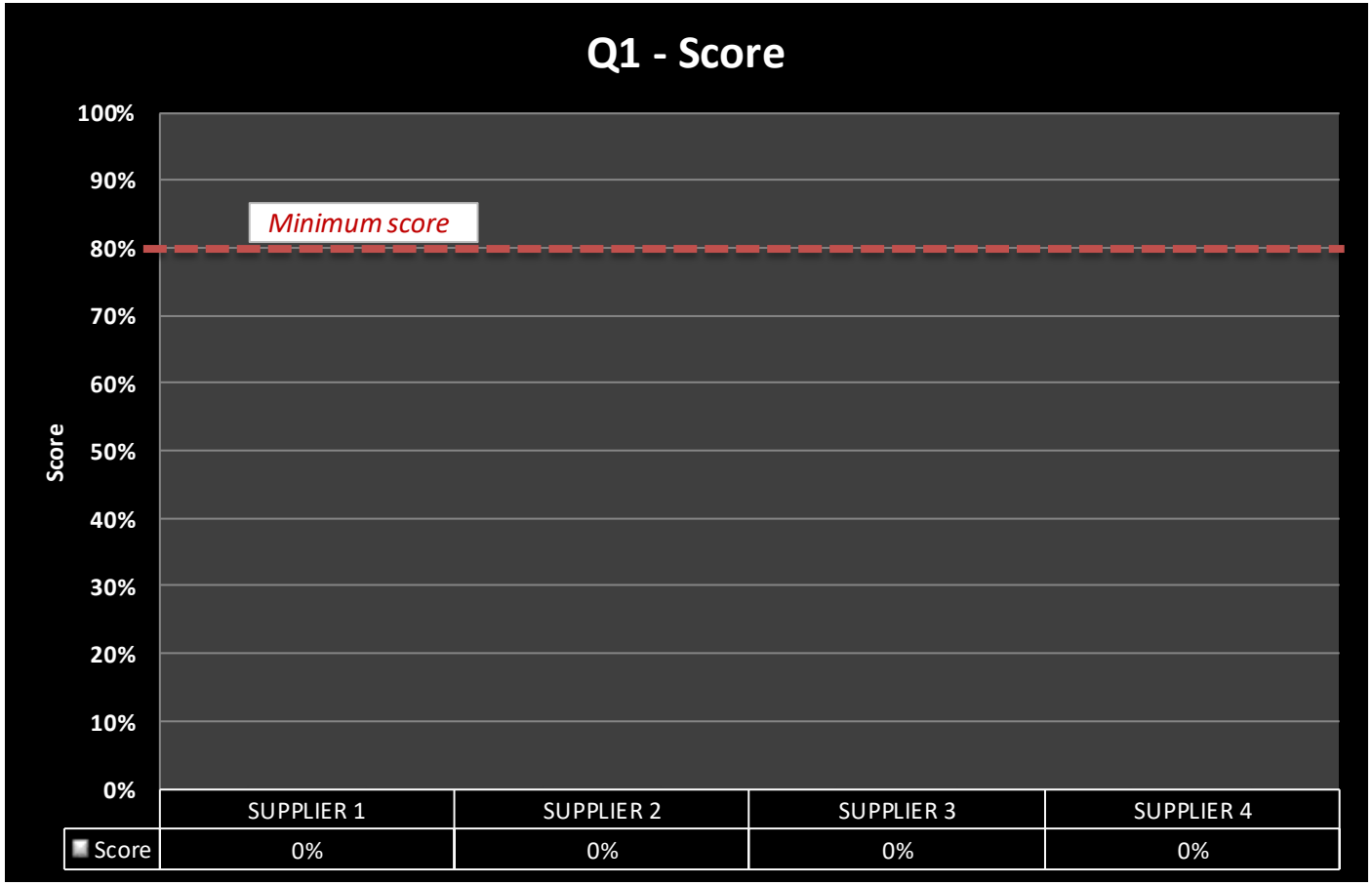
Q4 - DATE:	

Evaluation fields	Evaluation items	0	1	2	3	Weight	Your score	Max Score	Comments
Management Information	1) Correct data received at the right time					27.5	0	83	
Continuity of Supply	2) Stock held equal to three months supply					19.5	0	59	
	3) Stock out					25.5	0	77	
Customer Satisfaction	4) Complaint about supplier received					27.5	0	83	
						TOTAL	0	300	Total score:
		Recommendation:					NOT APPROVED		0%

SUPPLIER NAME	
Q1	0%
Q2	0%
Q3	0%
Q4	0%



Score
0%
0%
0%
0%



11.2 CMU will operate a Customer Complaints procedure and all customer complaints will be recorded. This procedure will assist CMU in monitoring supplier performance. Any such complaints will be taken up with the supplier and a resolution to the issue sought.

11.3 CMU will conduct review meetings with suppliers and expect successful Offerors to attend such meetings.

11.4 Individual Participating Authorities may set individual SLAs with successful Offerors to monitor supplier performance.

11.5 Successful Offerors are required to operate a customer complaints procedure and have an escalation process in place to deal with customer issues. Both the customer complaints procedure and escalation process must be provided upon request.

11.6 Successful Offerors are required to have a product recall procedure in place. The recall procedure must be provided upon request.

12 Participating Authorities

12.1 A list of the Participating Authorities in this framework agreement can be found in Document No. 04d – Haemophilia A - Participating Authorities.

13 Supplementary Information

13.1 Offerors are given the opportunity to provide the additional information set out in Document No. 05a – Haemophilia A - Offer Schedule - Additional Information to supplement their offer. No other supplementary information will be accepted.

13.1.1 Alternative pricing proposals **will NOT** be accepted from any bidder as part of their supplementary information. Supplementary information is classified as any value-added services a bidder may have in place and could offer to patients, treaters and/or the NHS.

13.1.2 Such information may be included by the CMU in the final Framework Agreement Stakeholder Briefing Document which is shared with Participating Authorities but **will NOT** be evaluated as part of this tender.

13.1.3 Please ensure any supplementary information is labelled clearly and is included with your offer submission. Please note due to system restrictions each attachment can be no larger than 2MB.

FAO: Catherine Harrison

Sheffield Haemophilia & Thrombosis Centre (p100) p Floor
Royal Hallamshire Hospital
Glossop Road
Sheffield
S10 2JF

Supplier Name:
……
…….

Reference: CM/PHS/17/5564

Schedule 6

Award Schedule

Description	Brand Name	Vial sizes available	Diluent (ml)	Marketing Authorisation Number	Product EAN code	Unit of issue	Price per unit of issue excl. VAT	Price per Vial / Bag excl. VAT
octocog alfa	ADVATE®	250 500 1000 1500 2000 3000 250 500	2 2 5 5 5 5 5 5	EU/1/03/271/017 EU/1/03/271/018 EU/1/03/271/013 EU/1/03/271/014 EU/1/03/271/015 EU/1/03/271/016 EU/1/03/271/011 EU/1/03/271/012	0642621018981 0642621018998 0642621013740 0642621013757 0642621013764 0642621013771 0642621013726 0642621013733	IU	THIS SECTION HAS BEEN REDACTED – SECTION 43 (COMMERCIAL INTERESTS	THIS SECTION HAS BEEN REDACTED – SECTION 43 (COMMERCIAL INTERESTS
rurioctocog alfa	ADYNOVI®	250 500 1000 2000	2 2 2 5	EU/1/17/1247/002 EU/1/17/1247/006 EU/1/17/1247/010 EU/1/17/1247/014	0642621069099 0642621069105 0642621069112 0642621069129	IU	THIS SECTION HAS BEEN REDACTED – SECTION 43 (COMMERCIAL INTERESTS	THIS SECTION HAS BEEN REDACTED – SECTION 43 (COMMERCIAL INTERESTS

Schedule 7

Ordering Procedure

1 Awards under the Framework Agreement

1.1 If a Participating Authority decides to source any Goods through the Framework Agreement then it may satisfy its requirements for the Goods by awarding a Contract in accordance with the terms laid down in this Framework Agreement without re-opening competition.

1.2 Any Participating Authority ordering Goods under the Framework Agreement without re-opening competition shall:

1.2.1 identify the relevant Lot which its Goods' requirements fall into;

1.2.2 in the first instance call off product from the highest ranked Framework Provider in the relevant Lot as set out in Clause 3 of this Schedule 7 following the evaluation of its Offer. If this product is unsuitable to meet the requirements of the patient then product from the Framework Provider ranked second maybe called off, if this product is also unsuitable to meet the requirements of the patient then product from the Framework Provider ranked third maybe called off and so on.

2 Form of Order

2.1 Subject to Clauses 1.1 and 1.2 of this Schedule 7, each Participating Authority may place an Order with the Supplier by serving an Order Form.

2.2 In the event that the Participating Authority places an Order with the Supplier pursuant to the Ordering Procedure, the Supplier agrees that it shall be obliged to fulfil the Order.

3 Lots

3.1 The Supplier has been appointed under this Framework Agreement to the Lot(s) specified in the Award Schedule.

3.2 Such Lot(s) have been awarded as follows:

NAME OF LOT	FRAMEWORK PROVIDERS AND THEIR RANKING
Lot 1	**Rank 1: Grifols (UK) Ltd**

	Rank 2: Bio Products Laboratory Ltd **Rank 3: Biotest (UK) Ltd** **Rank 4: Octapharma Ltd**
Lot 2	**Rank 1: Shire Pharmaceuticals Ltd** **Rank 2: Novo Nordisk Ltd** **Rank 3: Pfizer Ltd** **Rank 4: Pfizer Ltd** **Rank 5: Octapharma Ltd**
Lot 3	**Rank 1: Novo Nordisk Ltd** **Rank 2: Swedish Orphan Biovitrum Ltd (SOBI UK)** **Rank 3: Shire Pharmaceuticals Ltd**
Lot 4	**Rank 1: Roche Products Ltd**

Schedule 8

Participating Authorities

ORG_NAME	Department	Hospital
Oxford University Hospitals NHS Foundation Trust	Oxford Haemophilia and Thrombosis Centre	Churchill Hospital
Kettering	Kettering Haemophilia Centre	Kettering General Hospital
Northampton	Clinical Haematology	Northampton General Hospital NHS Trust
Bournemouth / Poole	Department of Haematology	The Royal Bournemouth And Christchurch Hospitals NHS Foundation Trust
Dorchester	Department of Haematology	West Dorset Hospital
Portsmouth	Pathology Department	Queen Alexandra Hospital
Salisbury NHS Foundation Trust	Department of Pathology	Salisbury District Hospital
Royal Devon And Exeter NHS Foundation Trust	Haemophilia	Royal Devon And Exeter NHS Foundation Trust
Barnstaple	North Devon Haemophilia Centre	North Devon District Hospital
Bristol (Infirmary & Children's)	Avon Haematology Unit	University Hospitals Bristol NHS Foundation Trust
Exeter	Department of Haematology	Royal Devon & Exeter Hospital
University Hospitals Plymouth NHS Trust	Haematology Department	Derriford Hospital
Taunton / Yeovil	Taunton Haemophilia Centre	Taunton And Somerset NHS Foundation Trust
Torquay	Torbay Haemophilia Centre	Torbay And South Devon NHS Foundation Trust
Truro	Truro Haemophilia Centre	Royal Cornwall Hospitals NHS Trust
Birmingham (Queen Elizabeth)	West Midlands Adult Haemostasis and Thrombosis Haemophilia Centre	Queen Elizabeth Hospital
Birmingham Children's	Birmingham Children's Hospital Haemophilia Comprehensive Care Centre	Birmingham Children's Hospital NHS Trust
University Hospitals Birmingham NHS Foundation Trust	Haemophilia	University Hospitals Birmingham NHS Foundation Trust
Coventry	UHCW Haemophilia Centre Coventry	University Hospitals Coventry & Warwickshire NHS Trust
Shrewsbury and Telford Hospital NHS Trust	Haematology Department	Shrewsbury Hospital
North Staffordshire (Stoke on Trent)	North Midlands Haemophilia Centre	University Hospital of North Midlands Trust
Royal Wolverhampton NHS Trust	Wolverhampton Haemophilia Centre	New Cross Hospital
North Hampshire (Basingstoke)	Hampshire Haemophilia Centre	Hampshire Hospitals NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust	Haemophilia Centre	Southampton General Hospital
Sheffield Teaching Hospital (Royal Hallamshire)	Haemophilia & Thrombosis Centre	Royal Hallamshire Hospital
Sheffield (Children's)	Roald Dahl Paediatric Haematology Centre	Sheffield Children's Hospital
University Hospitals of Derby and Burton NHS Foundation Tr	Derby Haemophilia Centre, Department of Clinical Haematology	Royal Derby Hospital
University Hospitals Of Leicester NHS Trust	Leicester Haemophilia Centre, Haemostasis & Thrombosis Unit	The Leicester Royal Infirmary
Nottingham	Nottingham Haemophilia Comprehensive Care Centre	Nottingham University Hospital
Bradford Teaching Hospitals NHS Foundation Trust	Department of Haematology	Bradford Royal Infirmary
Kingston upon Hull (Hull)	Hull Haemophilia Centre	Castle Hill Hospital
Hull University Teaching Hospitals NHS Trust	Haemophilia	Hull University Teaching Hospitals NHS Trust
Leeds Teaching Hospitals NHS Trust	Haemophilia	Leeds Teaching Hospitals NHS Trust
Leeds	Leeds Haemophilia Centre	St James's University Hospital
York Teaching Hospital NHS Foundation Trust	York Haemophilia Centre	York District Hospital
United Lincolnshire Hospitals NHS Trust	Department of Haematology	Lincoln County Hospital
Manchester (Adults)	Haemophilia Comprehensive Care Centre	Manchester University NHS Foundation Trust
Manchester Children's	Paediatric Haemophilia Comprehensive Care Centre	Royal Manchester Children's Hospital
Lancaster	Haematology Department	Royal Lancaster Infirmary
Royal Liverpool And Broadgreen University Hospitals NHS Tr	Roald Dahl Haemophilia Comprehensive Care Centre	Royal Liverpool University Hospital
Liverpool Children's	Liverpool Children's Haematology Treatment Centre	Alder Hey Children's NHS Foundation Trust
Bangor	Department of Haematology	Ysbyty Gwynedd
Belfast - Adult's	Northern Ireland Haemophilia & Thrombosis Centre	Belfast City Hospital
Belfast - Children's	Children's Haematology Unit	Royal Belfast Hospital for Sick Children
Royal Free	Katherine Dormandy Haemophilia Centre	Royal Free Hospital
Hammersmith Hospital, London	Haemophilia Centre	Hammersmith Hospital
University College Hospital, London	Department of Haematology	University College Hospital
Imperial College Healthcare NHS Trust	Haemophilia	St Mary's Hospital
Great Ormond Street	Haemophilia Comprehensive Care Centre	Great Ormond Street Hospital for Children
The Royal London Hospital/ Barts Health NHS Trust	Haemophilia Department	The Royal London Hospital
Cambridge	The Haemophilia and Thrombophilia Centre	Addenbrooke's Hospital
Norwich	Colney Centre	Norfolk & Norwich University Hospital
Luton	Haemophilia Centre	Luton & Dunstable Hospital
Colchester	Haemophilia Centre	Colchester General Hospital
Ipswich	Haematology Department	The Ipswich Hospital
Peterborough	Pathology Department	Peterborough District Hospital
St Thomas' and Guy's Hospital	Centre for Haemostasis and Thrombosis (Haemophilia Reference Centre)	St Thomas' Hospital
St George's Hospital, London	St George's Haemophilia Centre	St George's Hospital
Lewisham	Haemophilia Centre	University Hospital Lewisham
East Kent Hospitals University NHS Foundation Trust	Kent Haemophilia Centre	Kent & Canterbury Hospital
Gillingham, Kent (Medway)	Pathology Laboratory	Medway Maritime Hospital
Brighton	Adult Haemophilia Centre	Royal Sussex County Hospital
Eastbourne	Eastbourne Haemophilia Centre	Eastbourne District General Hospital
Chichester	Haematology Department	St Richard's Hospital
James Paget	Haematology Department	James Paget Hospital
Ashford & St. Peters	Department of Haematology	St Peter's Hospital
The Newcastle Upon Tyne Hospitals NHS Foundation Trust	Newcastle Haemophilia Comprehensive Care Centre	Royal Victoria Infirmary
Cardiff	Arthur Bloom Haemophilia Centre	University Hospital of Wales
Swansea	Swansea Haemophilia Centre	Singleton Hospital
Abergavenny	Haematology Department	Nevill Hall Hospital
Aberdeen	Grampian Area Haemophilia Centre	Aberdeen Royal Infirmary
Dundee	Dundee Haemophilia Centre	Ninewells Hospital & Medical School
Edinburgh	Edinburgh Haemophilia Centre	Royal Infirmary of Edinburgh
Glasgow (R.I.)	Haemophilia & Thrombosis Centre	Glasgow Royal Infirmary
Glasgow (R.H.S.C.)	Department of Haematology	Royal Hospital for Sick Children
Inverness	Inverness Haemophilia Centre	Raigmore Hospital

Additional

Pharmaceutical buying groups in the NHS - https://www.gov.uk/government/publications/pharmaceutical-buying-groups-in-the-nhs

For Any NHS Trust named on this list - all secondary purchasing points are also covered

Wales Participating Authorities - see TAB Welsh Purchasing Authorities

Scotland Participating Authorities - see TAB Scottish Purchasing Authorities

Northern Ireland Participating Authorities - see TAB Irish Purchasing Authorities

Welsh Blood Service

Access to CMU framework pricing may be requested by the NHS Trust for authorised outsourced service providers (e.g homecare service providers or out-patient dispensing departments)

Third party homecare suppliers awarded on the CMU homecare delivery framework agreement (CM/MSR/15/5480) and suppliers on any future CMU homecare delivery frameworks
Homecare suppliers on framework agreement CM/MSR/15/5480 and future frameworks may include providers contained in the following link: http://www.clinicalhomecare.org/nchamembers/

Name	Department
HMP BIRMINGHAM	Pharmacy Department
HMP BRINDSFORD REMAND CENTRE	Pharmacy Department
HMP DONCASTER	Pharmacy Department
HMP RANBY	Pharmacy Department
HMP NORTH SEA CAMP	Pharmacy Department
HMP LOWDHAM GRANGE	Pharmacy Department
HMP LINCOLN	Pharmacy Department
HMP NOTTINGHAM	Pharmacy Department
HMP GLEN PARVA	Pharmacy Department
HMP LINDHOLME	Pharmacy Department
HMP THE MOUNT	Pharmacy Department
HMP BEDFORD	Pharmacy Department
HMP THAMESIDE	Pharmacy Department
HMP BELMARSH	Pharmacy Department
HMP HOLLOWAY	Pharmacy Department
HMP WANDSWORTH	Pharmacy Department
HMP & YOI LEWES	Pharmacy Department
HMP ELMEY	Pharmacy Department
HMP ROCHESTER	Pharmacy Department
HMP WETHERBY	Pharmacy Department
HMP EVERTHORPE	Pharmacy Department
HMP ALTCOURT HOSPITAL	Pharmacy Department
HMP GARTH	Pharmacy Department
HMP MANCHESTER	Pharmacy Department
HMP PRESTON	Pharmacy Department
HMP WALTON	Pharmacy Department
HMP WARRINGTON	Pharmacy Department
HMP CHANNING WOOD	Pharmacy Department
HMP DARTMOOR	Pharmacy Department
HMP GUYS MARSH	Pharmacy Department
HMP WINCHESTER	Pharmacy Department
HMP WOODHILL	Pharmacy Department

It should be assumed that all HMP pharmacies operated by private sector organisations do not have access to CMU frameworks

Welsh Participating Authorities

List of Welsh Hospital Ordering Points

Cwm Taf Health Board		
Prince Charles Hospital	Merthyr Tydfil, Mid Glamorgan	CF47 9DT
Royal Glamorgan Hospital	Ynysmaerdy, Pontyclun, Llantrisant	CF72 8XR
Ysbyty Cwm Cynon	New Road, Mountain Ash, Rhondda Cynon Taff	CF45 4BZ
Ysbyty Cwm Rhondda	Partridge Road, Llwynypia	CF40 2LX
Pontypridd & District Cottage Hospital (Y Bwthyn)	The Common, Pontypridd, Glamorgan	CF37 4AL
Dewi Sant Hospital	Albert Road, Pontypridd, Mid Glamorgan	CF37 1LB
Ysbyty George Thomas	Cwmparc Road, Ystrad Fechan, Treorchy, Mid Glamorgan	CF42 6YG
Aneurin Bevan Health Board		
Nevill Hall Hospital	Brecon Road, Abergavenny, Gwent	NP7 7EG
Royal Gwent Hospital	Cardiff Road, Newport, Gwent	NP20 2UB
Ysbyty Aneurin Bevan	Festival Drive, Ebbw Vale, Blaenau Gwent	NP23 6GL
Ysbyty Ystrad Fawr	Ysbyty Ystrad Fawr, Ystrad Fawr Way, Ystrad Mynach, Hengoed	CF82 7GP
St. Woolos Hospital	St. Woolos Hospital, Stow Hill, Newport	NP20 4SZ
Chepstow Community Hospital	Tempest Way, Chepstow, Monmouthshire	NP16 5YX
County Hospital	Coed y Gric Road, Griffithstown, Pontypool, Gwent	NP4 5YA
Monnow Vale Health & Social Care Facility	Trefynwy Suite (Wards), Drybridge Park, Monmouth, Monmouthshire	NP25 5BL
Abertawe Bro Morganwg University Health Board		
Morriston Hospital	Swansea, Heol Maes Eglwys, Cwmrhydyceirw, Swansea	SA6 6NL
Princess of Wales Hospital	Princess of Wales Hospital, Coity Road, Bridgend, Mid Glamorgan	CF31 1RQ
Neath Port Talbot Hospital	Baglan Way, Port Talbot	SA12 7BX
Singleton Hospital	Sketty Lane, Sketty, Swansea	SA2 8QA
Gorseinon Hospital	Gorseinon, Swansea	SA4 4UU
Maesteg Community Hospital	Neath Road, Maesteg, Bridgend	CF34 9PW
Hwyel Dda Health Board		
Bronglais General Hospital	Caradoc Road, Aberystwyth	SY23 1ER
Glangwili General Hospital	Dolgwili Road, Glangwili, Carmarthen	SA31 2AF
Withybush General Hospital	Fishguard Road, Haverfordwest, Pembs.	SA61 2PZ
Prince Philip Hospital	Bryngwyn Mawr, Dafen, Llanelli	SA14 8QF
Amman Valley Hospital	Folland Road, Glanamman, Ammanford	SA18 2BQ
Cardigan & District Memorial Hospital	Pontyceifion, Cardigan	SA43 1DP
Llandovery Hospital	Llanfair Road, Llandovery	SA20 0LA
South Pembrokeshire Hospital	Fort Road, Pembroke Dock, Pembrokeshire	SA72 6SY
Tenby Cottage Hospital	Gas Lane, The Norton, Tenby, Pembrokeshire	SA70 8AG
Tregaron Hospital	Tregaron	SY25 6JP
Cardiff & Vale University Health Board		
University Hospital of Wales	Heath Park, Cardiff	CF14 4XW
Barry Hospital	Colcot Road, Barry, South Glamorgan	CF62 8YH
Cardiff Royal Infirmary	Glossop Terrace, Cardiff	CF24 0SZ
Children's Hospital for Wales	University Hospital of Wales, Heath Park, Cardiff	CF14 4XW
St. Davids Hospital (Cardiff)	Cowbridge Road East	CF11 9XB
University Hospital Llandough	Penlan Road, Penarth	CF64 2XX
Betsi Cadwaladr University Health Board	**Address**	**Postcode**
Glan Clwyd Hospital	Rhuddlan Road, Bodelwyddan, Rhyl, Denbighshire	LL18 5UJ
Wrexham Maelor Hospital	Croesnewydd Road, Wrexham	LL13 7TD
Ysbyty Gwynedd	Penrhosgarnedd, Bangor, Gwynedd	LL57 2PW
Abergele Hospital	Llanfair Road, Abergele	LL22 8DP
Amethyst SARC	1-3 Bryn Eirias Close off Elian Road, Colwyn Bay, Conwy	LL29 8AB
Chirk Community Hospital	John's Street, Chirk, Wrexham	LL14 5LN
Colwyn Bay Community Hospital	Hesketh Road, Colwyn Bay, Conwy	LL29 8AY
Deeside Community Hospital	Plough Lane, Higher Shotton, Deeside, Flintshire	CH5 1XS
Eryri Hospital	Lôn Parc, Caernarfon, Gwynedd	LL55 2YE
Royal Alexandra Hospital	Marine Drive, Rhyl, Denbighshire	LL18 3AS
Ruthin Community Hospital	Llanrhydd Street, Ruthin, Denbighshire	LL15 1PS
Powys Teaching Health Board	**Address**	**Postcode**
Bronllys Hospital	Bronllys, Brecon, Powys	LD3 0LS
Glan Irfon Health and Social Care Centre (Builth W	Love Lane, Builth Wells, Powys, Wales	LD2 3DG
Llanidloes War Memorial Hospital	Eastgate Street, Llanidloes, Powys	SY18 6HF
Machynlleth Community Hospital (Bro Ddyfi)	Newtown Road, Machynlleth, Powys	SY20 8AD
Montgomery County Infirmary	Llanfair Road, Newtown, Powys	SY16 2DW

Scottish Participating Authorities

List of Scottish Hospital Ordering Points

NHS AYRSHIRE & ARRAN

Ayr Hospital
Dalmellington Road
Ayr
KA6 6DX

Crosshouse Hospital
Kilmarnock Road
Kilmarnock
KA2 0BE

NHS BORDERS

Borders General Hospital
MELROSE
Roxburghshire
TD6 9BS

NHS DUMFRIES & GALLOWAY

Dumfries & Galloway Royal Infirmary
Bankend Road
DUMFRIES
DG1 4AP

NHS FIFE

Queen Margaret Hospital
Whitefield Road
Dunfermline Fife KY12 0SU

Victoria Hospital
Hayfield Road
Kirkcaldy Fife KY2 5AH

NHS FORTH VALLEY

Stirling Royal Infirmary
Livilands
Stirling
FK8 2AU

Forth Valley Royal
Stirling Road
Larbert
FK5 4WR

NHS GRAMPIAN

Aberdeen Royal Infirmary
Foresterhill Road
ABERDEEN
AB25 2ZN

NHS GREATER GLASGOW and CLYDE

Pharmacy Distribution Centre (PDC)
10 Dava Street
Moorpark Central
Govan
GLASGOW
G51 2BQ
Telephone: 0141 347 8986

Pharmacy Production Unit
Western Infirmary
Glasgow
G11 6NT

NHS HIGHLAND

Raigmore Hospital
Old Perth Road
Inverness
IV2 3UJ

NHS LANARKSHIRE

Monklands Hospital
Monkscourt Avenue,
Airdrie
ML6 0JS

Hairmyres Hospital
Eaglesham Road,
East Kilbride
G75 8RG

Wishaw General Hospital
50 Netherton Street,
Wishaw
ML2 0DP

NHS LOTHIAN

Western General Hospital
Crewe Road
EDINBURGH
EH4 2XU
Tel: 0131 537 1000

Royal Infirmary of Edinburgh
51 Little France Crescent
EDINBURGH
EH16 4SA
Tel: 0131 536 1000

Royal Hospital for Sick Children
9 Sciennes Road
EDINBURGH
EH9 1LF
Tel: 0131 536 0000

St John's Hospital (Acute Services)
Howden Road West
LIVINGSTON
West Lothian
EH54 6PP
Tel: 01506 419666

Roodlands Hospital
Hospital Road
Haddington
East Lothian
EH41 3PF
Telephone: 0131 536 8300

NHS NATIONAL WAITING TIMES CENTRE

Golden Jubilee National Hospital
Beardmore Street
Clydebank
GLASGOW
G81 4HX

NHS TAYSIDE

Ninewells Hospital & Medical School
Dundee
DD1 9SY

NHS WESTERN ISLES

Western Isles Hospital
MacAulay Road
Stornoway
Isle of Lewis
HS1 2AF

TAYSIDE PHARMACEUTICALS

Level 5, Ninewells Hospital	
Dundee	
Scotland	
DD1 9SY	

NHS SHETLAND

Gilbert Bain Hospital
South Road
Lerwick
Shetland
ZE1 0TB

NHS ORKNEY

NHS Orkney
Balfour Hospital
New Scapa Road
Kirkwall
Orkney KW15 1BH

Irish Participating Authorities

List of Irish Hospital Ordering Points

Belfast Health and Social Care Trust		
The Royal Hospitals	274 Grosvenor Road, Belfast	BT12 6BA
Belfast City Hospital	51 Lisburn Road, Belfast	BT9 7AB
Mater Hospital	45-51 Crumlin Road, Belfast	BT14 6AB
Musgrave Park Hospital	Stockman's Lane, Belfast	BT9 7JB
The Royal Hospital for Sick Children	274 Grosvenor Road, Belfast	BT12 6BA
Forster Green Hospitals	110 Saintfield Rd, Belfast	BT8 6HD
Knockbracken Healthcare Park	Saintfield Road	BT8 8BH
Northern Health and Social Care Trust		
Antrim Area Hospital	Bush Road, Antrim	BT41 2RL
Braid Valley Care Complex	Cushendall Road, Ballymena	BT43 6HL
Causeway Hospital	4 Newbridge Road, Coleraine	BT52 1HS
Dalriada Hospital	1A Coleraine Road, Ballycastle	BT54 6EY
Holywell Hospital	60 Steeple Road, Antrim	BT41 2RJ
Mid Ulster Hospital	Hospital Road, Magherafelt	BT45 5EX
Robinson Hospital	23 Newal Road, Ballymoney	BT53 6HB
Whiteabbey Hospital	Doagh Road, Newtownabbey	BT37 9RH
South Eastern Health and Social Care Trust		
Ards Community Hospital	Church St, Newtownards	BT23 4AS
Bangor Community Hospital	Castle St, Bangor	BT20 4TA
Downe Hospital	2 Struell Wells Road	BT30 6RL
Lagan Valley Hospital	39 Hillsborough Road, Lisburn, Co.Antrim	BT28 1JP
Ulster Hospital	Upper Newtownards Road, Dundonald, Belfast	BT16 1RH
Southern Health and Social Care Trust		
Armagh Community Hospital	Tower Hill, Armagh	BT61 9DR
Craigavon Area Hospital	68 Lurgan Road, Portadown	BT63 5QQ
Daisy Hill Hospital	5 Hospital Road, Newry	BT35 8DR
Lurgan Hospital	100 Sloan Street, Lurgan	BT66 3NX
South Tyrone Hospital	Carland Road, Dungannon	BT71 4AU
St Luke's Hospital	Loughgall Road, Armagh	BT61 7NQ
Western Health and Social Care Trust		
Altnagelvin Area Hospital	Altnagelvin Area Hospital, Glenshane Road, Londonderry	BT47 6SB
Grangewood	Gransha Park, Clooney Road, Londonderry	BT47 1TF
Lakeview Hospital	12a Gransha Park, Clooney Road, Londonderry	BT47 6WJ
South West Acute Hospital	124 Irvinestown Road, Enniskillen Co Fermanagh	BT74 6DN
Tyrone County Hospital	Hospital Road, Omagh, Co Tyrone	BT79 0AP
Tyrone and Fermanagh Hospital	1 Donaghanie Road, Omagh	BT79 0NS
Waterside Hospital	16 Gransha Park, Londonderry	BT47 6WH

Appendix A

Call-off Terms and Conditions for the Supply of Goods

Where an Order is placed by the Authority that refers to the Framework Agreement, the Contract is made between the Authority and the Supplier on the date of that Order Form. The Contract is subject to the terms set out in the schedules of these Call-off Terms and Conditions listed below ("**Schedules**").

The Authority and the Supplier undertake to comply with the provisions of the Schedules in the performance of the Contract.

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

For the avoidance of doubt, any actions or work undertaken by the Supplier prior to the receipt of an Order Form 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 Order Form.

The Definitions in Schedule 4 of these Call-off Terms and Conditions apply to the use of all capitalised terms in the Contract.

Schedules

Schedule 1 of these Call-off Terms and Conditions	Key Provisions
Schedule 2 of these Call-off Terms and Conditions	General Terms and Conditions
Schedule 3 of these Call-off Terms and Conditions	Information and Data Provisions
Schedule 4 of these Call-off Terms and Conditions	Definitions and Interpretations

Schedule 1 of these Call-off Terms and Conditions

Key Provisions

1 Application of the Key Provisions

1.1 The standard Key Provisions at Clauses 1 to 9 of this Schedule 1 of these Call-off Terms and Conditions shall apply to this Contract.

1.2 Extra Key Provisions shall only apply to this Contract where such provisions are set out as part of the Order Form.

2 Marketing Authorisation

2.1 The award of this Contract shall be conditional upon the Supplier being in possession of a valid marketing authorisation(s) from the Licensing Authority required for supply of the Goods (such validity to be determined by the Licensing Authority) on or prior to the Commencement Date or on such other date as is agreed between the Parties (such date always being prior to the delivery of any Goods under this Contract). The Authority may request that the Supplier delivers to the Authority evidence of the grant of such valid marketing authorisation(s). For the avoidance of doubt a marketing authorisation which has been expired or has been suspended or withdrawn by the Licensing Authority does not constitute a valid marketing authorisation for the purposes of this Clause 2.1.

2.2 If the Supplier fails to be in possession of the documentation required by Clause 2.1 of this Schedule 1 of these Call-off Terms and Conditions by the agreed date then the Authority shall be entitled to terminate this Contract with immediate effect on giving written notice to the Supplier.

2.3 The Authority may in its sole discretion at any time agree to waive compliance with the requirement in Clause 2.1 of this Schedule 1 of these Call-off Terms and Conditions by giving the Supplier notice in writing.

3 Term

3.1 This Contract commences on the Commencement Date.

3.2 The Term of this Contract shall be as set out in the Order Form.

3.3 The Term may be extended in accordance with Clause 15.2 of Schedule 2 of these Call-off Terms and Conditions provided that the duration of this Contract shall be no longer than any maximum duration applicable to the Contract if such maximum duration is set out in the Framework Agreement (including any options to extend).

4 Contract Managers

4.1 The Contract Managers at the commencement of this Contract shall be as set out in the Order Form or as otherwise agreed between the Parties in writing.

5 Names and addresses for notices

5.1 Unless otherwise agreed by the Parties in writing, notices served under this Contract are to be delivered to such persons at such addresses as referred to in the Order Form.

6 Management levels for escalation and dispute resolution

6.1 Unless otherwise agreed by the Parties in writing, the management levels at which a dispute will be dealt with are as follows:

Level	Authority representative	Supplier representative
1	Contract Manager	Contract Manager
2	Assistant Director or equivalent	Assistant Director or equivalent

7 Order of precedence

7.1 Subject always to Clause 1.10 of Schedule 4 of these Call-off Terms and Conditions, should there be a conflict between any other parts of this Contract the order of priority for construction purposes shall be:

7.1.1 the Order Form;

7.1.2 the applicable provisions of the Framework Agreement other than the Specification;

7.1.3 the provisions on the front page (page 1) of these Call-off Terms and Conditions for the Supply of Goods;

7.1.4 Schedule 1 of these Call-off Terms and Conditions: Key Provisions;

7.1.5 the Specification;

7.1.6 Schedule 2 of these Call-off Terms and Conditions: General Terms and Conditions;

7.1.7 Schedule 3 of these Call-off Terms and Conditions: Information and Data Provisions;

7.1.8 Schedule 4 of these Call-off Terms and Conditions: Definitions and Interpretations; and

7.1.9 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.

8 Failure to Supply

8.1 The Supplier shall deliver the exact quantity of Goods specified in an Order Form within fourteen (14) days of receipt by the Supplier of the Order Form, or within such other time period as may have been agreed in writing between the Parties in accordance with Clause 2 of Schedule 2 of these Call-Off Terms and Conditions ("**Delivery Time**") to the location address specified by the Authority. Time shall be of the essence in relation to such Delivery Time.

8.2 If the Supplier is unable to supply the Goods in accordance with Clause 8.1 of this Schedule 1 of these Call-Off Terms and Conditions due to circumstances beyond its reasonable control, the Supplier shall be entitled to provide essentially similar goods to the Authority provided that:

8.2.1 the Supplier notifies the Authority without delay and within the Delivery Time when it becomes aware that it will not be able to supply the Goods in accordance Clause 8.1 of this Schedule 1 of these Call-Off Terms and Conditions;

8.2.2 the notice referred to in Clause 8.2.1 of this Schedule 1 of these Call-Off Terms and Conditions stipulates the reason for the Supplier's inability to supply the Goods so ordered;

8.2.3 the Supplier supplies to the regional quality control pharmacist or the Authority all information set out on PharmaQC or any drug quality assurance database that replaces PharmaQC in respect of the essentially similar goods;

8.2.4 the essentially similar goods are approved in writing by the regional quality control pharmacist or the Authority; and

8.2.5 the Supplier provides such quantities of alternative essentially similar goods as are necessary to make up any shortfall in the Goods to the Authority prior to expiry of the Delivery Time.

8.1 If the Supplier fails to deliver the exact quantity of Goods or essentially similar goods within the Delivery Time in accordance with Clauses 8.1 and/or 8.2 of this Schedule 1 of these Call-Off Terms and Conditions, then the Authority shall be entitled to terminate this Contract with immediate effect on giving written notice to the Supplier and the Authority shall be entitled to purchase other goods to make good such default and recover from the Supplier the amount by which the cost of purchasing other goods from a third party exceeds the amount that would have been payable to the Supplier in respect of the Goods replaced by such purchase provided that the Authority uses all reasonable endeavours to

mitigate its losses. If the Supplier has been paid in advance for the Goods, then the Supplier shall also reimburse the Authority for the monies paid in respect of those Goods, or the essentially similar goods, that it has failed to deliver.

8.2 If the Authority wishes to claim any sum from the Supplier under Clause 8.1 of this Schedule 1 of these Call-Off Terms and Conditions, the Authority shall give a written notice to the Supplier to that effect. The Supplier shall pay any such sum within thirty (30) days from the date of such written notice.

8.3 Where essentially similar goods are supplied to the Authority such essentially similar goods shall be deemed to be Goods for the purposes of interpretation of this Contract.

9 Shelf Life

9.1 Where any Goods are supplied under this Contract, the Post Delivery Shelf Life:

9.1.1 shall not, subject to Clause 9.1.2 of this Schedule 1 of these Call-Off Terms and Conditions, be less than twelve (12) months; or

9.1.2 in respect of certain Goods may be less than twelve (12) months if stated as such by the Supplier in the Offer. Where the Supplier has stated in the Offer that the Post Delivery Shelf Life may be less than twelve (12) months, the Post Delivery Shelf Life shall be no less than the time period so stated.

9.2 In the event that the Supplier supplies Goods with a Post Delivery Shelf Life of less than the relevant periods referred to at Clause 9.1 of this Schedule 1 of these Call-off Terms and Conditions, the Supplier shall, upon written request by the Authority and at no cost to the Authority, immediately replace those Goods with Goods that have a Post Delivery Shelf Life equal to or greater than the relevant periods referred to at Clause 9.1 of this Schedule 1 of these Call-off Terms and Conditions. Alternatively, the Authority shall be entitled, at is sole discretion, to terminate the Contract with immediate effect on giving written notice to the Supplier, treat the Goods so delivered as Rejected Goods and the provisions of Clauses and 4.3.1, 4.4 and 4.5 of Schedule 2 of these Call-off Terms and Conditions shall apply to such Goods.

Schedule 2 of these Call-off Terms and Conditions

General Terms and Conditions

Contents

31. Notice
32. Assignment, novation and subcontracting
33. Other participants
34. Prohibited Acts
35. General

1 Supply of Goods

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

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

1.1.2 in accordance with 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 the provisions of the Framework Agreement as applicable and/or the provisions of the Order Form;

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/or the Order Form (to include, without limitation, the KPIs and all obligations in relation to the quality, performance characteristics, supply, delivery and installation and training in relation to use of the Goods).

1.3 Unless otherwise agreed by the Parties in writing, the Goods shall be new, consistent with any sample, and shall comply with any applicable specification set out in this Contract (to include, without limitation, the requirements set out in the Specification and the Supplier's response to such requirements) and any applicable manufacturers' specifications.

1.4 Without prejudice to Clause 2.1 of Schedule 1 of these Call-off Terms and Conditions, the Supplier shall ensure that all relevant consents, authorisations, licences and accreditations (including but not limited to a valid marketing authorisation issued by the Licensing Authority) required to supply the Goods are in place prior to the delivery of any Goods to the Authority.

1.5 The Supplier shall immediately and in any event within seven (7) days inform the Authority in writing if any marketing authorisation in relation to the Goods is:

1.5.1 withdrawn by the Licensing Authority for whatever reason;

1.5.2 suspended by the Licensing Authority for whatever reason; or

1.5.3 not renewed by the Licensing Authority following its expiry for whatever reason,

and, in each case, provide all relevant details and reasons to the Authority. If any marketing authorisation in relation to the Goods is withdrawn, suspended and/or not renewed by the Licensing Authority at any time during the Term the Authority shall be entitled to terminate this Contract with immediate effect on giving written notice to the Supplier.

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

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

1.8 Upon receipt of any such reports, notices, alerts or other communications pursuant to Clause 1.5 of this Schedule 2 of these Call-off Terms and Conditions, 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

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, the Order Form 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 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 With the prior written agreement of both Parties, the arrangements set out in Clause 2.3 of this Schedule 2 of these Call-off Terms and Conditions may be suspended in favour of alternative arrangements (including use of an Electronic Trading System and new logistics process) provided that such alternative arrangements improve service levels and/or reduce costs for the benefit of the Authority.

2.5 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 2.5 of this Schedule 2 of these Call-off Terms and Conditions, 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.

2.6 Unless otherwise set out in the Specification 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 2.6 of this Schedule 2 of these Call-off Terms and Conditions, unless otherwise stated in the Specification 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.

2.7 If the Supplier has notified the Authority in the Offer (or otherwise in writing) that it has appointed, or it intends to appoint, a third party (including, without limitation, a full line national or regional pharmaceutical wholesalers as appointed by the Department of Health and Social Care) to act as its distribution agent:-

2.7.1 such appointment shall not relieve the Supplier of its obligations under this Contract; and

2.7.2 the Supplier shall be liable for the acts or omissions of its distribution agent. Without prejudice to the generality of the foregoing, the Supplier agrees that any delivery time agreed between the authority and the distribution agent in writing shall be binding on the Supplier.

3 Passing of risk and ownership

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 of these Call-off Terms and Conditions, 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

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 of these Call-off Terms and Conditions and subject to Clause 4.7 of this Schedule 2 of these Call-off Terms and Conditions, the Authority shall visually inspect the Goods within a reasonable time following delivery (or such other period as may be set out as part of the requirements in the Specification, 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 of these Call-off Terms and Conditions, upon the rejection of any Goods in accordance with the Key Provisions and/or Clauses 4.2 and/or 4.6 of this Schedule 2 of these Call-off Terms and Conditions, 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 when rejected in accordance Clauses 4.2 and/or 4.6 of this Schedule 2 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions.

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 of these Call-off Terms and Conditions; 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 the Key Provisions, Clauses 4.2 and/or 4.6 of this Schedule 2 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions.

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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions 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 as part of the requirements in the Specification, 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.

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 of these Call-off Terms and Conditions;

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

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.

6 Business continuity

6.1 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:

6.1.1 the criticality of this Contract to the Authority;

6.1.2 the impact of and any disruption caused by EU Exit;

6.1.3 any reasonably foreseeable risks; and

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

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

6.2 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 6.2 of this Schedule 2 of these Call-off Terms and Conditions 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.

6.3 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.

6.4 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

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 of these Call-off Terms and Conditions.

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.

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 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. Should the Specification not state the frequency, then the first such meeting shall take place on a date to be agreed on or around the end of the first month after the Commencement Date. Subsequent meetings shall take place at monthly intervals or as may otherwise be agreed in writing between the Parties.

8.3 Two weeks prior to each review meeting (or at such time and frequency as may be specified in the Specification) the Supplier shall provide a written contract management report to the Authority regarding the supply of the Goods and the operation of this Contract. Unless otherwise agreed by the Parties in writing, such contract management report shall contain:

8.3.1 details of the performance of the Supplier when assessed in accordance with the KPIs since the last such performance report;

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 Specification;

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, 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 process set out in Clause 5 of the Key

Provisions and Clause 23.3 of this Schedule 2 of these Call-off Terms and Conditions.

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: (a) 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); or (b) manage the Framework Agreement with the Supplier ("**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 of these Call-off Terms and Conditions, 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

9.1 The Contract Price shall be calculated in accordance with the provisions of the Framework Agreement, as confirmed in the Order Form.

9.2 Unless otherwise stated in the Framework Agreement and/or the Order Form, 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, all appropriate tax (excluding VAT) and duty, 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 of these Call-off Terms and Conditions; 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 Framework Agreement and/or the Order Form:

9.3.1 where the Framework Agreement and/or the Order Form confirms 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; or

9.3.2 where Clause 9.3.1 of this Schedule 2 of these Call-off Terms and Conditions does 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 scheme agreed with government and/or statutory pricing

regulation, the Parties shall comply with such 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 Where the Supplier submits an invoice to the Authority pursuant to Clause 9.3 of this Schedule 2 of these Call-off Terms and Conditions, the Authority will consider and verify that invoice in a timely fashion.

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

9.8 Where the Authority fails to comply with Clause 9.7 of this Schedule 2 of these Call-off Terms and Conditions and there is undue delay in considering and verifying the invoice, the invoice shall be regarded as valid and undisputed for the purposes of Clause 9.7 of this Schedule 2 of these Call-off Terms and Conditions after a reasonable time has passed.

9.9 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 agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with Clause 26 of this Schedule 2 of these Call-off Terms and Conditions. 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 queries or disputed invoice sums unless the process referred to in this Clause 9.9 of this Schedule 2 of these Call-off Terms and Conditions 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.

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

9.10.1 provisions having the same effect as Clauses 9.6 to 9.8 of this Schedule 2 of these Call-off Terms and Conditions; and

9.10.2 a provision requiring the counterparty to that Sub-contract to include in any Sub-contract which it awards provisions having the same effect as Clauses 9.6 to 9.8 of this Schedule 2 of these Call-off Terms and Conditions.

In this Clause 9 of this Schedule 2 of these Call-off Terms and Conditions, a "**Sub-contract**" means a contract between two or more suppliers, at any stage of remoteness from the Authority in a subcontracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract.

9.11 The Authority reserves the right to set-off:

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

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

10 Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 it shall comply with the Framework Agreement;

10.1.2 the Goods shall be suitable for the purposes and/or treatments as referred to in the Specification, be of satisfactory quality, fit for their intended purpose and shall comply with the standards and requirements set out in this Contract;

10.1.3 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification), it will ensure that the Goods comply with requirements five (5) to eight (8), as set out at 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;

10.1.4 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;

10.1.5 without prejudice to the generality of the warranty at 10.1.4 of this Schedule 2 of these Call-off Terms and Conditions, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good distribution practice, as may be defined under any Law and/or Guidance relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;

10.1.6 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;

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

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

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

10.1.10 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;

10.1.11 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;

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

10.1.13 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 (including but not limited to the requirements of the Licensing Authority and the Department of Health and Social Care) and shall at all times comply with such quality controls and processes and make available to the Authority and/or the Department of Health and Social Care on demand the results of such quality control monitoring;

10.1.14 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);

10.1.15 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;

10.1.16 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;

10.1.17 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;

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

10.1.19 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;

10.1.20 it will comply with all Law, Guidance and Policies in so far as is relevant to the supply of the Goods;

10.1.21 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;

10.1.22 it shall:

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

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

10.1.23 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 10.1.23 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy;

10.1.24 it will promptly respond to all requests for information regarding this Contract and the Goods at the frequency and in the format that the Authority may reasonably require;

10.1.25 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, the Terms of Offer and/or Order Form) and all accompanying materials is accurate;

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

10.1.27 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its

obligations under this Contract and the documents referred to in this Contract;

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

10.1.29 there are no pending or threatened actions or proceedings before any court or administrative agency which would materially adversely affect the financial condition, business or operations of the Supplier;

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

10.1.31 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract;

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

10.1.33 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 of these Call-off Terms and Conditions, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid CE marking (where applicable), 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 issued by the Licensing Authority and 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 of these Call-off Terms and Conditions, 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 (where applicable) and/or marketing authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.

10.3 If the Supplier is in breach of Clause 10.2 of this Schedule 2 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions, 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 Terms of Offer shall be submitted to the Authority in the format and in accordance with any timescales set out in the Specification and Terms of Offer.

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 of these Call-off Terms and Conditions 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

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

12 Indemnity

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 10.1.19 and/or Clause 11 of this Schedule 2 of these Call-off Terms and Conditions;

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 of these Call-off Terms and Conditions and Clause 2.5 of Schedule 3 of these Call-off Terms and Conditions shall be unlimited. Liability under Clauses 4.9.4, 10.3 and 12.1.2 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2 of these Call-off Terms and Conditions.

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

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 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions shall be deemed to have been deleted and replaced with one hundred and five percent (105%).

13.6 Clause 13 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

14 Insurance

14.1 Subject to Clauses 14.2 and 14.3 of this Schedule 2 of these Call-off Terms and Conditions 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 (in each case) 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 specified in the Framework Agreement, if any.

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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions and/or the provisions of the Framework Agreement 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 Authority shall:

15.2.1 subject to Clause 15.2.2 of this Schedule 2 of these Call-off Terms and Conditions, be entitled to extend the Term on one or more occasions by giving the Supplier written notice 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 referred to in the Key Provisions; or

15.2.2 where the Term or any extension of the Term expires at a date the same as or after expiry of the Framework Agreement (including any extensions of the Framework Agreement in accordance with its terms), only be entitled to extend the Term with the prior written agreement of the Supplier, such agreement not to be unreasonably withheld or delayed.

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 KPI and, subject to Clause 9.9 of this Schedule 2 of these Call-Off Terms and Conditions, any breach of any payment obligations under this Contract), the non-breaching Party shall, without prejudice to its other rights and remedies under this Contract, issue notice of the breach and 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 15.4.2 of this Schedule 2 of these Call-off Terms and Conditions. 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 15.4.2 of this Schedule 2 of these Call-off Terms and Conditions, 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 forthwith by notice in writing to the other Party if such other Party commits a material breach of any of the terms of this Contract which is:

15.4.1 not capable of remedy; or

15.4.2 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 forthwith by notice in writing to the Supplier:

15.5.1 if 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 if 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 if the Supplier purports to assign, subcontract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 29.1 of this Schedule 2 of these Call-off Terms and Conditions;

15.5.4 pursuant to and in accordance with any termination rights set out in any Key Provisions and Clauses 1.5, 15.6, 27.8, 29.2, 29.4, 30.2 and 34.2 of this Schedule 2 of these Call-off Terms and Conditions;

15.5.5 if the warranty given by the Supplier pursuant to Clause 10.7 of this Schedule 2 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.7 of this Schedule 2 of these Call-off Terms and Conditions that in the reasonable opinion of the Authority are acceptable; or

15.5.6 where a court (or other competent authority) or the Authority (acting reasonably) makes a finding or determination that any of the Intellectual Property Rights required for the purposes of supplying the Goods is invalid or unenforceable for whatever reason; or

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 of these Call-off Terms and Conditions 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 (as set out in Clause 26.3 of this Schedule 2 of these Call-off Terms and Conditions) shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.4.1 of this Schedule 2 of these Call-off Terms and Conditions.

In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.6 of this Schedule 2 of these Call-off Terms and Conditions, 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 forthwith by notice in writing to the Supplier where:

15.7.1 the Contract has been substantially amended to the extent that the Regulations 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 Regulations from the procurement procedure leading to the award of the 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 of these Call-off Terms and Conditions shall be deemed mutual termination rights and the Supplier may terminate this Contract forthwith by notice in writing 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 earlier 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.

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.

16.5 The expiry or earlier termination of the Framework Agreement shall not affect this Contract. For the avoidance of doubt, any obligations set out in the Framework Agreement that form part of this Contract shall continue to apply for the purposes of this Contract notwithstanding any termination of the Framework Agreement.

17 Suspension of Supplier's appointment

17.1 Without prejudice to the Authority's rights to terminate this Contract, if a right for the Authority to terminate this Contract arises (irrespective of whether the circumstances leading to such right are capable of remedy) in accordance with Clause 15 of this Schedule 2 of these Call-off Terms and Conditions, the Authority may suspend the Supplier's appointment under this Contract by giving notice in writing to the Supplier.

17.2 If the Authority provides notice to the Supplier in accordance with Clause 17.1 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier's appointment shall be suspended for the period set out in the notice or such other period notified to the Supplier by the Authority in writing from time to time provided that such suspension shall be lifted where:

17.2.1 the circumstances leading to the Authority's right to terminate this Contract have been remedied;

17.2.2 the Authority has satisfied itself that the risk and/or impact of the circumstances giving rise to the Authority's right to terminate this Contract no longer requires such suspension; or

17.2.3 the Authority exercises its rights to terminate this Contract in accordance with Clause 15 of this Schedule 2 of these Call-off Terms and Conditions.

18 Packaging, identification and end of use

18.1 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.

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

18.3 Unless otherwise (a) specified in the Specification; (b) agreed with the Authority in writing; or (c) required to comply with any regulatory requirements, the following details shall be shown on the outside of every package:

18.3.1 a description of the Goods which shall include, without limitation, the weight of the Goods where available and any order number allocated to the Goods by the Authority and/or the Supplier;

18.3.2 the quantity in the package where available;

18.3.3 any special directions for storage;

18.3.4 the expiry date of the contents where applicable;

18.3.5 the batch number; and

18.3.6 the name and address of the manufacturer of the Goods and the Supplier.

18.4 All Goods that customarily bear 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 must be delivered with all the said marks, tabs, brands, labels, serial numbers or other devices intact. Without prejudice to the generality of the foregoing, the Supplier shall label all Goods supplied to the Authority, and the packaging of such Goods, to highlight environmental and safety information as required by applicable Law.

18.5 Unless otherwise set out in the Specification or agreed with the Authority in writing, the Supplier shall collect without charge any returnable containers (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers 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 or return.

19 Coding requirements

19.1 Unless otherwise confirmed and/or agreed by the Authority in writing and subject to Clause 19.1 of this Schedule 2 of these Call-off Terms and Conditions, the Supplier shall ensure full compliance with any Guidance issued by the Department of Health and Social Care in relation to adoption of GS1 and PEPPOL standards (to include without limitation any supplier compliance timeline and other policy requirements published by the Department of Health and Social Care in relation to the adoption of GS1 and PEPPOL standards for master data provision and exchange, barcode labelling and purchase-to-pay transacting).

19.2 Once compliance with any published timelines has been achieved by the Supplier pursuant to Clause 19.1 of this Schedule 2 of these Call-off Terms and Conditions the Supplier shall, during the Term, maintain the required level of compliance relating to the Goods in accordance with any requirements and Guidance referred to as part of this Contract.

19.3 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.

20 Sustainable development

20.1 The Supplier shall comply in all material respects with applicable environmental, social and labour Law requirements in force from time to time in relation to the Goods. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such

agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification. Without prejudice to the generality of the foregoing, the Supplier shall:

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

20.1.2 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

20.1.3 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 20.1.2 of this Schedule 2 of these Call-off Terms and Conditions.

20.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 20 of this Schedule 2 of these Call-off Terms and Conditions.

21 Electronic product information

21.1 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.

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

21.3 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.

21.4 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 21.5 of this Schedule 2 of these Call-off Terms and Conditions, no obligation to illustrate or advertise the Product Information is imposed on the Authority, as a consequence of the licence conferred by this Clause 21.4 of this Schedule 2 of these Call-off Terms and Conditions.

21.5 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.

21.6 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 21.6 of this Schedule 2 of these Call-off Terms and Conditions or otherwise under the terms of this Contract.

21.7 The Supplier shall indemnify the Authority from against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with the Product Information save for where this is a result of the Authority's wilful or negligent misrepresentation of the Product Information.

21.8 If requested in writing by the Authority, and to the extent not already agreed as part of the Specification or otherwise under Clause 2.4 of Schedule 2 of these Call-off Terms and Conditions, the Supplier and the Authority shall discuss and seek to agree in good faith arrangements to use any Electronic Trading System.

22 Sales information

22.1 If requested by the Authority, the Supplier shall provide the Authority with statements giving accurate and complete details of the quantity and value of the Goods supplied by the Supplier to the Authority pursuant to this Contract. The frequency, format and level of detail to be included in such statements shall be as specified by the Authority in the Order (or, if no such description is set out in or attached to the Order, as set out in or attached to any documentation inviting the Supplier to tender for the appointment to supply the Goods.

22.2 The Supplier shall keep at its normal place of business detailed, accurate and up to date records of the amount and value of the Goods sold by it to any Authority on or after the date of this Contract and pursuant to this Contract together with accurate details of the identity of the Authority to which such goods were sold. Subject to any other auditing process being agreed between the Authority and the Supplier the Authority shall be entitled on reasonable notice to enter the Supplier's premises during normal office hours and to inspect such records in order to verify whether any statement supplied by the Supplier to the Authority pursuant to Clause 22.1 of this Schedule 2 of these Call-off Terms and Conditions is accurate and complete.

23 Accidents and Untoward Incidents

23.1 When delivering the Goods at the Authority's premises, the Supplier shall procure that its employees are aware of the nature of the hospitals/units and NHS Trusts and other such bodies and the special care they should have for patients generally.

23.2 The Supplier is responsible for instituting a safe system of working in these circumstances and should take particular care that vehicles or equipment are not left open or unattended. In the event of an accident or an untoward incident the Supplier and/or his employee(s) will be required to submit a report of the occurrence to the authorised officer.

24 Training

24.1 If requested by the Authority, the Supplier shall as soon as reasonably practicable and at the Supplier's expense provide reasonable assistance to the Authority in the training of such persons as the Authority may reasonably specify in the use of the Goods.

25 Change management

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

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

26 Dispute resolution

26.1 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).

26.2 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 26.3 of this Schedule 2 of these Call-off Terms and Conditions as the first stage of the Dispute Resolution Procedure

26.3 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 6 of the Key Provisions. Respective representatives at each level, as set out in Clause 6 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 leveluntil 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.

26.4 If the procedure set out in Clause 26.3 of this Schedule 2 of these Call-off Terms and Conditions 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 26 of this Schedule 2 of these Call-off Terms and Conditions, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

26.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 26.4 of this Schedule 2 of these Call-off Terms and Conditions or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one Party has failed to participate in the mediation process. 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.

26.6 Nothing in this Contract shall prevent:

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

26.6.2 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.

26.7 Clause 26 of this Schedule 2 of these Call-off Terms and Conditions shall survive the expiry of or earlier termination of this Contract for any reason.

27 Force majeure

27.1 Subject to Clause 27.2 of this Schedule 2 of these Call-off Terms and Conditions 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.

27.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in Clause 27 of this Schedule 2 of these Call-off Terms and Conditions and will not be considered to be in default or liable for breach of any obligations under this Contract if:

27.2.1 the Supplier has fulfilled its obligations pursuant to Clause 6 of this Schedule 2 of these Call-off Terms and Conditions;

27.2.2 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

27.2.3 the Supplier has complied with the procedural requirements set out in Clause 27 of this Schedule 2 of these Call-off Terms and Conditions.

27.3 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.

27.4 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.

27.5 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.

27.6 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.

27.7 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.

27.8 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 on service of written notice on the Supplier.

27.9 Following such termination in accordance with Clause 27.8 of this Schedule 2 of these Call-off Terms and Conditions and subject to Clause 27.10 of this Schedule 2 of these Call-off Terms and Conditions, neither Party shall have any liability to the other.

27.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 27.8 of this Schedule 2 of these Call-off Terms and Conditions shall continue in full force and effect unless otherwise specified in this Contract.

28 Records retention and right of audit

28.1 Subject to any statutory requirement and Clause 28.2 of this Schedule 2 of these Call-off Terms and Conditions, 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.

28.2 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.

28.3 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.

28.4 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.

28.5 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:

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

28.5.2 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.

28.6 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 28 of this Schedule 2 of these Call-off Terms and Conditions 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.

28.7 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.

28.8 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.

29 Conflicts of interest and the prevention of fraud

29.1 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.

29.2 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 29.2 of this Schedule 2 of these Call-off Terms and Conditions shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

29.3 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.

29.4 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.

30 Equality and human rights

30.1 The Supplier shall:

30.1.1 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;

30.1.2 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

30.1.3 the Supplier shall impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by Clause 30 of this Schedule 2 of these Call-off Terms and Conditions.

30.2 If the Supplier fails to comply with the provisions of Clause 30.1 and/or contravenes the Equality Legislation, the Authority may terminate this Framework Agreement and recover from the Supplier the amount of any direct loss suffered by the Authority resulting from the termination.

30.3 The Supplier shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under the Equality Legislation due directly or indirectly to any act or omission by the Supplier, its agents, employees or sub-contractors.

30.4 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of Clause 30 of this Schedule 2 of these Call-off Terms and Conditions.

31 Notice

31.1 Subject to Clause 26.5 of Schedule 2 of these Call-off Terms and Conditions, 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 Order Form or such other person as one Party may inform the other Party

in writing from time to time or to a director of the relevant Party at the head office, main UK office or registered office of such Party.

31.2 A notice shall be treated as having been received:

31.2.1 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

31.2.2 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

31.2.3 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.

32 Assignment, novation and sub-contracting

32.1 In this Clause 32 of this Schedule 2 of these Call-off Terms and Conditions, a "**Sub-contract**" means a contract between two or more suppliers, at any stage of remoteness from the Authority 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.

32.2 The Supplier shall not, except where Clause 32.3 of this Schedule 2 of these Call-off Terms and Conditions 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.

32.3 Notwithstanding Clause 32.1 of this Schedule 2 of these Call-off Terms and Conditions, 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 32.3 of this Schedule 2 of these Call-off Terms and Conditions shall be subject to:

32.3.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.11 of this Schedule 2 of these Call-off Terms and Conditions;

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

32.3.3 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;

32.3.4 the provisions of Clause 9 of this Schedule 2 of these Call-off Terms and Conditions continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and

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

32.4 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.

32.5 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:

32.5.1 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;

32.5.2 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;

32.5.3 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);

32.5.4 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;

32.5.5 requires the Supplier or other party receiving goods under the contract to consider and verify invoices under that contract in a timely fashion;

32.5.6 provides that is the Supplier or other party fails to consider and verify an invoice in accordance with Clause 32.5.5 of this Schedule 2 of these Call-of Terms and Conditions, the invoice shall be regarded as valid and undisputed for the purpose of Clause 32.5.7 of this Schedule 2 of these Call-off Terms and Conditions after a reasonable time has passed;

32.5.7 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;

32.5.8 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 of these Call-off Terms and Conditions;

32.5.9 permitting the Supplier to terminate, or procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 32.6 of this Schedule 2 of these Call-off Terms and Conditions; and

32.5.10 requires the Sub-contractor to include a clause to the same effect as this Clause 32.5 of this Schedule 2 of these Call-off Terms and Conditions in any Sub-contract which it awards.

32.6 Where the Authority considers the grounds for exclusion under Regulation 57 of the Regulations apply to any Sub-contractor then:

32.6.1 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

32.6.2 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.

32.7 The Supplier shall pay any undisputed sums which are due from it to a Sub-contractor within thirty (30) days of verifying that the invice 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.

32.8 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.

32.9 The Supplier shall also include in every Sub-contract:

32.9.1 a right for the Supplier to terminate that Sub-contract if the relevant Sub-contractor fails to comply in the performance of its contract with legal obligations in the fields of environmental, social or labour law; and

32.9.2 a requirement that the Sub-contractor includes a provision having the same effect as Clause 32.9.1 of this Schedule 2 of these Call-off Terms and Conditions in any Sub-contract which it awards.

32.10 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.

33 Other participants

33.1 The Authority reserves the right to include within the Contract the requirements of any other healthcare establishments outside the boundaries of the National Health Service (such healthcare establishments being as specified in the Contract) and the Supplier shall be required to supply the Goods on the same terms as quoted in the Contract it being the intention of the Parties that Goods supplied hereunder are for consumption and not for resale only by such other healthcare establishments as are referred to in the relevant Order. The Supplier will only be required to make a delivery to any such other healthcare establishment outside of the UK by separate agreement with the Authority.

34 Prohibited Acts

34.1 The Supplier warrants and represents that:

34.1.1 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 any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the Authority or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the Authority; or

(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; and

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

34.2 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:

34.2.1 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;

34.2.2 any termination under Clause 34.2.1 of this Schedule 2 of these Call-off Terms and Conditions shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority; and

34.2.3 notwithstanding Clause 26 of this Schedule 2 of these Call-off Terms and Conditions, any dispute relating to:

(i) the interpretation of Clause 34 of this Schedule 2 of these Call-off Terms and Conditions; 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.

35 General

35.1 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.

35.2 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.

35.3 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.

35.4 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.

35.5 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.

35.6 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.

35.7 The rights and remedies provided in this Contract are cumulative and not exclusive of any rights or remedies provided by general law, or by any other contract or document. In this Clause 35.7 of this Schedule 2 of these Call-off Terms and Conditions, right includes any power, privilege, remedy, or proprietary or security interest.

35.8 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.

35.9 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.

35.10 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.

35.11 Subject to Clause 26 of this Schedule 2 of these Call-off Terms and Conditions, the Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Contract or its subject matter.

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

Schedule 3 of these Call-off Terms and Conditions

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 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions 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 The Recipient shall be entitled to disclose the Confidential Information of the Discloser where:

1.2.1 the Recipient is required to disclose the Confidential Information by Law, provided that Clause 3 of this Schedule 3 of these Call-off Terms and Conditions shall apply to disclosures required under the FOIA or the Environmental Regulations;

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

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

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

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

(iv) the Recipient has reasonable grounds to believe that the Discloser is involved in activity that may constitute a criminal offence under the Bribery Act 2010 and the disclosure is being made to the Serious Fraud Office.

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

1.3.1 on a confidential basis to any Central Government Body or other Contracting Authority for any proper purpose of the Authority or of the relevant Central Government Body or other 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 to Parliament and any Parliamentary Committees or if required by any Parliamentary reporting requirement;

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

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

1.3.5 on a confidential basis for the purpose of the exercise of its rights under this Contract; or

1.3.6 to a proposed transferee, assignee or novatee of, or successor in title to the Authority,

and for the purposes of the foregoing, 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 Clause 1 of this Schedule 3 of these Call off Terms and Conditions.

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 of these Call-off Terms and Conditions 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 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions 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 To the extent that the nature of this Contract means that the Parties are acting both as Controllers, each Party undertakes to comply at all times with its obligations under the Data Protection Legislation and shall:

2.2.1 implement such measures and perform its obligations (as applicable) in compliance with the Data Protection Legislation;

2.2.2 be responsible for determining its data security obligations taking into account the state of the art, the costs of implementation and the

nature, scope, context and purposes of the Processing as well as the risk of varying likelihood and severity for the rights and freedoms of the Data Subjects, and implement appropriate technical and organisational measures to protect the Personal Data against unauthorised or unlawful Processing and accidental destruction or loss and ensure the protection of the rights of the Data Subject, in such a manner that Processing will meet the requirements of the Data Protection Legislation where Personal Data has been transmitted by it, or while the Personal Data is in its possession or control;

2.2.3 where appropriate, promptly refer to the other Party any requests, from (i) Data Subjects in regards to the right of access to Personal Data by that Data Subject in accordance with the Data Protection Legislation; (ii) the Information Commissioner; or (iii) any other law enforcement authority and to the extent it is reasonable and practical to do so consult with the other Party (for the avoidance of doubt at no additional cost) before responding to such request.

2.3 Where Personal Data is shared between the Parties, each acting as Controller:

2.3.1 the Data Transferor warrants and undertakes to the Data Recipient that such Personal Data has been collected, Processed and transferred in accordance with the Data Protection Legislation and this Clause 2 of this Schedule 3 of these Call-off Terms and Conditions;

2.3.2 the Data Recipient will Process the Personal Data in accordance with the Data Protection Legislation and this Clause 2 of this Schedule 3 of these Call-off Terms and Conditions; and

2.3.3 where the Data Recipient is in breach of its obligations under this Schedule 3 of these Call-off Terms and Conditions and the Data Protection Legislation, the Data Transferor may temporarily suspend the transfer of the Personal Data to the Data Recipient until the breach is repaired.

2.4 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).

2.5 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 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 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 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 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 and Environmental Regulations and the Supplier itself is subject to the FOIA 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 and Environmental Regulations and the Supplier is not itself subject to the FOIA 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 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 and Environmental Regulations.

3.5 In preparing a copy of this Contract for publication under Clause 3.4 of this Schedule 3 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions, 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 of these Call-off Terms and Conditions, 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.

Schedule 4 of these Call-off Terms and Conditions

Definitions and Interpretations

1 Definitions

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

"Authority"	means the authority named on the Order Form;
"Authority's Obligations"	means the Authority's further obligations, if any, referred to in the Specification and/or the Order Form;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including an influenza pandemic, EU Exit and any Force Majeure Event;
"Business Continuity Plan"	means the Supplier's business continuity plan which includes its plans for continuity of the supply of the Goods during a Business Continuity Event;
"Business Day"	means any day other than Saturday, Sunday, Christmas Day, Good Friday or a statutory bank holiday in England and Wales;
"Call-off Terms and Conditions"	means these Call-off Terms and Conditions for the supply of Goods;
"Central Government Body"	means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency.
"Commencement Date"	means the date of the Order Form;

"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract including any procurement process which is: (a) Personal Data including without limitation which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"Contract"	means the Order Form, the provisions on the front page (page 63) and all Schedules of these Call-off Terms and Conditions, the Specification, the Offer and the applicable provisions of the Framework Agreement;
"Contracting Authority"	means any contracting authority as defined in Regulation 3 of the Regulations (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Order Form or as otherwise agreed between the Parties in writing 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 of these Call-off Terms and Conditions;
"Controller"	shall have the same meaning as set out in the GDPR;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract calculated in accordance with the provisions of the Framework Agreement and as confirmed in the Order Form;
"Data Protection Legislation"	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;
"**Data Recipient**"	means the Controller who agrees to receive Personal Data from the Data Transferor for further Processing in accordance with Schedule 3 of these Call-off Terms and Conditions;
"Data Subject"	shall have the same meaning as set out in the GDPR;
"**Data Transferor**"	means that Controller who transfers the relevant Personal Data;
"Defective Goods"	has the meaning given under Clause 4.6 of Schedule 2 of these Call-off Terms and Conditions;
"Delivery Times"	has the meaning given under Clause 8.1 of Schedule 1 of these Call-off Terms and Conditions;
"Dispute Resolution Procedure"	means the process for resolving disputes as set out in Clause 26 of Schedule 2 of these Call-off Terms and Conditions;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"EMA"	means the European Medicines Agency;
"Environmental Regulations"	the Environmental Information Regulations 2004, together with any guidance and/or codes of practice issued by the

	Information Commissioner or any Central Government Body in relation to such Regulations;
"eProcurement Guidance"	means the NHS eProcurement Strategy available via: http://www.gov.uk/government/collections/nhs-procurement together with any further Guidance issued by the Department of Health and Social Care in connection with it;
"Equality Legislation"	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000, the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034), the Human Rights Act 1998 and the National Minimum Wage Regulations 2015 (as amended by the National Minimum Wage (Amendment) Regulations 2016);
"EU Exit"	means the process of the UK leaving the EU pursuant to Article 50 of the Treaty on the Functioning of the European Union and any resulting changes in Law, customs duties and/or tariffs, and/or import/export rules or restrictions;
"FOIA"	means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time, together with any guidance and/or codes of practice issued by the Information Commissioner or any relevant Central Government Body in relation to such Act;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire;

	(e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but, for the avoidance of doubt, not including EU Exit unless and to the extent that a consequence of EU Exit falls within one of the above defined circumstances;
"Framework Agreement"	means the Framework Agreement referred to in the Order Form;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"GDPR"	means the General Data Protection Regulation (Regulation (EU) 2016/679);
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and

	(b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Goods"	means any and all goods, materials or items that the Supplier is required to supply to the Authority under this Contract;
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Department of Health and Social Care, Monitor, NHS England, the MHRA, the European Medicine Agency the European Commission, the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Invitation to Offer"	means the document referred to in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
"Key Provisions"	means the key provisions set out in Schedule 1 of these Call-off Terms and Conditions and/or as part of the Order Form;

"KPI"	means the key performance indicators as set out in the Specification and/or the Order Form, if any;
"Law"	means any applicable legal requirements including without limitation: (a) any applicable statute or proclamation or any delegated or subordinate legislation or regulation as applicable in England and Wales; (b) (subject to EU Exit) any applicable European Union directive, regulation, decision or law; (c) (subject to EU Exit) any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; (f) any relevant code of practice as applicable in England and Wales; (g) any relevant collective agreement and/or international law provisions (to include without limitation as referred to in (a) to (f) above).
"Licensing Authority"	means the MHRA or the EMA or such other licensing authority as the Authority shall determine;
"Lots"	means the Goods divided into lots as referred to in the OJEU Notice;
"MHRA"	means the Medicines and Healthcare products Regulatory Agency;
"NHS"	means the National Health Service;
"Occasion of Tax Non-Compliance"	means: (a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of: (i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or

	the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; (ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or (b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion;
"Offer"	means the offer submitted by the Supplier to the Authority in response to the Invitation to Offer;
"Order Form"	means the order form used by the Participating Authority to place an order in writing for the Goods (such order form being in such form as the Participating Authority and the Supplier shall agree from time to time);
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in the GDPR;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Post Delivery Shelf Life"	means the shelf life of the Goods remaining at the point of the completion of the delivery of the Goods in accordance with this Contract (e.g. if the Goods have two (2) years shelf life at the point of the completion of their manufacture and the completion of their delivery under this Contract is at a point six (6) months after the completion of their manufacture, the post-delivery shelf life shall be eighteen (18) months);
"Process"	shall have the same meaning as set out in the GDPR. Processing and Processed shall be construed accordingly;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 21 of

	Schedule 2 of these Call-off Terms and Conditions for inclusion in the Authority's product catalogue from time to time;
"Regulations"	means the Public Contracts Regulations 2015 (SI 2015/102) as amended;
"Rejected Goods"	has the meaning given under Clause 4.2 of Schedule 2 of these Call-off Terms and Conditions;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"Remedial Proposal"	has the meaning given under Clause 15.3 of Schedule 2 of these Call-off Terms and Conditions;
"Requirement to Recall"	has the meaning given under 4.9 of Schedule 2 of these Call-off Terms and Conditions;
"Specification"	means the specification set out in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors;
"Sub-contract"	means a contract between two or more suppliers at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Framework Agreement;
"Sub-contractor"	means a party to a Sub-contract other than the Supplier;
"Supplier"	means the supplier named on the Order Form;
"Term"	means the term as referred to in the Key Provisions;
"Terms of Offer"	means the document referred to in the Framework Agreement as supplemented by any further information set out and/or referred to in the Order Form and as amended and/or updated in accordance with this Contract;
"Third Party Body"	has the meaning given under Clause 8.5 of Schedule 2 of these Call-off Terms and Conditions; and

"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax.

1.2 References to any statute or order shall include any statutory extension, modification or re-enactment, and any order, regulation, bye-law or other subordinate legislation.

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 Contract as a chargeable item and subject to Clause 35.6 of Schedule 2 of these Call-off Terms and Conditions, 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 requirements set out in the Specification 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.