TERMS AND CONDITIONS FOR THE SUPPLY OF FAVIPIRAVIR TABLETS 200MG (AVIGAN)

UNLICENSED MEDICINES

The Authority	The Secretary of State for Health and Social Care acting as part of the Crown through the Department of Health and Social Care, 39 Victoria St, Westminster, London SW1H 0EU
The Supplier	Vertical Pharma Resources Limited, 41 Central Avenue, West Molesey, Surrey KT8 2QZ. Company Registration number - 06077026

Date	10 February 2022
Description of Medicine (the Goods)	Favipiravir tablets 200mg (Avigan)

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

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

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

Schedules

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

Signed by the authorised representative of THE AUTHORITY

Name: FOIA Section 40 (Personal Information)

Position: Senior Manager Vaccines and Countermeasures

Signature: FOIA Section 40 (Personal Information)

Signed by the authorised representative of THE SUPPLIER

Name: FOIA Section 40 (Personal Information)

Position: Fi

Signature: FOIA Section 40 (Personal Information)

Schedule 1

Key Provisions

1. Application of the Key Provisions

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

2. Term

2.1 Subject to Clause 2.2 of this Schedule 1, this Contract shall commence on the **10 of February 2022** ("**Commencement Date**") and shall expire on **11 April 2022** (**"Term"**).

2.2 This Contract shall come into force on the later of either:

2.2.1 the Commencement Date; or

2.2.2 the date that the Authority notifies the Supplier that it is satisfied that the Licensing Authority has approved the importation of the Goods or that it is satisfied that the Licensing Authority does not object to the importation of the Goods in accordance with Schedule 4 of the 2012 Regulations.

3. Contract Managers

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

3.1.1 for the Authority:

FOIA Section 40 (Personal Information) **– Procurement Consultant Department of Health and Social Care**

3.1.2 for the Supplier:

FOIA Section 40 (Personal Information) **– Director Strategic Partnerships Vertical Pharma Resources**

4. Names and addresses for notices

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

4.1.1 for the Authority:

Department of Health and Social Care, 2nd Floor, Rutland House, Runcorn, WA7 2ES

4.1.2 for the Supplier:

Vertical Pharma Resources Limited, 41 Central Avenue, West Molesey, Surrey KT8 2QZ.

5. Management levels for escalation and dispute resolution

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

Level	Authority representative	Supplier representative
1	Contract Manager	Director Strategic
2	Senior Manager	Chief Executive
3	Deputy Director	Executive Chairman

6. Order of precedence

6.1 Subject always to Clause 4.1 of Schedule 2 and Clause 1.10 of Schedule 4, should there be and only to the extent that there is, a conflict between any of the provisions of this Contract the descending order of priority for construction purposes shall be:

6.1.1 the provisions on page 1 of this Contract;

6.1.2 Schedule 1: Key Provisions;

6.1.3 Schedule 2: General Terms and Conditions;

6.1.4 Schedule 6: Commercial Schedule;

6.1.5 Schedule 8: Offer Schedule;

6.1.6 **Schedule 5: Specification;**

6.1.7 Schedule 4: Definitions and Interpretations;

6.1.8 Schedule 3: Information Provisions;

6.1.9 Schedule 9: Business Continuity Plan (not used); and

6.1.10 Schedule 7: Proforma Change Control Notice.

7. Purchase Orders

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

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

8. Time of the essence

8.1 Time is of the essence as to any delivery dates under this Contract and if the Supplier fails to meet any delivery date this shall be addressed in accordance with Clause 4.3 of Schedule 2.

9. Regulatory and information requirements

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

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

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

9.4 If the Marketing Authorisation is:

9.4.1 withdrawn by the Licensing Authority;

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

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

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

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

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

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

9.6 The Supplier shall:

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

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

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

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

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

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

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

9.10 Without prejudice to the Supplier's obligation to comply with all applicable Law and Guidance, where the sale, manufacture, assembly, importation, storage, distribution, supply, delivery, or installation of the Goods under this Contract relates to 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. The applicable Law and Guidance is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland. In particular, but without limitation, the Supplier warrants that:

9.10.1 at the point such Goods are supplied to the Authority, all such Goods which are medical devices shall have valid UKCA 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 9.10, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of such valid UKCA marking, and evidence of any other authorisations, registrations, approvals or documentation required;

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

9.10.3 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 UKCA marking and/or Marketing Authorisation) required in relation to the Goods in accordance with Law and Guidance until such time as the Goods expire or the Authority notifies the Supplier in writing that it has used or disposed of all units of the Goods supplied under this Contract.

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

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

Schedule 2

General Terms and Conditions

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30. General

1. Supply of Goods

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

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

1.1.2 in accordance with the provisions of this Contract;

1.1.3 using reasonable skill and care in their delivery;

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

1.1.5 in accordance with any quality assurance standards as set out in the Key Provisions, and the Specification;

1.1.6 in accordance with the applicable Law and Guidance. The applicable Law and Guidance is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland;

1.1.7 in accordance with Good Industry Practice;

1.1.8 in accordance with the Policies; and

1.1.9 in a professional and courteous manner.

1.2 The Supplier shall comply fully with its obligations set out in the Specification and all obligations in relation to the quality, performance characteristics, supply, delivery and installation, and training in relation to use of the Goods). The applicable Specification is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland.

1.3 Unless otherwise agreed by the Parties in writing, the Goods shall: not previously have left the control of the Supplier nor have deviated from their defined distribution path; be consistent with any sample; have not been rejected by any other entity prior to their supply to the Authority under this Contract; and comply with any applicable specification set out in this Contract (to include, without limitation, the provisions of the Authority's requirements set out in the Specification and the Supplier's proposals for meeting such requirements and any applicable manufacturers' specifications.

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

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

questions and/or requests for information that the Authority may have in this context in relation to the Goods.

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

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

2. Performance review and delay

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

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

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

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

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

3. Quality assurance

3.1 The Supplier shall comply with its quality control monitoring system, details of which are included in the applicable Marketing Authorisation and the Manufacturing Licence. The Supplier shall manufacture the Goods in accordance with Good Manufacturing Practice. The applicable Marketing Authorisation is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland. The Supplier shall at all times comply with those standards set out in the QTA.

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

3.2.1 notifying the Authority in writing in advance of its intention to implement such change and giving the Authority the opportunity to make representations to the Supplier within twenty one (21) days of receipt by the Authority of notice that the Supplier intends making such change. Such notice by the Supplier to include details of the consequences which will follow such change being implemented; and

3.2.2 the relevant Licensing Authority formally approving such change.

4. Delivery

4.1 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 Delivery Schedule or a Purchase Order or as otherwise agreed with the Authority in writing. For the avoidance of doubt and notwithstanding Clause 6.1 of Schedule 1, where there is any conflict between the provisions of any of the aforementioned documents, the provisions of the Delivery Schedule shall always take precedence.

4.2 Delivery shall be completed when the Goods have been unloaded at the location (including any location in Northern Ireland) 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, such collection by the Authority is deemed delivery for the purposes of the Contract.

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

4.3.1 be entitled to refuse or cancel delivery of any such Goods not delivered in accordance with the Delivery Schedule;

4.3.2 cease to have any liability to pay for any such Goods not delivered in accordance with the Delivery Schedule where such Goods have been refused delivery or had their delivery cancelled in accordance with Clause 4.3.1 of this Schedule 2;

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

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

(b) any wasted expenditure or charges; and

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

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

4.3.4 be entitled to treat this as a breach not capable of remedy and terminate this Contract in accordance with Clause 15.3 of this Schedule 2.

4.4 The Supplier's obligations under Clauses **4.4 and 4.5** of this Schedule 2 are without prejudice to its obligations under Clause 18 of this Schedule 2. The Supplier shall deliver all Goods securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

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

4.4.2 the quantity in the package;

4.4.3 special directions for storage (if any);

4.4.4 expiry date for the Goods in the package;

4.4.5 batch number;

4.4.6 name of Supplier; and

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

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

4.6 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods. Such delivery note shall contain the information specified in the Specification or as otherwise agreed with the Authority in writing. Where such

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

4.7 Part deliveries may be refused unless the Authority has previously agreed in writing to accept such part deliveries. Where delivery of the Goods is refused by the Authority in accordance with this Clause 4.7 **of this Schedule 2**, the Supplier shall be responsible for all risks, costs and expenses associated with the re-delivery of the Goods in accordance with the agreed delivery times/dates. Where the Authority accepts delivery more than five (5) days before the agreed delivery date, the Authority shall be entitled to charge the Supplier for the costs of insurance and storage of the Goods until the agreed date for delivery.

4.8 Unless otherwise agreed with the Authority in writing (including where stated in the Specification), 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 4.8 of **Schedule 2**, unless otherwise agreed with the Authority in writing (including where stated in the Specification), 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.

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

5. Passing of risk and ownership

5.1 Risk in the Goods shall pass to the Authority when the Goods are delivered as specified in this Contract.

5.2 Ownership of the Goods shall pass to the Authority on the earlier of:

5.2.1 full payment for such Goods; or

5.2.2 where the goods are consumables or are non-recoverable (e.g. used in clinical procedures), at the point such Goods are delivered as

specified in this Contract. For the avoidance of doubt, where ownership passes in accordance with this Clause 5.2.2 of this Schedule 2, then the full Contract Price for such Goods shall be recoverable by the Supplier from the Authority as a debt if there is non-payment of a valid undisputed invoice issued by the Supplier to the Authority in relation to such Goods.

5.3 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.

6. Inspection, rejection, return and recall

6.1 As relevant and proportionate to the Goods in question and subject to reasonable written notice, the Supplier shall permit any person authorised by the Authority, to inspect work being undertaken in relation to the Goods and/or the storage facilities used in the storage of the Goods at all reasonable times at the Supplier's premises or at the premises of any Sub-contractor or agent of the Supplier in order to confirm that the Goods are being manufactured and/or stored in accordance with Good Industry Practice and Good Manufacturing Practice and in compliance with the requirements of this Contract and/or that stock holding and quality assurance processes are in accordance with the requirements of this Contract.

6.2 Without prejudice to the provisions of Clause 6.8 of this Schedule 2 and subject to Clause 6.9 of this Schedule 2, the Authority shall visually inspect the Goods within a reasonable time following delivery and shall verify the batch numbers, expiry dates and temperature records within seven (7) days following delivery, and may by written notice reject any Goods found to be damaged or otherwise not in accordance with the requirements of this Contract ("**Rejected Goods**"). The whole of any delivery may be rejected if a reasonable sample of the Goods taken indiscriminately from that delivery is found not to conform in all material respects to the requirements of the Contract.

6.3 Without prejudice to the provisions of Clause 6.6 of this Schedule 2, upon the rejection of any Goods in accordance with Clauses 6.2 and/or 6.8 of this Schedule 2, the Supplier shall at the Authority's written request:

6.3.1 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

6.3.2 without extra charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) supply replacements for the Rejected Goods to the Authority, subject to the Authority not cancelling its purchase obligations in accordance with Clause 6.6 of this Schedule 2.

6.4 If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority rather than returned to the Supplier, the Authority reserves the right to charge the Supplier for the costs associated

with the disposal of the Rejected Goods and the Supplier shall promptly pay any such costs.

6.5 Risk and title in respect of any Rejected Goods shall pass to the Supplier on the earlier of: (a) collection by the Supplier in accordance with Clause 6.3 of this Schedule 2; or (b) immediately following the expiry of ten (10) Business Days from the Authority issuing written notification rejecting the Goods. If Rejected Goods are not collected within ten (10) Business Days of the Authority issuing written notification rejecting the Goods, the Authority may return the Rejected Goods at the Supplier's risk and expense for the avoidance of doubt which includes the cost of transportation and charge the Supplier for the cost of storage from the expiry of ten (10) Business Days from the date of notification of rejection.

6.6 Where the Authority rejects any Goods in accordance with Clauses 6.2 and/or 6.8 of this Schedule 2 and the Authority no longer requires replacement Goods or elects to source replacement Goods or any substitute of the same from elsewhere, the Authority may by written notice cancel its purchase obligations in relation to such quantity of Rejected Goods. Should the Authority have paid for such Rejected Goods the Supplier shall refund such payment to the Authority within thirty (30) days of the Authority cancelling such purchase obligations and informing the Supplier that the Authority does not require replacements for such Rejected Goods.

6.7 The Authority shall be entitled to charge the Supplier for any Loss Costs incurred by the Authority as a result of rejection of any Goods in accordance with this Contract provided that the Authority shall use its reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within thirty (30) days of the date of the Authority's invoice for the same.

6.8 Without prejudice to any other provisions of this Contract or any other warranties or guarantees applicable to the Goods supplied and subject to Clause 6.10 of this Schedule 2, if at any time following the date of the delivery of any Goods, all or any part of such Goods are found to be defective or otherwise not in accordance with the requirements of this Contract ("**Defective Goods**"), the Supplier shall, at the Authority's discretion:

6.8.1 upon written request and without charge, promptly (and in any event within twenty (20) Business Days or such other time agreed by the Parties in writing acting reasonably) remedy the deficiency by replacing such Defective Goods; or

6.8.2 upon written notice of rejection from the Authority, treat such Defective Goods as Rejected Goods in accordance with Clauses 6.2 to 6.6 of this Schedule 2.

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

6.10 The Supplier shall be relieved of its liabilities under Clauses 6.2 to 6.6 (inclusive) and/or Clause 6.8 of this Schedule 2 to the extent only that the Goods are damaged, there are defects in the Goods and/or the Goods fail to comply with the requirements of this Contract due, in each case, to any acts or omissions of the Authority.

6.11 The Authority's rights and remedies under Clause 6.8 of this Schedule 2 shall cease within a reasonable period of time from the date on which the Authority discovers or might reasonably be expected to discover that the Goods are Defective Goods or within such other period as may be set out in the Key Provisions, if any. For the avoidance of doubt, Goods not used before their expiry date shall not be considered Defective Goods following the date of expiry provided that at the point such Goods were delivered to the Authority they met any shelf life requirements set out in the Specification.

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

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

6.12.2 from the date of the Requirement to Recall treat the Goods the subject of such recall as Defective Goods in accordance with Clause 6.8 of this Schedule 2;

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

6.12.4 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.

7. Business continuity

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

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

7.2.1 the criticality of this Contract to the Authority; and

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

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

7.3 The Supplier shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every twelve (12) months starting from the Commencement Date, or such other period as may be agreed between the Parties taking into account the criticality of this Contract to the Authority and the size and scope of the Supplier's business operations. The Supplier shall promptly provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, reasonable and proportionate documentary evidence that the Supplier tests its Business Continuity Plan in accordance with the requirements of this Clause 7.3, 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.

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

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

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

8. Contract management

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

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

8.3 Where the Supplier and/or the Authority provide the management information to a Third Party Body pursuant to Clause 8.2 of this Schedule 2 and such management information is subject to obligations of confidentiality under this Contract, the Authority shall ensure that any Third Party Body receiving the management information is bound by obligations of confidentiality no less stringent than those which the Authority is bound by under this Contract in relation to such confidential management information.

8.4 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:

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

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

8.5 If the Third Party Body and/or the Authority shares the management information or any other information provided under Clause 8.4 of this Schedule 2, any Contracting Authority receiving the management information shall, where such management information is subject to obligations of confidence under this Contract and such management information is provided direct by the Authority to such Contracting Authority, be informed of the confidential nature of that information by the Authority and shall be requested by the Authority not to disclose it to any body that is not a Contracting Authority (unless required to do so by Law).

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

9. Price and payment

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

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

9.2.1 shall remain fixed during the Term; and

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

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

b) any royalties, licence fees or similar expenses in respect of the making, use or exercise by the Supplier of any Intellectual Property Rights for the purposes of performing this Contract, and any licence rights granted to the Authority in accordance with Clause 11 of this Schedule 2; and

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

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

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

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

9.6 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 9.3 of this Schedule 2 within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Clause 9.6, the invoice shall be regarded as valid and undisputed for the purposes of this Clause 9.6 after a reasonable time has passed.

9.7 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums unless the process referred to in this Clause 9.7 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination.

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

9.9 The Authority reserves the right to set-off:

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

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

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

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

10. Warranties

10.1 The Supplier warrants and undertakes that:

10.1.1 the Goods shall be **suitable for the purposes and/or treatments as referred to in the applicable Specification, be** of satisfactory quality, fit for their intended purpose as indicated in the Marketing Authorisation, and shall comply with the standards and requirements set out in this Contract, The applicable Specification and Marketing Authorisation is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland;

10.1.2 unless otherwise confirmed by the Authority in writing (to include, without limitation, as part of the Specification), it will ensure that the Goods comply with requirements five (5) to seven (7), as set out in Annex 1 of the Cabinet Office Procurement Policy Note -

Implementing Article 6 of the Energy Efficiency Directive (Action Note 07/14 3rd June 2014), to the extent such requirements apply to the relevant Goods;

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

10.1.4 without prejudice to the generality of the warranty at Clause 10.1.3 of this Schedule 2, it shall ensure that, the Goods are manufactured, stored and/or distributed in accordance with good manufacturing practice and/or good warehousing practice and/or good distribution practice, as may be defined under any Law, Guidance and/or Good Industry Practice relevant to the Goods, and in accordance with any specific instructions of the manufacturer of the Goods;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10.1.19 it will comply with all Law, Guidance, Policies and the Supplier Code of Conduct in so far as is relevant to the supply of the Goods including Title II of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency where the Goods are being supplied to Northern Ireland;

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

10.1.21 it shall: (i) comply with all relevant Law and Guidance to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;

10.1.22 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.22 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy.

10.1.23 it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the Goods, any complaints and any Disputes at the frequency, in the timeframes, and in the format as requested by the Authority from time to time (acting reasonably);

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

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

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

10.1.27 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;

10.1.28 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;

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

10.1.30 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;

10.1.31 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;

10.1.32 it has and will continue to have the capacity, funding and cash flow to meet all its obligations under this Contract; 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 If the Supplier is in breach of Clause 10.1 of this Schedule 2, then, without prejudice to any other right or remedy of the Authority, the Authority shall be entitled to reject and/or return the Goods and the Supplier shall, subject to Clause 13.2 of this Schedule 2, indemnify and keep the Authority indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings suffered or incurred by the Authority as a result of such breach.

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

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

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

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

10.5.2 promptly provide to the Authority:

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

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

10.6 The Supplier further warrants and undertakes to the Authority that it will inform the Authority in writing immediately upon becoming aware that any of the warranties set out in this Clause 10 have been breached or there is a risk that any warranties may be breached.

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

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 10.1.18 and/or Clause 11 of this Schedule 2;

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

12.2 Liability under Clauses 12.1.1 and 12.1.3 of this Schedule 2 shall be unlimited. Liability under Clauses 6.12.4, 10.2, and 12.1.2 of this Schedule 2 shall be subject to the limitation of liability set out in Clause 13 of this Schedule 2.

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

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

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

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

13. Limitation of liability

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

13.1.1 for death or personal injury resulting from its negligence;

13.1.2 for fraud or fraudulent misrepresentation; or

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

13.2 Subject to Clauses 12.2, 13.1, 13.3 and 13.5 of this Schedule 2, the total liability of each Party to the other under or in connection with this Contract whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall be limited in aggregate to the greater of: (FOIA Section 43(2) (Commercial Information) [redacted]

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 FOIA Section 43(2) (Commercial Information) [redacted]

[redacted]

FOIA Section 43(2) (Commercial Information)

[redacted]

[redacted]

[redacted]

13.6 This Clause 13 shall survive the expiry of or earlier termination of this Contract for any reason.

14. Insurance

14.1 Subject to Clause 14.2 of this Schedule 2 and unless otherwise confirmed in writing by the Authority, as a minimum level of protection, the Supplier shall put in place and/or maintain in force, at its own cost with a reputable commercial insurer, insurance arrangements in respect of employer's liability, public liability and product liability in accordance with Good Industry Practice with the minimum cover per claim of the greater of five million GBP (£5,000,000) or any sum as required by Law unless otherwise agreed with the Authority in writing.

14.2 Provided that the Supplier maintains all indemnity arrangements required by Law, the Supplier may self insure in order to meet other relevant requirements referred to at Clause 14.1 of this Schedule 2 on condition that such self insurance arrangements offer the appropriate levels of protection and are approved by the Authority in writing prior to the Commencement Date.

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

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

14.5 The Supplier shall from time to time and in any event within five (5) Business Days of written demand provide documentary evidence to the Authority that insurance arrangements taken out by the Supplier pursuant to this Clause 14 are fully maintained and that any premiums on them and/or contributions in respect of them (if any) are fully paid.

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

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 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 9.7 of this Schedule 2, any breach of any payment obligations, under this Contract), the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 15.3.2 of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:

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

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

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

shall be deemed, for the purposes of Clause 15.3.2 of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.

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

15.3.1 not capable of remedy; or

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

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

15.4.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;

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

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

15.4.4 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in breach of Clause 28.1 of this Schedule 2;

15.4.5 pursuant to and in accordance with the Key Provisions and Clauses 9.4 of Schedule 1 and 15.5, 23.8; 25.2; 25.4 and 29.2 of this Schedule 2; or

15.4.6 the warranty given by the Supplier pursuant to Clause 10.5 of this Schedule 2 is materially untrue, the Supplier commits a material

breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 10.5 of this Schedule 2, or the Supplier fails to provide details of proposed mitigating factors as required by Clause 10.5 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable.

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

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

15.5.2 a failure or refusal by the Supplier to provide the financial or other security and/or assurances requested in accordance with this Clause 15.5 in accordance with any reasonable timescales specified in any such notice issued by the Authority shall be deemed a breach of this Contract by the Supplier and shall be referred to and resolved in accordance with the Dispute Resolution Procedure; and

15.5.3 a failure to resolve such breach in accordance with such Dispute Resolution Procedure by the end of the escalation stage of such process shall entitle, but shall not compel, the Authority to terminate this Contract in accordance with Clause 15.3.1 of this Schedule 2.

15.6 In order that the Authority may act reasonably in exercising its discretion in accordance with Clause 15.5 of this Schedule 2, the Supplier shall provide the Authority with such reasonable and proportionate up-to-date financial or other information relating to the Supplier or any relevant third party entity upon request.

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

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

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

15.7.3 there has been a failure by the Supplier and/or one of its Sub-contractors to comply with legal obligations in the fields of environmental, social or labour Law. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority may request the replacement of such Sub-contractor and the Supplier shall comply with such request as an alternative to the Authority terminating this Contract under this Clause 15.7.3.

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 Clauses 15.4.1 and 15.4.3 to 15.4.5 of this Schedule 2 shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clauses apply to the entity assuming the position of the Authority.

16. Consequences of expiry or early termination of this Contract

16.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Goods which have been supplied and delivered by the Supplier and not rejected by the Authority in accordance with this Contract prior to expiry or earlier termination of this Contract, provided that this shall be the extent of the compensation due by the Authority to the Supplier upon termination of this Contract for any reason.

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

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

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

17. Post termination provisions

17.1 The Supplier acknowledges and agrees that:

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

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

17.2 The Authority and any Central Government Body will not disclose the Contract Price to any Administering Entity (which for the purposes of this Clause 17.2 shall not include a Health Service Board constituted under section 2 of the National Health Service (Scotland) Act 1978, a Special Health Board constituted under that section, the NHS Wales, or any statutory successors to such entities) without the Supplier's written consent (such consent not to be unreasonably withheld, delayed or conditioned).

17.3 This Clause 17.3 and the following Clauses shall survive the expiry or termination for any reason of this Contract: Schedule 1 (Key Provisions) Clauses 4 (Names and addresses for notices), 5 (Management levels for escalation and dispute resolution), 6 (Order of precedence), Clause 9 (Regulatory and information requirements), Schedule 2 (General Terms and Conditions) Clauses 6 (Inspection, rejection, return and recall), 11 (Intellectual property), 12 (Indemnity), 13 (Limitation of liability), 16 (Consequences of expiry or early termination of this Contract), 22 (Dispute Resolution), 23.10 (Force majeure), 24 (Records retention and right of audit), 25.4 (Conflicts of interest and the prevention of fraud), 30.3 (waiver), 30.4 (severance), 30.11 (entire agreement), 30.12 (Governing law), 30.13 (jurisdiction), Schedule 3 (Information Provisions) Clauses 1 and 2, Schedule 4 (Definitions and Interpretations), and any Clauses and/or Schedules which are expressly or by implication intended to continue.

18. Packaging, identification and end of use

18.1 The Supplier shall comply with all obligations imposed on it by the applicable Law and Guidance relevant to the Goods in relation to packaging, identification, and obligations following end of use by the Authority. The applicable Law and Guidance is dependent upon whether the Goods are being supplied to Great Britain or Northern Ireland.

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 deliveries of the same or similar goods in the same quantities within the United Kingdom.

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

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

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 and/or packages (including pallets) within twenty one (21) days of the date of the relevant delivery. Empty containers and/or packages not so removed may be returned by the Authority at the Supplier's expense or otherwise disposed of at the Authority's discretion. The Supplier shall credit the Authority in full for any containers for which the Authority has been charged upon their collection, return and/or disposal by the Authority.

18.6 Without prejudice to the Supplier's obligation to comply with all applicable Law and Guidance, the Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Goods. Where the provisions of any such legislation are implemented by the use of voluntary agreements or codes of practice, the Supplier shall comply with such agreements or codes of practice as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification. Without prejudice to the generality of the foregoing, the Supplier shall:

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

18.6.2 promptly provide such data as may reasonably be requested by the Authority from time to time regarding the weight and type of packaging according to material types used in relation to the Goods;

18.6.3 comply with all obligations imposed on it in relation to the Goods by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871) (or any other equivalent legislation

giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive 94/62/EC as amended);

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

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

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

18.7 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 18.

19. Sustainable development

19.1 The Supplier shall comply in all material respects with applicable environmental and social and labour Law requirements in force from time to time in relation to the Goods. Where the provisions of any such Law are implemented by the use of voluntary agreements, the Supplier shall comply with such agreements as if they were incorporated into English law subject to those voluntary agreements being cited in the Specification. 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/or any applicable Crown Commercial Services' Procurement Policy Note (as may be in force from time to time) in relation to any stated environmental and social and labour requirements, characteristics and impacts of the Goods and the Supplier's supply chain;

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 this Clause 19.

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 this Clause 20.

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.

20.5 Before any publication of the Product Information (electronic or otherwise) is made by the Authority, the Authority will submit a copy of the relevant sections of the Authority's product catalogue to the Supplier for approval, such approval not to be unreasonably withheld or delayed. For the avoidance of doubt the Supplier shall have no right to compel the Authority to exhibit the Product Information in any product catalogue as a result of the approval given by it pursuant to this Clause 20.5 or otherwise under the terms of this Contract.

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

21. Change Control

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

21.2 Either Party may submit a written request for Change to the other Party in accordance with this Clause 21, but no Change will come into effect until a

Change Control Note has been signed by the authorised representatives of both parties.

21.3 If the Authority requests a Change:

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

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

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

21.5 A Change Control Note will be in the form set out in Schedule 7.

21.6 If, following the Authority's receipt of a Change Control Note pursuant to Clauses 21.3 or 21.4 of this Schedule 2:

21.6.1 the parties agree the terms of the relevant Change Control Note, then it shall, once signed by each of the Parties, constitute a binding change to the Contract for the purposes of Clause 21.8 of this Schedule 2; or

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

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

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

21.9 Subject to Clause 9.5, the Supplier shall neither be relieved of its obligations to supply the Goods in accordance with the terms and conditions of this Contract nor be entitled to an increase in the Charges as a result of a Change in Law.

22. Dispute resolution

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

22.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute, and shall follow the procedure set out in Clause 22.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

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

22.4 If the procedure set out in Clause 22.3 of this Schedule 2 above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Parties will attempt to settle it by mediation. The Parties shall, acting reasonably, attempt to agree upon a mediator. In the event that the Parties fail to agree a mediator within five (5) Business Days following the exhaustion of all levels of the escalation procedure at Clause 22.3 of this Schedule 2, the mediator shall be nominated and confirmed by the Centre for Effective Dispute Resolution, London.

22.5 The mediation shall commence within twenty eight (28) days of the confirmation of the mediator in accordance with Clause 22.4 of this Schedule 2, or at such other time as may be agreed by the Parties in writing. Neither Party will terminate such mediation process until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour, or one Party has failed to participate in the mediation process. After this time, either Party may terminate the mediation process by notification to the other Party (such notification may be verbal provided that it is followed up by written confirmation). The Authority and the Supplier will cooperate with any person appointed as mediator, providing them with such information and other assistance as they may require and will pay their costs, as they shall determine, or in the absence of such determination such costs will be shared equally.

22.6 Nothing in this Contract shall prevent:

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

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

22.7 This Clause 22 shall survive the expiry of or earlier termination of this Contract for any reason.

23. Force majeure

23.1 Subject to Clause 23.2 of this Schedule 2, neither Party shall be liable to the other for any failure to perform all or any of its obligations under this Contract nor be liable to the other Party for any loss or damage arising out of the failure to perform its obligations to the extent only that such performance is rendered impossible by a Force Majeure Event.

23.2 The Supplier shall only be entitled to rely on a Force Majeure Event and the relief set out in this Clause 23, and will not be considered to be in default or liable for breach of any obligations under this Contract, if:

23.2.1 the Supplier has fulfilled its obligations pursuant to Clause 7 of this Schedule 2;

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

23.2.3 the Supplier has complied with the procedural requirements set out in this Clause 23.

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

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

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

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

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

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

23.9 Following such termination in accordance with Clause 23.8 of this Schedule 2 and subject to Clause 23.10 of this Schedule 2, neither Party shall have any liability to the other.

23.10 Any rights and liabilities of either Party which have accrued prior to such termination in accordance with Clause 23.8 of this Schedule 2 shall continue in full force and effect unless otherwise specified in this Contract.

24. Records retention and right of audit

24.1 Subject to any statutory requirement and Clause 24.2 of this Schedule 2, the Supplier shall keep secure and maintain for the Term and seven (7) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.

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

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

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

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

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

24.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.

24.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier, and may require the Supplier to provide such oral and/or written explanations as they consider necessary. This Clause 24 does not constitute a requirement or agreement for the examination, certification or

inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.

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

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

25. Conflicts of interest and the prevention of fraud

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

25.2 The Authority reserves the right to terminate this Contract immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Contract. The actions of the Authority pursuant to this Clause 25.2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the Authority.

25.3 The Supplier shall take all reasonable steps to prevent Fraud by Staff and/or the Supplier (including its owners, members and directors). The Supplier shall notify the Authority immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

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

26. Equality and human rights

26.1 The Supplier shall:

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

26.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the

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

26.1.3 the Supplier shall impose on all its Sub-contractors and suppliers obligations substantially similar to those imposed on the Supplier by this Clause 26.

26.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 26.

27. Notice

27.1 Subject to Clause 22.5 of Schedule 2, any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the Key Provisions or such other person as a Party may inform the other Party in writing from time to time.

27.2 A notice shall be treated as having been received:

27.2.1 if delivered by hand within normal business hours when so delivered, or, if delivered by hand outside normal business hours, at the next start of normal business hours; or

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

27.2.3 if sent by email, if sent within normal business hours when so sent, or, if sent outside normal business hours, at the next start of normal business hours, provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

28. Assignment, novation and Sub-contracting

28.1 The Supplier shall not, except where Clause 28.2 of this Schedule 2 applies, assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. If the Supplier Sub-contracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.

28.2 Notwithstanding Clause 28.1 of this Schedule 2, the Supplier may assign to a third party ("**Assignee**") the right to receive payment of any sums due and owing to the Supplier under this Contract for which an invoice has been issued. Any assignment under this Clause 28.2 shall be subject to:

28.2.1 the deduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.9 of this Schedule 2;

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

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

28.2.4 the provisions of Clause 9 of this Schedule 2 continuing to apply in all other respects after the assignment which shall not be amended without the prior written approval of the Authority; and

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

28.3 Any authority given by the Authority for the Supplier to Sub-contract any of its obligations under this Contract shall not impose any duty on the Authority to enquire as to the competency of any authorised Sub-contractor. The Supplier shall ensure that any authorised Sub-contractor has the appropriate capability and capacity to perform the relevant obligations and that the obligations carried out by such Sub-contractor are fully in accordance with this Contract.

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

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

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

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

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

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

28.4.6 provide that if the Supplier or other party fails to consider and verify an invoice in accordance with Clause 28.4.5 of this Schedule 2, the invoice shall be regarded as valid and undisputed for the purpose of Clause 28.4.7 of this Schedule 2 after a reasonable time has passed;

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

28.4.8 permit 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 15.7.3 of this Schedule 2;

28.4.9 permit the Supplier to terminate, or to procure the termination of, the relevant Sub-contract where the Supplier is required to replace such Sub-contractor in accordance with Clause 28.5 of this Schedule 2; and

28.4.10 require the Sub-contractor to include a clause to the same effect as this Clause 28.4 in any Sub-contract which it awards.

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

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

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

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

28.7 The Authority shall upon written request have the right to review any Sub-contract entered into by the Supplier in respect of the provision of the Goods and the Supplier shall provide a certified copy of any Sub-contract within five (5) Business Days of the date of a written request from the Authority. For the avoidance of doubt, the Supplier shall have the right to redact any confidential pricing information in relation to such copies of Sub-contracts.

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

29. Prohibited Acts

29.1 The Supplier warrants and represents that:

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

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

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

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

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

29.2.1 the Authority shall be entitled:

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

b) to recover from the Supplier the amount or value of any gift,

consideration or commission concerned; and

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

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

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

a) the interpretation of this Clause 29; or

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

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

30. General

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

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

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

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

30.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation,

undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.

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

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

30.8 The rights and remedies provided in this Contract are independent, cumulative and not exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 30.8, right includes any power, privilege, remedy, or proprietary or security interest.

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

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

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

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

30.13 Subject to Clause 22 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.

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

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

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

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

SCHEDULE 3

Information Provisions

1. Confidentiality

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

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

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

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

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

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

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

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

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

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

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

1.3.2 on a confidential basis, to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 1.3.1 of this Schedule 3 (including any benchmarking organisation) for any purpose relating to or connected with this Contract;

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

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

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

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

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

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

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

1.5 For the avoidance of doubt, save as required by Law or as otherwise set out in this Schedule 3, the Supplier shall not, without the prior written consent of the Authority (such consent not to be unreasonably withheld or delayed), announce that it has entered into this Contract and/or that it has been appointed as a supplier to the Authority and/or make any other announcements about this Contract.

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

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

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

the Authority may disclose the Contract Price (or, in the case of another product, the unit price paid by the Authority to the Supplier for such other product) on a confidential basis to the Third Party Supplier for a purpose directly related to or connected with the Authority verifying and/or evidencing to the Third Party Supplier the costs that the Authority has incurred in excess of what would have been paid by the Authority to the Third Party Supplier for delivery of the product(s) in accordance with the timescales and/or delivery requirements

set out in the Third Party Supplier Agreement. References to disclosure on a confidential basis in this Clause 1.6 shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law.

1.7 This Clause 1 shall remain in force:

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

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

2. Freedom of Information and Transparency

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

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

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

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

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

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

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

2.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the

Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.

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

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

2.5 In preparing a copy of this Contract for publication under Clause 2.4 of this Schedule 3, the Authority may consult with the Supplier to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.

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

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

3. Information Security

3.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:

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

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

Schedule 4

Definitions and Interpretations

1. Definitions

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

"Administering Entity"	means any body administering the Goods including all Health Service Bodies;
"Authority"	means the authority named on the form of Contract on page 1;
"Breach Notice"	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier and its ability to supply the Goods including, without limitation, an influenza pandemic and any Force Majeure Event but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom (or any part of it) from the European Union and any related circumstances, events, changes or requirements;
"Business 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 a Saturday, Sunday or bank holiday in England;
"Central Government Body"	means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics: (a) Government Department; (b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); (c) Non-Ministerial Department; or (d) Executive Agency;
"Change"	means any change to this Contract;
"Change Control Note"	means the written record of a Change agreed or to be agreed by the Parties pursuant to the procedure set out in Clause 21 of Schedule 2;
"Change in Law"	means any change in Law which impacts on the supply of the Goods (including taxation or duties of any sort affecting the Supplier) which comes into force after the Commencement Date;
"Charges"	means the Contract Price together with any applicable VAT;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;

"Commencement Date"	shall have the meaning given to it in Clause 0of Schedule 1;
"Commercial Schedule"	means the document set out at Schedule 6;
"Confidential Information"	means information, data and material of any nature, which either Party may receive or obtain in connection with the conclusion and/or operation of the Contract, including any procurement process, which is: (a) Personal Data including, without limitation, that which relates to any patient or other service user or his or her treatment or clinical or care history; (b) designated as confidential by either Party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored); and/or (c) Policies and such other documents which the Supplier may obtain or have access to through the Authority's intranet;
"Contract"	means the agreement between the Parties in the form of contract at the front of this document and all schedules attached to the form of contract;
"Contracting Authority"	means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with Clause 8.1 of Schedule 2;
"Contract Price"	means the price exclusive of VAT that is payable to the Supplier by the Authority under the Contract for the full and proper performance by the Supplier of its obligations under the Contract;
"Defective Goods"	has the meaning given under Clause 6.8 of Schedule 2;
"Delivery Period"	means the month(s) during the Term that the Authority requires the supply of the Goods as set out in Schedule 6;
"Delivery Schedule"	means the delivery schedule setting out deliveries during the Term as set out in Schedule 6 and any delivery schedule agreed as part of an Additional Goods Order by the Parties in accordance with Clause **Error! Reference source not found.** of Schedule 2 or any revised Delivery Schedule agreed in accordance with Clauses **Error! Reference source not found.** or 4.3 of Schedule 2;
"Devolved Administration"	means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly);
"Directive 2001/83"	means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (and any amended and/or successor legislation applicable to the UK);

"Directive 2003/94"	means Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (and any amended and/or successor legislation applicable to the UK);
"Discloser"	has the meaning given under Clause 1.1 of Schedule 3;
"Dispute(s)"	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
"Dispute Notice"	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;
"Dispute Resolution Procedure"	means the process for resolving Disputes as set out in Clause 22 of Schedule 2. For the avoidance of doubt, the Dispute Resolution Procedure is subject to Clause 29.2.3 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"EMA"	means the European Medicines Agency (or any statutory successor);
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"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), and the Human Rights Act 1998;
"EU References"	has the meaning given to it in Clause 1.2.1 of Schedule 4;
"Exit Day"	shall have the meaning in the European Union (Withdrawal) Act 2018;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation: (a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract; (b) acts of terrorism; (c) flood, storm or other natural disasters; (d) fire; (e) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning; (f) government requisition or impoundment to the extent such requisition or impoundment does not result from any failure by the Supplier to comply with any relevant regulations, laws or procedures (including such laws or regulations relating to the payment of any duties or taxes) and subject to the Supplier having used all reasonable legal means to resist such requisition or impoundment; (g) compliance with any local law or governmental order, rule, regulation or direction applicable outside of England and Wales that could not have been reasonably foreseen; (h) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier; and (i) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties; but excluding, for the avoidance of doubt, any event or other consequence arising as a result of or in connection with: (i) Pandemic or epidemic;

	(ii) the withdrawal of the United Kingdom from the European Union; or (iii) the COVID-19 pandemic, except for circumstances caused by or related to the COVID-19 pandemic which are changes in applicable Law and/or governmental guidance which mean that the Goods cannot be provided as set out in this Contract (in all material respects) without such Laws and/or government guidance being breached, or if the Supplier can reasonably demonstrate that despite all reasonable endeavours, it is unable to secure non-COVID-19 infected personnel to provide the Goods due to the levels of COVID-19 infections in the population of the United Kingdom;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"General Anti-Abuse Rule"	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions;
"Good Industry Practice"	means the exercise of that degree of skill, diligence, prudence, risk management, quality management and foresight which would reasonably and ordinarily be expected from a skilled and experienced supplier engaged in the manufacture and/or supply of goods similar to the Goods under the same or similar circumstances as those applicable to this Contract, including in accordance with any codes of practice published by relevant trade associations;
"Good Manufacturing Practice"	shall have the meaning set out in Directive 2003/94;
"Goods"	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, under Schedule 5 which sets out the requirements of the Authority and Schedule 8 which sets out the Supplier's response to these requirements);
"Guidance"	means any applicable guidance, direction or determination and any policies, advice or industry alerts which apply to the Goods, to the extent that the same are published and publicly available or the existence or contents of them have been notified to the Supplier by the Authority and/or have been published and/or notified to the Supplier by the Authority, NHS Improvement, NHS England, the MHRA,

	the EMA or the European Commission (in each case to the extent applicable to Great Britain, Northern Ireland or the whole of the UK), the Care Quality Commission and/or any other regulator or competent body;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Health Service Bodies"	means: (a) the Department of Health and Social Care and all divisions and agencies thereof and any independent NHS board or similar body that may be established including regional agencies of such board; (b) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not)); (c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41); (d) the Secretary of State for Health and Social Care; (e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41); (f) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service act 2006 (c.41); (g) any body replacing or providing similar or equivalent services to any of the above in any area of the United Kingdom including any bodies established pursuant to the Health and Social Care Act 2012, including but not limited to NHS England; and (h) any statutory successor to any of the above;
"Term"	shall have the meaning given to the term in Clause 0 of Schedule 1;
"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;
"Issuing Party"	has the meaning given to it in Clause 1.12 of Schedule 4;
"Key Provisions"	means the key provisions set out in Schedule 1;
"KPI"	means the key performance indicators as set out in Part 3 of Schedule 6;
"Law"	means any applicable legal requirements including, without limitation: (a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales; (b) to the extent binding under UK law, any applicable European Union obligation, directive, regulation, decision, law or right (including any such

	obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument); (c) to the extent in force in the UK, any enforceable community right within the meaning of section 2(1) European Communities Act 1972; (d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; (e) requirements set by any regulatory body as applicable in England and Wales; (f) any relevant code of practice as applicable in England and Wales; (g) any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above); and (h) where Goods are to be delivered into Northern Ireland, any of the applicable legal requirements in (a) to (g) as are applicable in Northern Ireland to such Goods.
"Licensing Authority"	means the MHRA or EMA as the case may be (in the case of the latter, to the extent that any Marketing Authorisation and/or Manufacturing Licence issued by such entity is valid in the Northern Ireland);
"Loss Costs"	means to the extent that the Authority and/or Administering Entity and/or Devolved Administration has taken all reasonable steps to mitigate such losses: (a) all costs in connection with receiving and storing Defective Goods; (b) where the Defective Goods have been despatched by or on behalf of the Authority or Devolved Administration, the costs of recalling the Defective Goods; (c) all wasted administrative and personnel costs of the Authority and/or any Administering Entity and/or Devolved Administration relating to Defective Goods; (d) where individuals are required to be given further treatments of the Goods because their initial course was Defective Goods, the costs of providing such further treatments of the Goods to such individuals; (e) all costs in excess of the Charges paid or payable by the Authority for Rejected Goods incurred in sourcing alternative products from third parties; and (f) all costs associated with advising, screening, testing, treating or otherwise providing healthcare to patients in relation to Defective Goods;
"Manufacturing Licence"	means the manufacturing licence in respect of the Goods granted by the Licensing Authority;

"Marketing Authorisation"	means: (a) the marketing authorisation number as specified in Schedule 8 for Goods delivered to Great Britain; and (b) the marketing authorisation number as specified in Schedule 8 for Goods delivered to Northern Ireland, granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time;
"MHRA"	means the Medicines and Healthcare products Regulatory Agency;
"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 that 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 that gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date, or to a civil penalty for fraud or evasion;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in Section 3(2) of the Data Protection Act 2018 (as amended) in relation to data processed under this Contract;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier from time to time;
"Product Information"	means information concerning the Goods as may be reasonably requested by the Authority and supplied by the Supplier to the Authority in accordance with Clause 20 of Schedule 2 for inclusion in the Authority's product catalogue from time to time;
"Prohibited Acts"	has the meaning given under Clause 29.1.1 of Schedule 2;
"Purchase Order"	means the purchase order required by the Authority's financial systems substantially in the form set out in Part 4

	of Schedule 6, where a purchase order is referred to in the Key Provisions;
"QTA"	means the Quality Technical Agreement between the Authority and the Supplier as amended and updated from time to time by the Parties (to the QTA);
"Recipient"	has the meaning given under Clause 1.1 of Schedule 3;
"Receiving Party"	has the meaning given to it in Clause 1.12 of Schedule 4;
"Rejected Goods"	has the meaning given under Clause 6.2 of Schedule 2;
"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 15.2 of Schedule 2;
"Requirement to Recall"	has the meaning given under Clause 6.12 of Schedule 2;
"Specification"	means the document set out in Schedule 5 as amended and/or updated in accordance with this Contract as applicable – in relation to whether the Goods are being supplied to Great Britain and/or to Northern Ireland;
"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 Contract;
"Sub-contractor"	means a party to a Sub-contract other than the Supplier;
"Summary of Product Characteristics"	means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation;
"Supplier"	means the supplier named on the form of Contract on page 1;
"Supplier Code of Conduct"	means the code of that name published by the Government Commercial Function originally dated September 2017, as may be amended, restated, updated, re-issued or re-named from time to time;
"Term"	means the Term as set out in the Key Provisions;
"Termination Notice"	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
"Third Party Body"	has the meaning given under Clause 8.2 of Schedule 2;
"Third Party Supplier"	has the meaning given under Clause 1.6.1 of Schedule 3;

"Third Party Supplier Agreement"	has the meaning given under Clause 1.6.1 of Schedule 3;
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax; and
"Volume"	means the total quantity of the Goods to be delivered during the Term.

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

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

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

1.2.2 any EU institution or EU authority or other such EU body shall be read on and after Exit Day as a reference to the UK institution, authority or body to which its functions were transferred.

Nothing in this Clause 1.2 shall affect the applicability of EU References as they apply to Goods delivered by the Supplier into Northern Ireland.

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

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

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

1.6 Unless set out in the Commercial Schedule as a chargeable item and subject to Clause 30.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Contract.

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

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

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

1.10 Where there is a conflict between the Supplier's responses to the Authority's requirements (the Supplier's responses being set out in Schedule 5) and any other part of this Contract, such other part of this Contract shall prevail.

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

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

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

1.14 Any reference to a Party "procuring" another person to act or omit to act in a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.

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

SCHEDULE 5

Specification

1 Introduction

The Authority's intention in carrying out this procurement exercise is to enter into a contract for the supply of the Goods for use as a trial candidate in a UK platform trial for Covid-19 therapeutics. The repacking, relabelling and distribution to the Trial Lead of the Goods will all be considered part of this exercise.

2 Mandatory Requirements

The requirements set out below are mandatory requirements:

2.1 The Goods must be Favipiravir 200mg tablets.

2.2 To Goods must be supplied as 200mg tablets in packs of 50 with trial specific labelling in English.

2.3 The following conditions must be met for the import of the Goods which is only licensed in Japan

2.3.1 If sourced from outside the EEA, this would require importation by an MIA(IMP) holder and QP certification for release to the Sponsor for use in a clinical trial, following any (re)packaging or labelling as applicable.

2.3.2 A QP Declaration of GMP equivalence would need to be submitted by the QP of the MIA(IMP) holder responsible for import as part of the CTA application (or amendment for an ongoing trial).

2.3.3 A copy of the MIA(IMP) for the licence holder responsible for the import / QP certification would be needed with the CTA application.

2.3.4 This would need to be reviewed and approved by the Clinical Trials Unit at MHRA prior to use in the trial.

3 Volume required

200 tablets in packs of 50 tablets per pack to be delivered during the term of the Contract.

4 Shelf life

There must be a minimum of 24 months shelf life remaining on the Goods at the time of delivery to the Authority's storage agent.

5 Delivery

5.1 Delivery will be to a nominated delivery point within England. Precise arrangements for delivery will be notified to the Supplier at the time of order.

5.2 The Supplier, or their appointed logistics provider, will need to make contact with the Trial Lead to schedule inbound deliveries. Each delivery will be allocated a unique reference number and time slot. Vehicles arriving without a reference number or outside the allocated time slot will be refused access.

5.3 Delivery should be made on wooden Euro pallets :

5.3.1 Delivery can be made on either:

UK (ISO) Pallet

• 1200mm (L) x 1000mm (W) x 150mm (H)

• Four way accessible

• 1400mm Height inclusive of pallet

• Total weight, 750kg inclusive of pallet

• Pharma Heat treated

• No over-hang of product outside the pallet foot print.

• Product to be secured to the pallet to minimise any movement in transit.

OR

Euro Pallet

• 1200mm (L) x 800mm (W) x 150mm (H)

• Two way accessible

• 1400mm Height inclusive of pallet

• Total weight, 500Kg inclusive of pallet

• Pharma Heat treated

• No over-hang of product outside the pallet foot print.

5.3.2 • Product to be secured to the pallet to minimise any movement in transit

5.4 Delivery systems used must ensure the Goods are not adversely affected.

5.5 Further instructions and obligations on the Supplier as to delivery are set out in clause 4 of Schedule 2 (General Terms and Conditions) of the Contract.

6 Medicines packaging, labelling and information

6.1 The pack design should comply with the principles of MHRA's "Best practice guidance on the labelling and packaging of medicines".

6.2 All critical information should be present, this is defined as :

- The generic name of the medicine
- The strength of the medicine
- The form of the medicine
- The route of administration
- Posology
- Warnings

6.3 The name of the medicine expressed on the packaging should be the same as registered in the summary of product characteristics (SPC). NB this will be the brand name for a proprietary product, but the generic name should also be clearly expressed. Abbreviations should not be used.

6.4 The batch number and expiry date should be present and legible, particularly when embossing is used rather than print. The expiry date should be unambiguously expressed.

6.5 Temperature storage conditions should be clearly stated on both the primary and secondary packaging.

6.6 Outer boxes should be robust and offer adequate protection to the inner products containers.

Annex

SCHEDULE 6

Commercial Schedule

Part 1 – Price

PRODUCT/REPACKAGING/RELABELLING	Unit	Price Per Unit excluding VAT	Total
Favipiravir Tablet 200mg – 100 packs		FOIA Section 43(2)	
Repackaging, Relabelling to 200 packs of 50 tablets		FOIA Section 43(2)	
Total Contract Value			FOIA Section 43(2)

Part 2 - Delivery Schedule

include separate schedules for deliveries directly to Northern Ireland if required

Product	Unit	Delivery Date, no later than	Number of Units to be delivered	Minimum shelf life on delivery
Favipiravir Tablets 200mg	Pack of 50 tablets	7 days from Purchase order	200	24 months

Part 3 - Key performance indicators

Not used.

Annex

SCHEDULE 7

Proforma Change Control Note

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

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

Annex

SCHEDULE 8

Offer Schedule – Tender Response Document

Annex

Schedule 8 (for unlicenced medicines)

To be issued to potential suppliers in the Invitation to Offer as Table 4 of the Offer Schedule

Product details	Product description (including product strength)	Favipiravir Tablets 200mg
	Proprietary name (Brand name)	Avigan®
	Marketing Authorisation holder (ie the company who owns the licence for the product)	N/A unlicensed in UK, Licenced in Japan , Fujifilm Toyama Chemical Co. Ltd
	Product dosage form (e.g. plastic ampoule, pre-filled syringe)	Tablets
	Storage conditions	Store at Room Temperature (1-30°C)
	Shelf life	08/2030 (10 years from manufacturing)
	Shelf-life after reconstitution or first opening	Nov-22
	Product grade e.g. BP, USP (State whether product is listed in British/US/European Pharmacopoeia)	JP (Japanese Pharmacoepia)
	Route/s of administration	Oral
	EEA Marketing Authorisation number or	N/A
	Marketing Authorisation number from outside the EEA	Approval No: 22600AMX0053000 Japan
	Declared excipients with potential side effects	Povidone, colloidal silicon dioxide, low-substituted hydroxypropyl cellulose, crospovidone, sodium steryl fumarate, hypromellose, titanium dioxide, talc, yellow ferric oxide. (no known potential side effects for these exipients.
Manufacture details	Manufacturer (responsible for batch release of the product as shown on the patient information leaflet)	FujifilmToyama Chemical Company Ltd.
	Manufacturing licence number	NHI Number 87625
	Country in which the manufacture is based	Japan
	Full address	TOYAMA CHEMICAL CO., LTD. 2-5, Nishishinjuku 3-chome, Shinjuku-ku, Tokyo 160-0023, Japan
	Manufacturer of bulk product	FujifilmToyama Chemical Company Ltd.
	Manufacturing licence number	NHI Number 87625
	Country in which the bulk is manufactured is based	Japan
	Full address	TOYAMA CHEMICAL CO., LTD. 2-5, Nishishinjuku 3-chome, Shinjuku-ku, Tokyo 160-0023, Japan
	Raw material supplier (provider of the active ingredient)	FujifilmToyama Chemical Company Ltd.
	Manufacturing licence number	NHI Number 87625
	Country in which the bulk is manufactured is based	Japan
	Full address	TOYAMA CHEMICAL CO., LTD. 2-5, Nishishinjuku 3-chome, Shinjuku-ku, Tokyo 160-0023, Japan
	Company responsible for packaging activity	Pack size100- Fujifilm Toyama Chemical Company Ltd Pack size 50: Vertical Pharma Resources Ltd T/A IPS Pharma
	Manufacturing licence number	MS32879
	Country in which the packager is based	United Kingdom - Pack size 50
	Full address	IPS Pharma, 41 Central Avenue, West Molesey, Surrey KT8 2QZ
Pack details	Pack size (Inner pack size)	Provisional UK Pack size: 115mm x 73mm x 45mm (50 tabs)
	Product code (if from inside UK)	IAVI01001
	PIP code (if from inside UK)	N/a
	Packaging type (description)	Carton / Blister (PVC/Aluminium) in strip of 10 tablets
	Tamper evidence - method used.	White rectangular tamper evident seals on both sides
	Does the pack/container meet the following requirements (Y/N):	
	English livery	*Repack - English*
	Expiry date displayed on the pack	Yes - November 2030 (Twenty Thirty)
	Date of manufacture displayed on pack	No - this is December '2020
	Batch number displayed on pack	Yes - HK2551
	Patient information leaflet in each pack	Not included - trial leads to advise
Quality documentation	*Confirm the following will be provided (Y/N):*	
	EU GMP certificates or equivalent	Yes - copy already supplied by email to DHSC
	Certificate of Analysis	Yes - copy already supplied by email to DHSC
	Certificate of Release/Compliance	Yes - copy already supplied by email to DHSC
	Transmissible Spongiform Encephalopathies (TSE) certificate	Yes - N/A not of human/animal origin. Copy already supplied by email DHSC
Animal derivatives	Details of any animal products or animal derived material which may be present in the Product	N/A not of human/animal origin.
Importation	Name and address of Importer	Vertical Pharma Resouces Ltd
	MS Licence Number of Importer	32879
	WDA (H) Licence Number of Importer	32879
Transport	Current location of offered medicine (full address including name of wholesaler if applicable)	IPS Pharma, 41 Central Ave, East Molesey, West Molesey KT8 2QZ
	Transport route and method used (from current location to place to delivery) and full description of the supply chain	Air frieght, temperature controlled into UK UK Distribution via courier network
	Method of temperature control systems that will be employed, including the records that will be provided to the Authority.	Data loggers included.
Packaging/Shipper details	Pack dimensions (mm) h x w x d	115mm x 73mm x 45mm
	Outer, or shipper pack quantity	Depending on quantity ordered
	Outer pack dimensions (mm) h x w x d	Depending on quantity ordered
	Outer pack weight (Kg)	N/A until quantity determined.
	Delivery on Europallets?	N/A until quantity determined.
	Number of outer packs per pallet	N/A until quantity determined.
	Maximum pallet dimensions (mm) h x w x d	N/A until quantity determined.
	Pallet weight (Kg)	N/A until quantity determined.

Annex

Schedule 9

Business Continuity Plan

Not required