Document no.3

Conditions of Contract

The Supply of Antibiotics and IV Fluids under a Dynamic Purchasing System.
Offer ref number: CM/EMI/15/5462/6
Delivery Period: The DPS arrangement shall have a 10-year life span
Official Journal of the European Union reference: 2016/S 090-161095

THIS AGREEMENT is made on …26 August 2022……

BETWEEN:

(1) *The Secretary of State for Health and Social Care acting as part of the Crown through the UK Health Security Agency whose principal office is at Nobel House, 17 Smith Square, London, SW1P 3JR ("**Authority**")* and

(2) B. Braun Medical Limited company number 02296559 whose registered office is at Brookdale Road, Thorncliffe Park, Chapeltown, Sheffield, S35 2PW ("**Supplier**").

BACKGROUND:

(A) All Products(s) supplied must be FMD compliant and not decommissioned (unless exempt), and must be subject to Marketing Authorisation(s) which must cover their authorised use in the United Kingdom (Great Britain and Northern Ireland) or is authorised by the holder of such Marketing Authorisation to supply the Product and holds a Wholesale Dealers Licence granted by the Medicines and Healthcare products Regulatory Agency in respect of the supply of the Product

(B) The Supplier holds a UK Marketing Authorisation for **Redacted Under FOIA Section 43(2), Commercial Interests** (the "**Product**") or is authorised by the holder of such Marketing Authorisation to supply the Product.

(C) The Authority intends to purchase and the Supplier has agreed to supply the Product subject to the terms of this Agreement. The Authority intends to purchase, and the Supplier has agreed to supply the Product under a Dynamic Purchasing System (DPS) set up by the Authority subject to the terms of this Agreement.

(D) As set out in this Agreement, units of the Product(s) shall be delivered into the Authority's storage and distribution centre(s) within the United Kingdom. Precise arrangements for delivery will be notified to the Offeror at the time of the purchase order placement.

Contents

IT IS AGREED as follows:

1 INTERPRETATION

1.1 In this Agreement unless the context otherwise requires the following words and expressions shall have the following meanings:

Words and Expressions	**Meaning**
"Administering Entity"	anybody administering the Product including all Health Service Bodies
"Agreement"	this Agreement and the attached Schedules
"Authorised Agent"	any authorised agent appointed by the Authority as notified to the Supplier in writing
"Business Continuity Event"	any event or issue that could impact on the operations of the Supplier and its ability to supply the Products including, without limitation, any Force Majeure event
"Business Continuity Plan"	the Supplier's business contingency plan which includes continuity in the event of a Business Continuity Event and an executive summary of the current such plan is attached at Schedule 4
"Business Days"	a day (other than a Saturday, Sunday or public holiday) on which banks in the City of London are ordinarily open for the transaction of normal banking business
"Confidential Information"	means information, data and material of any nature which either Party may receive or obtain in connection with the operation of the Agreement and: (a) which comprises Personal Data or Sensitive Personal Data (as both terms are defined in the Data Protection Act 1998) or (in the case

	of the Authority) which relates to any patient or his or her treatment or medical history; or
	(b) the release of which is likely to prejudice the commercial interests of the Authority or the Supplier respectively; or
	(c) which is a trade secret.
"Crown"	means the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the Welsh Assembly Government), including, but not limited to, government ministers, government departments, government and particular bodies, and government agencies.
"Data Protection Legislation"	means all applicable data protection and privacy legislation in force from time to time in the UK including the General Data Protection Regulation (EU) 2016/679 as incorporated into, amended and applied under English law; the Data Protection Act 2018, the Regulation of Investigatory Powers Act 2000, and the Privacy and Electronic Communications Regulations 2003 (SI 2003/2426), together with any statutory codes and other guidance issued by the Information Commissioner from time to time
"Data Protection Protocol"	means any document of that name as provided to the Supplier by the Authority (as amended from time to time in accordance with its terms)
"Defective Product"	any Unit of the Product supplied under this Agreement which does not conform to or is not produced in accordance with Good Manufacturing Practice, the Specification or the Marketing Authorisation, or which otherwise fails to conform to the requirements of this Agreement relating to the safety and efficacy of the Product (including,

	without limitation, such requirements set out in Clauses 3.1.3, 3.9, 8.1 and 8.2)
“Delivery Period”	means (subject to clause 10) the duration of the Agreement, starting on the Effective Date and expiring once both Parties have fulfilled all their obligations under this Agreement.
“Delivery Schedule”	the delivery schedule setting out deliveries during the Delivery Period as set out in Schedule 3, or any revised delivery schedule agreed in accordance with Clause 2.9 (and in any event incorporating any variances agreed in advance with the Authority as described in Clause 3.2).
“Devolved Administrations”	The devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Government, the Welsh Assembly and the Northern Ireland Assembly).
“Directive 2001/83”	Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use
“Directive 2003/94”	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
“DOTAS”	the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue & Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions

	by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI 2012/1868 made under s.132A Social Security Administration Act 1992.
"Effective Date"	the date this Agreement is signed on behalf of both parties.
"EMA"	the European Medicines Agency (or any statutory successor)
"Exit Day"	shall have the meaning in the European Union (Withdrawal) Act 2018;
"FMD"	means the Falsified Medicines Directive (Directive 2011/62/EU)
"Force Majeure"	any of the following insofar as beyond the control of the Party in question: (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 Agreement; (b) acts of terrorism; (c) acts of God; (d) flood, storm or other like natural disasters; (e) fire; (f) prolonged unavailability of public utilities to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning;

(g) 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, without limitation, 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;

(h) compliance with any local law or governmental order, rule, regulation or direction that could not have been reasonably foreseen;

(i) Pandemic or epidemic;

(j) industrial action which affects the supply of the Products, but which is not confined to the workforce of the Supplier or the Supplier's sites or the workforce of any sub-contractor or sub-contractor sites used to undertake any obligations of the Supplier under this Agreement; or

(k) any other event or circumstance that is beyond the reasonable control of the Party in question:

to the extent that: (i) such event materially affects the ability of the Party seeking to rely upon it to perform its obligations under this Agreement; and (ii) its impact could not have been avoided or mitigated by the exercise of all reasonable measures and care by that Party.

"Fraud"	any offence under laws creating offences in respect of fraudulent acts or at common law in respect of fraudulent acts in relation to this Agreement or

	defrauding or attempting to defraud or conspiring to defraud the Crown
"General Anti-Abuse Rule"	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 Distribution Practice"	means good distribution practice in accordance with the European Commission 'Guidelines on Good Distribution Practice if Medicinal Products for Human Use' (OJ 1994, C63, p.3) or in accordance with Article 84 of Directive 2001/83/EU
"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/EC
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others.
"Health Service Body"	(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) anybody 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.; and

(h) any statutory successor to any of the above

"Holding Company"	has the meaning given to it in section 1159 of the Companies Act 2006
"Initial term"	From the Effective Date to 31st March 2023 *(the last date shown on the Delivery Schedule)*
"Intellectual Property Rights"	all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs

“Invitation to Offer”	the invitation to offer despatched on 27th January 2022 to the Supplier by the Authority
“Licensing Authority”	MHRA and/or EMA as the case may be
“Loss Costs”	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 Products; (b) where the Defective Product has been despatched by or on behalf of the Authority or Devolved Administration, the costs of recalling the Defective Product; (c) all wasted administrative and personnel costs of the Authority and/or any Administering Entity and/or Devolved Administration relating to a Defective Product; (d) where individuals are required to be given further treatments of the Product because their initial course was a Defective Product, the costs of providing such further treatments of the Product to such individuals; (e) all costs in excess of the price paid or payable by the Authority for Rejected Products 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 a Defective Product

"Manufacturing Licence"	manufacturing licence number in respect of the Product granted by the Licensing Authority
"Marketing Authorisation"	marketing authorisation number **Redacted Under FOIA Section 43(2), Commercial Interests** in respect of the Product granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time
"MHRA"	Medicines and Healthcare products Regulatory Agency
"Modern Slavery Act"	means the Modern Slavery Act 2015 as amended, updated or replaced from time to time
"Occasion of Tax Non-Compliance"	a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 is found, on or after 1 April 2013, to be incorrect as a result of: i. a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse Principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle; ii. the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or b) any tax return of the supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion,

“Offer”	the offer submitted by the Supplier in response to the Invitation to Offer
“OMCL”	Official Medicines Control Laboratory
“Pandemic”	any period of time in respect of which the ‘Pandemic Phase’ alert pursuant to the Revised WHO Classification System applies, or such other categorisation the World Health Organization may give to an influenza pandemic from time to time
“Parent Company”	any company which is the ultimate Holding Company of the Supplier or any other company of which the ultimate Holding Company of the Supplier is also the ultimate Holding Company and which is either responsible directly or indirectly for the business activities of the Supplier.
“Parent Company Guarantee”	a guarantee by the Supplier’s Parent Company or another guarantor to guarantee the Supplier’s performance of its obligations under this Agreement
“Party or Parties”	The Authority or the Supplier as appropriate and the Authority and the Supplier respectively.
“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.
“Process”	shall have the same meaning as set out in Section 3(4) of the Data Protection Act 2018 (as amended) in relation to data processed under this Contract. **Processing** and **Processed** shall be construed accordingly
“Product”	means all goods, materials or items that the Supplier is required to supply to the Authority under this Contract (including, without limitation, under Schedule 1 which sets out the requirements of the

	Authority as issued to tenderers as part of the procurement process)
“Relevant Tax Authority”	HM Revenue & Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established
“Rejected Product”	any Defective Products rejected by the Authority pursuant to Clause 4.2 or Clause 4.3
“Specification(s)”	the specification set out in Schedule 1
“Summary of Product Characteristics”	the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation
“Term of this Agreement”	the duration of the Agreement, starting on the Effective Date and expiring on the date of delivery of the final Unit of the Product under this Agreement or the date that the final payment is made by the Authority or the date of receipt by the Authority of the report described in Clause 9.7, whichever shall be the latest of these dates.
“Units”	As detailed within Schedule 2
“Use”	use in any activities carried out by or on behalf of the Authority or any Administering Entity or Devolved Administration in relation to the Product following delivery to the Authority including storage and distribution of the Product and its administration, as well as the supply, resale, or donation of the Product to any third party (including without limitation to any or all of the Devolved Administrations), and “Used” shall have an equivalent meaning
“Volume”	Units of the Product to be delivered during the Initial Term.

“Wholesale Distributor”	A wholesale distributor of the Product who currently holds a valid wholesaler dealers licence and is a full member of the Healthcare Distribution Association UK and operates on a UK wide basis.

1.2 In this Agreement unless a provision otherwise expressly provides:

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

1.2.1.1 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

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

1.2.2 references to persons shall be deemed to include those of any gender and also firms or any other body (whether corporate or unincorporated), trust, state or agency of state (in each case, whether or not having separate legal personality);

1.2.3 words importing the singular number only shall include the plural number and vice versa;

1.2.4 references to any statute or order shall include any statutory extension, modification or re-enactment thereof and any order, regulation or bye-law made thereunder;

1.2.5 Schedules shall mean the schedules to this Agreement;

1.2.6 Clauses shall mean the clauses of this Agreement;

1.2.7 headings shall be deemed not to form part of this Agreement and accordingly shall not be taken into account in the construction or interpretation thereof;

1.2.8 all communication between the Parties shall be in writing; and

1.2.9 each and every obligation of a Party under this Agreement is to be performed at that Party's cost.

1.3 Where a provision of this Agreement provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as being an exhaustive list. Any such list shall not be treated as excluding any item which might have been included in such list having regard to the context of the contractual term in question. The ejusdem generis principle is not to be applied when interpreting this Agreement. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.

1.4 All monetary amounts are expressed in pounds sterling but in the event that pounds sterling is replaced as legal tender in the United Kingdom by a different currency then all monetary amounts shall be converted into such other currency at the rate prevailing on the date such other currency first became legal tender in the United Kingdom.

1.5 Where the holder of the Marketing Authorisation is a third party, any obligation on the Supplier under this Agreement 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.

1.6 Where the holder of the Marketing Authorisation is a third party, any obligation on the Supplier to provide information, respond to queries, or keep the Authority updated on particular matters relevant to the Marketing Authorisation and/or the Use, effective administration, quality, performance, durability, safety and efficacy of the Product and/or third party claims relating to the Product and/or actual or suspected adverse reactions relating to the Product not described in the Summary of Product Characteristics and/or any amendments to the Summary of Product Characteristics or PIL shall be taken as a requirement on the Supplier to procure the compliance of the holder of the Marketing Authorisation with such obligations as if the holder of the Marketing Authorisation was the Supplier.

1.7 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.

1.8 All references to this Agreement include (subject to all relevant approvals) a reference to this Agreement as amended, supplemented, substituted, novated or assigned from time to time.

1.9 In performing its obligations under this Agreement, the Supplier shall comply with all applicable laws, statutes, regulations and codes from time to time in force.

2 PURCHASE AND SUPPLY OF PRODUCT

2.1 Upon receipt of a Purchase Order from the Authority, the Supplier shall supply the Volume to the Authority in accordance with this Contract, including, but not limited to, the Delivery Schedule, the Invitation to Tender and the Offer at the price set out in Schedule 2.

2.2 The Contract shall prevail over all other documents referenced and, in the event of any inconsistency between the Specification and the Offer, the former shall prevail. For the avoidance of doubt, any actions or work undertaken by the Supplier in relation to this Contract prior to the receipt of a Purchase Order shall be undertaken at the Supplier's risk and expense.

2.3 The Supplier shall ensure that all Units of the Product supplied to the Authority under this Agreement:

2.3.1 comply fully with the Specification and the Marketing Authorisation;

2.3.2 are supplied in the numbers set out in the Delivery Schedule;

2.3.3 have the shelf life set out in Schedule 1 less any period relating to the release of the Product provided that such release period shall not reduce the shelf life of the Product by more than that detailed in Schedule 3; and

2.3.4 are new and have not been rejected by any other entity prior to their supply to the Authority.

2.4 The Supplier shall:

2.4.1 ensure it has, or the manufacturer of the product has, manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract including Clause 2.1;

2.4.2 keep all facilities used in the manufacture and distribution of the Product in a state and condition necessary to enable the Supplier to comply with its obligations to supply the Product to the Authority in accordance with this Contract;

2.4.3 permit or procure permission for the Authority or Authority's nominee during normal business hours having given reasonable advance notice access to the production facilities used in the manufacture of the Product to enable the Authority to inspect and review the production and quality assurance processes in relation to the Product; and

2.4.4 where the Supplier is a distributor of the Products, ensure sufficient stock levels to comply with its obligations under this Contract including Clause 2.1 and permit or procure permission for the Authority or Authority's nominee during normal business hours having given reasonable advance notice access to the storage facilities used in the storage of the Product to enable the Authority to inspect and review the stock holding and quality assurance processes in relation to the storage of the Product prior to the point it is despatched for delivery to the Authority.

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

2.6 The Authority reserves the right to appoint an Authorised Agent to act on its behalf in dealing with the Supplier and/or in supplying the Product to Administering Entities, Devolved Administrations or patients. Where the Authority so appoints an Authorised Agent to act on its behalf in dealing with the Supplier, the Authority shall notify the Supplier in writing of this appointment and the Supplier shall continue to be bound by its obligations under this Contract and shall deal with and take instructions from such Authorised Agent. For the avoidance of doubt, there will be no obligation on the Authority to notify the Supplier where the Authority has appointed an Authorised Agent to act on its behalf in supplying the Product to Administering Entities, Devolved Administrations or patients.

2.7 Throughout the duration of this Agreement, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees that such Business Continuity Plan details and will continue to detail robust arrangements the

Supplier has and will retain in place with third parties regarding continuity of supply of raw materials and utilities and delivery of the Product during a Business Continuity Event. The Supplier shall test its Business Continuity Plan at reasonable intervals and shall provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, any updated or revised Business Continuity Plan, evidence that the Supplier tests its Business Continuity Plan at least once each year and information regarding the outcome of such tests.

2.8 Prior to completion of supply of the Volume in accordance with Clause 2.1, in the event of a Business Continuity Event, the Supplier shall implement and comply with its Business Continuity Plan and report to the Authority on such implementation.

2.9 In the event of a Business Continuity Event, the Parties may agree as appropriate a revised Delivery Schedule and review and update this at weekly intervals.

2.10 During a Business Continuity Event, the Supplier shall use all reasonable endeavours to fulfil its obligations to supply the Volume or Extension Volume in accordance with the Delivery Schedule and the provisions of this Agreement (including, without limitation, the price for the Products set out at Schedule 2) shall apply equally to all Units of the Product supplied by the Supplier in accordance with this Clause 2.10.

2.11 Notwithstanding Clause 2.7 above, for the avoidance of doubt the Parties acknowledge and agree that their intention is for the Products to be supplied prior to a Pandemic. The Parties further acknowledge and agree that should the World Health Organisation declare a Pandemic prior to the Supplier having supplied the Products, such declaration could impact on the ability of the Supplier to complete the supply of the Products in accordance with this Contract. Accordingly the Parties agree that Clauses 2.8 to 2.10 shall apply in the event a Pandemic is declared prior to completion of the Supplier's delivery obligations.

3 DELIVERY

3.1 The Supplier shall:

3.1.1 store all Units of the Product when manufactured in a good and proper manner in accordance with both the Good Manufacturing Practice and Good Distribution Practice guidance;

3.1.2 deliver all Units of the Product to the Authority's storage providers or distribution agents from time to time at such delivery points as specified in the Delivery Schedule. The Supplier shall be deemed to have delivered Units of the Product to the Authority upon delivery of the same to such storage provider or other person at the relevant location and provided the Supplier waits at the place of delivery for the Products to be unloaded by such storage provider or other person at the relevant location and once all relevant paperwork has been provided to such storage provider or other person at the relevant location; and

3.1.3 transport and deliver the Product in such manner necessary to ensure that it is delivered in good and usable condition.

3.2 Time for delivery of all Units of the Product as specified in the Delivery Schedule shall be of the essence and without prejudice to any other right or remedy of the Authority, should the Supplier not deliver the Units of the Product in accordance with the Delivery Schedule (provided that minor variances to the Delivery Schedule due to the unpredictable nature of the Product manufacturing process shall be permitted so long as agreed with the Authority prior to delivery) and other than where such failure to deliver is due to the default of the Authority or its agents, the Authority shall:

3.2.1 be entitled to refuse or cancel delivery of any such Units of the Product not delivered in accordance with the Delivery Schedule;

3.2.2 cease to have any liability to pay for any such Units of the Product not delivered in accordance with the Delivery Schedule where such Units have been refused delivery or had their delivery cancelled in accordance with Clause 3.2.1;

3.2.3 be entitled to charge the Supplier for any costs incurred by the Authority or an Administering Entity or Devolved Administration as a result of such failure to deliver (such costs to include, without limitation, all costs incurred in sourcing alternative products from third parties in excess of what would have been paid to the Supplier for such Units of the Product). The Supplier shall pay such costs due to the Authority under this Clause 3.2.3 within 30 days of the date of the Authority's invoice for the same;

and / or

3.2.4 be entitled to terminate this Agreement.

3.3 The Supplier shall deliver all Units of the Product securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

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

3.3.2 the quantity in the package;

3.3.3 special directions for storage (if any);

3.3.4 expiry date for the Product in the package;

3.3.5 batch number;

3.3.6 name of Supplier; and

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

3.4 The Supplier shall be responsible for all transport, all relevant licences, all related costs, and all other costs associated with the delivery of the Product. The Supplier shall supply the Product on pallets, unless otherwise instructed by the Authority (the Authority shall be under no obligation to return such pallets to the Supplier). The Supplier shall be responsible for ensuring that the Product is delivered to the loading bay of the Authority's storage providers and will cooperate in the unloading of the Products with such third parties as may be appropriate.

3.5 All third party carriers (other than the Authority's storage provider or distribution agents referred to in Clause 3.1) engaged to deliver the Product shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to deliver the Product to the Authority.

3.6 Subject to Clause 4.9 and 4.13, risk in all Units of the Product shall pass to the Authority upon completion of delivery, in accordance with Clause 3.1.2, of the relevant Units and title to all Units of the Product shall pass to the

Authority upon the earlier of delivery or the time of any payment being made by or on behalf of the Authority.

3.7 Each delivery of the Product shall be accompanied by an advice note stating the full description, weight, quantity, measure, order number, batch number and expiry date. All ancillary paperwork and literature (including invoices) shall include the same information.

3.8 The labelling and marking of all packages of the Product 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 Product.

3.9 The Supplier shall provide complete and accurate temperature records for each delivery of the Product to the Authority during the period of transport of the Product from the Supplier's facilities to the delivery location.

3.10 Consignment or part deliveries may be rejected unless the Authority has agreed to accept such deliveries.

3.11 In the event that Products are delivered before any agreed date then the Authority shall be entitled in its sole discretion to refuse to take delivery or charge for insurance and storage of the Products until the contractual date for delivery.

4 INSPECTION AND REJECTION OF PRODUCT

4.1 Without prejudice to the Authority's rights under Clauses 4.3 and 4.4, the Authority shall carry out a visual inspection of the Product promptly and in any event within 7 calendar days of the date of delivery to the Authority in accordance with Clause 3.1.2. Such visual inspection shall cover checking the relevant batches of Product to ensure there is no obvious damage, checking batch numbers and expiry dates in accordance with delivery documents, and quantity. The Authority shall notify the Supplier of any issues arising from such inspection promptly and in any event within 7 working days of the date of delivery to the Authority in accordance with Clause 3.1.2.

4.2 The Authority may reject any Units of the Product:

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

4.2.2 in respect of which the Supplier fails to provide complete and accurate temperature records in accordance with Clause 3.9 on the date of delivery.

4.3 The Authority may at any time by written notice to the Supplier reject any Defective Products. Where the Authority discovers more than one Defective Product in any given batch of the Product, the Authority shall be entitled to reject the entire batch provided always that the Authority shall take due account of all relevant guidance received from the Licensing Authority.

4.4 Without prejudice to any other right or remedy of the Authority,

4.4.1 the Authority may by written notice to the Supplier require the Supplier to replace Rejected Products with Units of the Product that are in compliance with this Agreement; or

4.4.2 the Authority may choose to source the Product or any substitute product from a third party.

4.4.3 Where the Authority requires the Supplier to replace the Rejected Products, the Supplier shall use its best endeavours to minimise the time taken to provide such replacement Product and in any event shall do so within one (1) month of the date of the rejection or such longer period as the Authority may agree in writing. Where the Authority notifies the Supplier that it will source replacement products elsewhere, the Supplier shall refund to the Authority any sums paid for the Rejected Products within 30 days of the date of such notification.

4.5 Where the Authority rejects any Product in accordance with this Clause 4 and the Authority no longer requires a replacement Product, either at the time of rejection or at any time prior to delivery of any replacement Product, the Authority may cancel the Purchase Order in relation to such quantity of Rejected Product. Should the Authority have paid for such Rejected Product the Supplier shall refund such payment to the Authority within 30 calendar

days of the Authority informing the Supplier that the Authority does not require such Product.

4.6 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 Units of the Product by the Authority shall constitute acceptance, waiver or approval of the Product or limit the Authority's right subsequently to reject Units of the Product should such Units be Defective Products.

4.7 Rejected Products shall be removed by the Supplier at its own expense within fourteen (14) days from the date of notification of rejection. If the Supplier fails to remove Rejected Products within such period the Authority may return such Rejected Products at the Supplier's risk and expense.

4.8 The Authority shall be entitled to charge the Supplier for any Loss Costs incurred by the Authority and/or any Administering Entity and/or Devolved Administration as a result of rejection of any Units of the Product in accordance with this Agreement provided that the Authority and/or the Administering Entity and/or Devolved Administration, as appropriate, shall use its/their reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within 30 days of the date of the Authority's invoice for the same.

4.9 Subject to Clause 4.7, risk in and title to Rejected Products shall remain with the Authority whilst such Rejected Products are in its possession until collection by the Supplier or its agent from the premises of the Authority or its nominee when risk and title shall pass to the Supplier.

4.10 Where the Supplier is required by law to order a product recall in respect of the Product, the Supplier shall:

4.10.1 immediately notify the Authority in writing of the product recall together with details of the circumstances giving rise to the product recall;

4.10.2 use its best endeavours to minimise the impact on the Authority and on the Delivery Schedule arising as a result of the product recall;

4.10.3 consult with the Authority as to the most efficient method of executing the product recall;

4.10.4 reimburse the Authority for any payment made in respect of a Product the subject of a product recall within 30 calendar days of the date on which the Authority is notified of the product recall; and

4.10.5 pay Loss Costs to the Authority in respect of the product recall.

4.11 Where any Product is the subject of a product recall, such Product shall be treated as Defective Product from the date on which the Authority is notified of the product recall.

4.12 Defective Products recalled shall be removed by the Supplier at its own expense within fourteen 14 Business Days from the date of notification of the Product recall to the Authority in accordance with Clause 4.10.1. If the Supplier fails to remove Defective Products recalled within such period the Authority may return such Rejected Products at the Supplier's risk and expense.

4.13 Subject to Clause 4.12, risk in and title to Defective Products recalled shall remain with the Authority whilst such Defective Products are in its possession until collection by the Supplier or its agent from the premises of the Authority or its nominee when risk and title shall pass to the Supplier.

5 PERFORMANCE REVIEW AND DELAY

5.1 In the event that the Supplier becomes aware that it is or it may become unable to supply the Product in accordance with the Delivery Schedule or any Additional Product Order the Supplier shall promptly notify the Authority.

5.2 The Authority reserves the right to request ad-hoc meetings as required should the performance of the Supplier become a matter of concern.

6 REGULATORY AND INFORMATION REQUIREMENTS

6.1 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 success legislation applicable to the UK). This obligation shall continue to apply after the expiry or termination of this Agreement until such time as the Authority notifies the Supplier in writing that it has used or disposed of all Units of the Product supplied under this Agreement.

6.2 The Supplier shall promptly and in any event within 7 days inform the Authority in writing if it knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal. If the Marketing Authorisation is:

6.2.1 withdrawn by the Licensing Authority;

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

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

6.2.4 in each case for reasons relating to the safety or efficacy of the Product or deficiencies in any application made by the Supplier to the Licensing Authority, then the Authority shall be entitled either to terminate:

(a) this Agreement upon written notice to the Supplier and the provisions of Clause 11.2 shall apply; or

(b) exercise its rights under Clause 6.3.

6.3 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 Product, the Authority shall be entitled to proportionately reduce the Volume or Extension Volume upon written notice to the Supplier provided that it shall take due account of all relevant guidance received from the Licensing Authority. Any such reduction in the Volume or Extension Volume shall apply first to the Units of Product specified for the final delivery in the Delivery Schedule and then to each immediately preceding delivery as necessary unless otherwise agreed in writing between the parties.

6.4 The Supplier shall:

6.4.1 reply promptly to all reasonable enquiries and complaints by the Authority relating to the Use, effective administration, quality, performance and durability of the Product;

6.4.2 to the extent relevant to the performance of this Agreement, 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 Product including the balance of risk and benefits of using the Product. 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;

6.4.3 promptly and in any event within 7 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 Product;

6.4.4 without prejudice to Clause 6.4.2, should the Supplier become aware of an actual or suspected adverse reaction to the Product which is not described in the Summary of Product Characteristics, promptly inform the Authority in writing and in any event within 7 days of becoming aware of the same; and

6.4.5 when attending the Authority's or any other relevant premises, procure that its employees and agents shall in the performance of this Agreement comply with all relevant health and safety policies and working practices in force within the Authority's or such other premises from time to time (including smoking and alcohol consumption policies) where the Supplier, its employees and agents have been informed in advance by the Authority or where notices of such policies and working practices are reasonably displayed at the relevant premises; and

6.4.6 when the Summary of Product Characteristics or the PIL of any Product supplied to the Authority under this Contract is amended prior to expiry date of the Product supplied, inform the Authority of the amendment within 7 calendar days of the said amendment approval by the Licensing Authority, and in the case of an amendment to the PIL shall on the request of the Authority supply

copies of the replacement PIL equivalent to the number of Product packs supplied.

7 QUALITY ASSURANCE

7.1 The Supplier shall comply with its quality control monitoring system details of which are included in the Marketing Authorisation and the Manufacturing Licence. The Supplier shall manufacture the Product in accordance with Good Manufacturing Practice and shall distribute the Product in accordance with Good Distribution Practice.

7.2 The Supplier shall maintain the Manufacturing Licence and all other licences necessary for the manufacture of the Product during the Term of this Agreement 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 Product) to the same or to the Specification or the Supplier's quality control monitoring system in relation to the Product without:

7.2.1 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 to include details of the consequences which will follow such change being implemented; and

7.2.2 the Licensing Authority formally approving such change.

8 WARRANTIES

8.1 The Supplier warrants and undertakes that:

8.1.1 all Units of the Product will comply with the Specification and the Marketing Authorisation;

8.1.2 it will manufacture the Product in accordance with Good Manufacturing Practice and distribute the Product in accordance with Good Distribution Practice;

8.1.3 the Product is suitable for the treatments and purposes as referred to in the Specification and this Agreement;

8.1.4 all Units of the Product will have at least the shelf life referred to at Clause 2.3.3; and

8.1.5 its Business Continuity Plan set out in Schedule 4 is sufficient to ensure continuity of supply of the Product to the Authority in accordance with this Agreement in the event of any manufacturing site failure including emergency maintenance work.

8.2 The Supplier warrants and undertakes that the Supplier shall comply with all laws and regulations applicable to the Product, including relevant provisions of:

8.2.1 Directive 2001/83;

8.2.2 Falsified Medicines Directive (Directive 2011/62/EU)

8.2.3 Medicines and Medical Devices Act 2021 (C.3)

8.2.4 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;

8.2.5 all laws, regulations and guidelines within the UK implementing the legislation referred to in Clause 8.2.1 to Clause 8.2.4 above;

8.2.6 any guidelines or directions or like documents that may be published during the Term of this Agreement by the MHRA or EMA and are applicable to the Product at the time of manufacture and / or distribution;

8.2.7 the Medicines Acts 1968 and 1971 and the Human Medicines Regulations 2012 and the regulations made thereunder in the respect of the sale, supply, importation, manufacture or assembly of the Product. For the avoidance of doubt the Human Medicines Regulations 2012 take precedence in all matters covered therein; and

8.3 The Supplier further warrants and undertakes that:

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

8.3.2 to the best of its knowledge and belief, all information included within the Supplier's response to the Invitation to Offer and all accompanying materials is accurate;

8.3.3 it is a properly constituted limited liability company and that it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Agreement and the documents referred to therein;

8.3.4 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;

8.3.5 there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into this Agreement;

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

8.3.7 as at the Effective 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.

8.3.8 it shall have in place enforceable commercial contracts with its suppliers, sub-contractors, agents and other relevant third parties and in the event of such suppliers, sub-contractors, agents and third parties being unable or unwilling to fulfil their obligations to the Supplier, the Supplier shall promptly seek to enforce such commercial contracts;

8.3.9 in an event of Force Majeure, it shall use its best endeavours to appoint alternative suppliers, sub-contractors, agents or other third parties, if possible, where the existing suppliers, sub-contractors, agents or other third parties are unable to fulfil their obligations to the Supplier;

8.3.10 it shall put in place and maintain appropriate security measures as detailed in the Business Continuity Plan to enable it to perform its obligations under this Contract and where maintenance of law and order is necessary for the fulfilment of such obligations use its best endeavours to secure the support of the appropriate public authority thereto; and

8.3.11 in the event the Authority resells or donates some of the Volume to other countries (including without limitation to any or all of the Devolved Administrations), the Supplier shall cooperate fully with the Authority in facilitating such resale or donation.

9 PRICE AND PAYMENTS

9.1 The prices to be paid by the Authority to the Supplier for the Product supplied to the Authority under this Agreement shall be as shown in Schedule 2. These prices will remain fixed during the Term of this Agreement and are inclusive of any royalties, licence fees, packaging, storage by the Supplier and the cost of delivery to the Authority's distribution agent, or similar expenses in connection with the Product. All prices set out in this Agreement are stated exclusive of any applicable VAT.

9.2 The Supplier shall issue a VAT invoice for the relevant Units of the Product upon their delivery to the Authority. All invoices shall be addressed to NHS Supply Chain, West Way, Cotes Park Industrial Estate, Alfreton, Derbyshire, DE55 4QJ.

9.3 Subject to Clause 9.2, the Authority shall pay the Supplier for the Product within 30 calendar days of the delivery of the relevant Units of the Product being affected or receipt of a valid invoice, whichever is later. In respect of any Rejected Products, no payment shall be due whatsoever.

9.4 In the event of late payment by either Party of any sums due to the other Party under this Agreement, the latter Party shall be entitled to charge interest on such outstanding sums at the rate of 2% above the London Inter-

Bank Offer Rate prevailing from time to time per annum calculated on a daily basis from the due date for payment until the date of payment. The Parties agree that this Clause 9.4 is a substantial remedy for late payment of any sum payable under this Agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.

9.5 The Authority reserves the right to deduct from any monies due to the Supplier any monies due to the Authority from the Supplier under this Agreement.

9.6 No payment will be made for containers, crates, pallets or packing materials of any description except by special arrangement agreed in writing by both Parties.

9.7 At the end of the Delivery Period, the Supplier shall provide to the Authority a written report summarising all business transacted pursuant to this Agreement during the Delivery Period including a breakdown of all Units of the Product supplied on a month by month basis setting out batch numbers, quantities, and expiry date of all Units of the Product supplied.

10 TERM AND TERMINATION

10.1 This Agreement shall commence on the Effective Date and continue for the Term of this Agreement unless terminated earlier in accordance with Clause 10.2.

10.2 The Authority may terminate this Agreement forthwith by notice in writing to the Supplier:

10.2.1 if the Supplier commits a material breach of any of the terms hereof and in the case of a breach capable of remedy if such breach shall not be remedied or made good within 30 days of written notice thereof;

10.2.2 if the Supplier 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); 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;

10.2.3 if the Licensing Authority, the Commission on Human Medicines or other relevant regulatory body advises the Authority not to use the Product;

10.2.4 if the Supplier undergoes a change of control within the meaning of section 416 of the Income and Corporation Taxes Act 1988 (other than for an intra-group change of control) without the prior written consent of the Authority which, in the reasonable opinion of the Authority, will have a material impact on the supply of the Products or the reputation of the Authority; or

10.2.5 if the Supplier is in breach of Clause 27.1.1; or

10.2.6 pursuant to Clause 3.2, Clause 6.2, Clause 19.4, Clause 20.7, Clause 20.9 or Clause 26.2.

10.2.7 in the event that:

(a) the warranty given by the Supplier pursuant to Clause 8.3.7 is materially untrue; or

(b) the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 16.1.1; or

(c) the Supplier fails to provide details of proposed mitigating factors which in the reasonable opinion of the Authority, are acceptable

10.3 The Supplier shall be entitled to terminate this Agreement forthwith by notice in writing if the Authority fails to pay undisputed invoices for three or more consecutive months.

11 POST TERMINATION PROVISIONS

11.1 Following termination of this Agreement for any reason other than effluxion of time or an inability of the Supplier to supply the Products, the Authority shall be entitled to require the Supplier at the prices prevailing as at the date of termination to deliver further Units of the Product in accordance with the Delivery Schedule and on the terms of this Agreement to the extent that they relate to the delivery of Product in such volumes as may be necessary to enable the Authority to meet demand for the Product existing at the date of termination and for a period of 6 months thereafter subject to payment for such Units of the Product upon delivery in accordance with Clause 9.

11.2 In the event of termination pursuant to Clauses 6.2, should the Authority inform the supplier that the Authority no longer requires unused Units of the Product, the Supplier shall:

11.2.1 refund to the Authority the price paid for all unused Units of the Product delivered to the Authority as at the date of termination and pay such refund to the Authority within 30 days of the date of the Authority's invoice for the same; and

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

11.3 In the event of termination of this Agreement under Clause 3.2, Clauses 10.2.1, 10.2.2, 10.2.5, Clauses 20.7, 20.9 or Clause 26.2 and without prejudice to any other right or remedy of the Authority and/or any Administering Entity, and/or Devolved Administration the Authority and/or any Administering Entity and/or Devolved Administration shall be entitled to claim the Loss Costs from the Supplier arising as a result of such termination provided that the Authority and/or Administering Entity and/or Devolved Administration, as appropriate, shall use its/their reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs

to the Authority within 30 days of the date of the Authority's invoice for the same.

11.4 Termination of this Agreement for whatever reason shall not affect the enforceability of provisions herein expressed to operate following termination and in any event shall be without prejudice to any subsisting right remedy or obligation of either Party.

11.5 Upon termination of this Agreement for any reason Clauses 1, 4, 6.1, 6.2, 6.4.2, 6.4.3, 6.4.4, 6.4.6, 8, 9.7, 11, 12, 13, 14, 15, 16.1, 17, 18, 20, 22.3, 22.7, 23, 25, 26, 27, 28, 30, 32, 33, 34, 35, 36 and 38 shall continue in force.

12 INTELLECTUAL PROPERTY RIGHTS

12.1 The Supplier warrants, represents and undertakes to the Authority that either it is the sole proprietor and legal and beneficial owner of all Intellectual Property Rights in the Product or it is licensed by the relevant owners to supply the Product in accordance with this Agreement and shall use best endeavours to ensure that it remains the owner and / or licensee (as applicable) of the Intellectual Property Rights in the Product throughout the Term of this Agreement.

12.2 The Supplier warrants and represents that any receipt and Use of the Product by the Authority or any Administrating Entity or Devolved Administration in accordance with this Agreement shall not infringe any Intellectual Property Rights of any third party.

12.3 The Supplier shall indemnify and hold harmless the Authority and any Administering Entity or Devolved Administration against all claims, liabilities, losses, damages, costs (including legal costs) and expenses incurred in connection with any claim by any party that its Intellectual Property Rights in the Product have been infringed as a result of the supply of the Product under this Agreement or the Use of the Product.

13 PRODUCT LIABILITY

13.1 Subject to Clause 13.2, the Supplier shall indemnify and hold harmless the Authority and any Administering Entity or Devolved Administration against all claims, liabilities, losses, damages, costs (including legal costs) and expenses in respect of or relating directly or indirectly to any death or personal injury suffered by any person, where such death or personal injury

arises or results or allegedly arises or results from the Product Used by the Authority or any Administering Entity or Devolved Administration.

13.2 The indemnity in Clause 13.1 shall not apply in respect of any death or personal injury arising from Use of the Product by the Authority or any Administering Entity or Devolved Administration contrary to any storage or administration requirements set out in the Summary of Product Characteristics. The Supplier shall also be relieved of any other liability under this Agreement to the extent such liability results directly from any Use or storage of the Products in contravention of any requirements set out in the Summary of Product Characteristics.

14 LIMITATION OF LIABILITY AND INSURANCE

14.1 Nothing in this Agreement shall exclude or restrict the liability of either Party:

14.1.1 for death or personal injury resulting from its negligence;

14.1.2 for fraud or fraudulent misrepresentation; or

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

14.2 Nothing in this Agreement shall exclude or restrict the liability of the Supplier under Clause 12.3 or Clause 13.1.

14.3 Subject to Clauses 14.1, 14.2 and 14.7, the total liability of the Supplier under this Agreement shall be limited in aggregate to the greater of (i) £5,000,000 (five million pounds) or 125% (one hundred and twenty five percent) of the total sums paid or payable by the Authority to the Supplier for the Products. Where any sums are refunded or due for refund by the Supplier pursuant to Clause 4.4 or Clause 11.2: (i) such refund shall not reduce the amount of the limit of liability of the Supplier under this Clause 14.3; and (ii) the sum received by the Authority by way of refund shall not be taken into account in calculating whether any such limit has been reached.

14.4 The Authority shall promptly after receipt of any claim or notification of other circumstances to which an indemnity in this Agreement may apply, notify the Supplier of such fact and the Supplier shall assume the defence of any relevant claim or legal proceedings and the Authority shall provide the

Supplier with all reasonable cooperation requested by the Supplier subject to the Supplier reimbursing the Authority's reasonable costs incurred in providing such cooperation; provided, however, that if the defendants in any such action include both of the Parties and/or both the Supplier and an Administering Entity and the Authority and/or the relevant Administering Entity and/or Devolved Administration have reasonably concluded that there may be defences available to it which are different from, additional to or inconsistent with those available to the Supplier, the Authority and/or the Administering Entity and/or Devolved Administration shall have the right to select separate counsel to participate in the defence of such action on behalf of the Authority or the relevant Administering Entity or Devolved Administration. In defending any legal proceedings under this Clause the Supplier:

14.4.1 shall use appropriately experienced lawyers;

14.4.2 shall defend any relevant claim robustly and expeditiously; and

14.4.3 shall not make an admission of liability or settle any relevant claim unless the admission or settlement is advised by the lawyer acting in defence of such claim and the Authority has provided its written consent to such admission or settlement, such consent not be unreasonably withheld or delayed.

Where the Supplier is not the manufacturer of the Product, the Parties may agree that the manufacturer may take conduct of any claim or legal proceedings subject to the manufacturer agreeing to grant the same rights and undertake the same obligations to the Authority, any Administering Entity and any Devolved Administration as granted or undertaken by the Supplier in accordance with this Clause 14.4.

14.5 The Supplier shall:

14.5.1 insure with a reputable commercial insurer against its liability under Clauses 12.3 and 13.1 with a minimum limit of indemnity of £5,000,000 (five million pounds) per annum or such other sum as may be agreed between the Authority and the Supplier in writing; or

14.5.2 to the extent such arrangements have been approved by the Authority in advance, self-insure against its liability under Clauses

12.3 and 13.1 with a minimum indemnity provision of £[5 million] per annum or such other sum as may be agreed between the Authority and the Supplier in writing.

14.6 In exercising any right to recover any sums in relation to any claims, liabilities, losses, damages, costs and expenses from the Supplier under any indemnity contained in this Agreement, such sums shall be reduced to the extent only that the Authority or any Administering Entity or Devolved Administration has not taken reasonable steps within its reasonable control to mitigate such claims, liabilities, losses, damages, costs or expenses and the direct effect of not taking such steps has been the inflation of such sums. Where the Authority has a right to invoice the Supplier for any sums under this Agreement, prior to issuing such invoice, the Authority shall notify the Supplier of the value of such invoice to allow the Supplier an opportunity to raise any questions the Supplier may have in relation to such sums. Any disputes relating to such sums payable by the Supplier in accordance with this Agreement must be raised by the Supplier within 10 calendar days of such notification and shall be dealt with in accordance with Clause 17.

14.7 In the event that the total sums paid or payable by the Authority to the Supplier for the Products exceeds or will exceed £50,000,000 (fifty million pounds) the figure of 125% at Clause 14.3 shall be deemed to have been deleted and replaced with 115% and in the event that the total sums paid or payable by the Authority to the Supplier for the Products exceeds or will exceed £100,000,000 (one hundred million pounds) the figure of 125% or 115% at Clause 14.3 shall be deemed to have been deleted and replaced with 105%.

15 CONFIDENTIALITY, FREEDOM OF INFORMATION ANDTRANSPARENCY

15.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("the Discloser") and subject always to the remainder of this Clause 15, each Party ("the 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:

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

15.1.2 the provisions of this Clause 15 shall not apply to any Confidential Information:

(a) which is in or enters the public domain other than by breach of this Agreement 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 from the Discloser; or

(e) the disclosure of which is required to ensure the compliance of the Authority or (as the case may be) an Administering Entity or Devolved Administration with any law including, but not limited to, the Freedom of Information Act 2000 (c.36) ("**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 (SI 2004/3391) ("**Environmental Regulations**").

15.2 Nothing in this Clause 15 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. Nothing in this Agreement shall prevent the Authority from disclosing Confidential Information:

15.2.1 to any contracting authority as defined in Regulation 2 of the Public Contracts Regulations 2015 ("**Contracting Authority**"). All Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority;

15.2.2 to any consultant, contractor or other person engaged by the Authority or any person conducting an Office of Government Commerce gateway review;

15.2.3 for the purpose of the examination and certification of the Authority's accounts; or

15.2.4 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.

15.3 The Supplier acknowledges that the Authority and Administrating Entities and Devolved Administrations are or may be subject to the FOIA, Codes of Practice and/or Environmental Regulations. The Supplier will act in accordance with the FOIA, the Codes of Practice and the Environmental Regulations (and any other applicable codes of practice or guidance notified to the Supplier from time to time) to the extent that they apply to the Supplier's performance under this Agreement. In no event shall the Supplier respond directly to a request for information (as defined under the FOIA and/or the Environmental Regulations) unless expressly authorised to do so by the Authority.

15.4 The Supplier agrees that:

15.4.1 without prejudice to the generality of Clause 15.3, the provisions of this Clause 15 are subject to the respective obligations and commitments of the Authority and any Administering Entity and Devolved Administration (as the case may be) under the FOIA, the Codes of Practice and the Environmental Regulations;

15.4.2 the decision on whether any exemption applies to a request for disclosure of recorded information is a decision solely for the Authority or an Administering Entity or Devolved Administration (as the case may be); and

15.4.1 where the Authority or an Administering Entity or Devolved Administration is managing a request as referred to in Clause 15.4.2, the Supplier shall co-operate with the Authority and any Administering Entity or Devolved Administration making the request and shall respond within five (5) Business Days of any request by it for assistance in determining how to respond to a request for disclosure.

15.5 The Supplier shall:

15.5.1 transfer any request for information, as defined under section 8 of the FOIA and/or the Environmental Regulations, to the Authority or an Administering Entity or Devolved Administration as soon as practicable after receipt and in any event within five (5) Business Days of receiving a request for information;

15.5.2 provide the Authority or an Administering Entity or Devolved Administration with a copy of all information in its possession or power in the form that the Authority or an Administering Entity or Devolved Administration requires within five (5) Business Days (or such other period as the Authority or an Administering Entity or Devolved Administration may specify) of the Authority or an Administering Entity or Devolved Administration requesting that information; and

15.5.3 provide all necessary assistance as reasonably requested by the Authority or an Administering Entity or Devolved Administration to enable the Authority or an Administering Entity or Devolved Administration to respond to a request for information within the time for compliance set out in section 10 of the FOIA.

15.6 The Supplier acknowledges that, except for any information which is exempt from disclosure in accordance with the provisions of the FOIA and/or the Environmental Regulations, the content of this Agreement is not Confidential Information. The Authority shall be responsible for determining whether any of the content of the Agreement is exempt from disclosure in accordance with the provisions of the FOIA and/or the Environmental Regulations and shall do this by following its own internal policies together with any applicable guidelines, including any published by the Treasury, the Cabinet Office or the Information Commissioner.

15.7 Subject to clause 15.6 above the Supplier hereby gives consent for the Authority to publish the Agreement in its entirety (but with any information which is exempt from disclosure in accordance with the provisions of the FOIA and or the Environmental Information Regulations redacted), including from time to time agreed changes to the Agreement, to the general public

15.8 The Authority may, at its sole discretion, redact information from the Agreement prior to publishing for one or more of the following reasons

15.8.1 national security

15.8.2 Personal Data

15.8.3 information protected by intellectual property law

15.8.4 third party confidential information

15.8.5 IT security; or

15.8.6 prevention of fraud.

15.9 The Authority may consult with the Supplier to inform its decision regarding any exemptions and/or redactions but the Authority shall have the final decision. The Supplier shall assist and cooperate with the Authority to enable the Authority to publish this Agreement. The Authority will follow its own internal policies together with any applicable guidelines, including any published by the Treasury, the Cabinet Office or the Information Commissioner.

15.10 The Authority or an Administering Entity or Devolved Administration may consult the Supplier in relation to any request for disclosure of the Supplier's Confidential Information in accordance with all applicable guidance.

15.11 This Clause 15 shall remain in force without limit in time in respect of Confidential Information which comprises Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid, this Clause 15 shall remain in force for a period of 3 years after the termination or expiry of this Agreement.

15.12 The Authority will use all reasonable endeavours to consult the Supplier in relation to any request for disclosure of the Supplier's Confidential Information under the FOIA and, subject to Clause 15.4.2, will take into account any reasonable comment received from the Supplier within five (5) Business Days of consulting with the Supplier.

15.13 The Supplier shall not, without the prior written consent of the Authority, announce or disclose to any third party that it has entered into this Agreement and/or that it has been appointed as a supplier to the Authority of the Product and/or any other information about this Agreement.

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

15.14.1 on a confidential basis to any Central Government Body for any proper purpose of the Authority or of the relevant Central Government Body;

15.14.2 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement;

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

15.14.4 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 15.14.1 (including any benchmarking organisation) for any purpose relating to or connected with this Agreement;

15.14.5 on a confidential basis for the purpose of the exercise of its rights under this Agreement, including the audit rights pursuant to Clause 20; or

15.14.6 on a confidential basis to a proposed successor body in connection with any assignment, novation or disposal of any of its rights, obligations or liabilities under this Agreement,

and for the purposes of the foregoing, references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement containing terms no less stringent than those placed on the Authority under this Clause 15.

16 TAX NON-COMPLIANCE

16.1 If, at any point during the Term, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

16.1.1 notify the Authority in writing of such fact within 5 Working Days of its occurrence; and

16.1.2 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;

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

17 DISPUTES

17.1 The Supplier confirms to the Authority that it is not aware of any dispute or circumstances likely to give rise to a dispute relating to the production, design, supply or Use of the Product.

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

17.3 If any dispute arises out of the Agreement (other than in relation to any matter in which the Authority has a discretion which is exercised in

accordance with the terms of the Agreement and which shall be final and conclusive) the Parties will use all of their respective reasonable endeavours to resolve it by negotiation with any disputes being escalated to the Chief Executive Officers (or equivalent) of each Party to the extent that such disputes cannot otherwise be resolved within 14 calendar days from the date of any dispute arising.

17.4 If negotiations fail to resolve such dispute the Parties will attempt to settle it by mediation in accordance with the Centre for Effective Dispute Resolution ("**CEDR**") Model Mediation Procedure or any other model mediation procedure as agreed by the Parties. To initiate mediation a Party shall give notice in writing (a "**Mediation Notice**") to the other Party requesting mediation of the dispute and shall send a copy thereof to CEDR or an equivalent mediation organisation as agreed by the Parties asking them to nominate a mediator in the event that the Parties shall not be able to agree such appointment by negotiation. The mediation shall commence within 28 days of the Mediation Notice being served. Neither party will terminate such mediation until each Party has made its opening presentation and the mediator has met each Party separately for at least one hour or one party has failed to participate in the mediation process. Neither Party will commence legal proceedings against the other until 30 days after such mediation of the dispute in question has failed to resolve the dispute. The Authority and the Supplier will co-operate with any person appointed as mediator providing him with such information and other assistance as he shall require and will pay his costs, as he shall determine or in the absence of such determination such costs will be shared equally.

17.5 Nothing in this Agreement shall prevent:

17.5.1 the Authority taking action in any court in relation to any death or personal injury arising or allegedly arising in connection with the Product; or

17.5.2 either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party, pending resolution of the relevant dispute in accordance with the CEDR procedure.

18 DATA PROTECTION

18.1 The Parties acknowledge their respective duties under the Data Protection Legislation and shall give each other all reasonable assistance as appropriate or necessary to enable each other to comply with those duties. For the avoidance of doubt, the Supplier shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation and shall comply with such obligations.

18.2 Where the Supplier is Processing Personal Data under or in connection with this Agreement, the Parties shall comply with the Data Protection Protocol.

18.3 The Supplier and the Authority shall ensure that Personal Data is safeguarded at all times in accordance with the Law, and this obligation will include (if transferred electronically) only transferring Personal Data (a) if essential, having regard to the purposes for which the transfer is conducted; and (b) that is encrypted in accordance with any applicable international data encryption standards for healthcare, and as otherwise required by those standards applicable to the Authority under any Law and guidance (this included data transferred over wireless or wired networks, held on laptops, CDs, memory sticks and tapes).

18.4 Where any Personal Data is Processed by any sub-contractor of the Supplier in connection with this Agreement, the Supplier shall procure that such sub-contractor shall comply with the relevant obligations set out in this Clause 18 as if such sub-contractor were the Supplier.

18.5 The Supplier shall indemnify and keep the Authority and any Administering Entity or Devolved Administration indemnified against any loss, damages, costs, expenses (including without limitation legal costs and expenses), claims or proceedings whatsoever or howsoever arising from the Supplier's unlawful or unauthorised processing, destruction and/or damage to Personal Data in connection with this Agreement.

18.6 Subject to Clause 14, the Supplier agrees to indemnify and keep indemnified the Authority and any Administering Entity or Devolved Administration against all claims and proceedings and all liability, loss, costs and expenses incurred in connection therewith by the Authority and any Administering Entity or Devolved Administration as a result of any claim made or brought by any individual or other legal person in respect of any loss, damage or distress caused to that individual or other legal person as a result of the Supplier's unauthorised processing, unlawful processing, destruction of and/or damage to any Personal Data processed by the

Supplier, its employees or agents in the Supplier's performance of the Agreement or as otherwise agreed between the Parties.

19 FORCE MAJEURE

19.1 Subject to Clause 19.2, neither Party shall be considered to be in default or liable for breach of any obligation hereunder nor liable to the other Party for any loss or damage whatsoever arising out of the prevention, hindrance or delay of the performance of any such obligation to the extent that the performance of such obligation is prevented, hindered or delayed by an event of Force Majeure.

19.2 The Supplier shall only be entitled to rely on an event of Force Majeure and will not be considered to be in default or liable for breach of any obligations hereunder if the Supplier has fulfilled its obligations pursuant to Clauses 2.7, 2.8 and 2.10.

19.3 A Party wishing to rely on an event of Force Majeure shall promptly and in any event within 7 days of becoming aware of the same give written notice to the other Party of the nature of the event of Force Majeure and shall use its best endeavours to mitigate the effects of such event of Force Majeure.

19.4 If an event of Force Majeure relied on by the Supplier shall subsist for 28 days or more then the Authority shall have the right to terminate this Agreement at once by giving notice to the Supplier.

19.5 On the occurrence of an event of Force Majeure the Parties shall meet as soon as reasonably practicable and acting in good faith shall use all reasonable endeavours (but without incurring undue costs) to agree the measures (if any) necessary to mitigate the effects of such event of Force Majeure and or to remedy any effects of the Force Majeure and, subject to Clause 19.2, the obligations of both parties shall be suspended to the extent that they are affected by such event of Force Majeure unless and until:

19.5.1 the event of Force Majeure shall have ceased and any such measures shall have been agreed and the damage shall have been remedied pursuant to such agreement; or

19.5.2 this Agreement is terminated

whichever shall be the earlier.

20 RIGHT OF AUDIT CONFLICTS OF INTEREST AND THE PREVENTION OF FRAUD

20.1 The Supplier shall keep secure and maintain for the Term of this Agreement and seven (7) years thereafter (or from the date of the last delivery, if later), or such longer period as may be agreed between the parties, full and accurate records of all matters relating to this Agreement.

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

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

20.2.2 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.

20.3 The Comptroller and Auditor General may examine such documents as he 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 he considers necessary. This Clause does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under section 6(3)(d) and 6(5) of the National Audit Act 1983.

20.4 The Authority shall have the right to audit the Supplier's compliance with this Agreement. The Supplier shall permit or procure permission for the Authority or its authorised representative during normal business hours having given advance notice of no less than five Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Agreement.

20.5 Should the Supplier subcontract any material part of its obligations under this Agreement (as set out in schedule 5), the Authority shall have the right to audit (including but not limited to a financial audit and a full manufacturing audit) and inspect such third party. The Supplier shall procure permission for the Authority or its authorised representative during normal business hours no more than once in any twelve (12) months having given advance notice of no less than five (5) Business Days, access to any premises and facilities, books and records used in the performance of the Supplier's

obligations under this Agreement that are subcontracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested.

20.6 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any staff is 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 Agreement. The Supplier will disclose to the Authority full particulars of any such conflict of interest which may arise.

20.7 The Authority reserves the right to terminate this Agreement immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of this Agreement. The actions of the Authority pursuant to this Clause 20.7 shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.

20.8 The Supplier shall take all reasonable steps to prevent Fraud by staff and the Supplier (including its shareholders, members and directors) in connection with the receipt of monies from the Authority. 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.

20.9 If the Supplier or its staff commits Fraud in relation to this or any other contract with the Crown (including the Authority) the Authority may:

20.9.1 terminate this Agreement and recover from the Supplier the amount of any loss suffered by the Authority resulting from the termination, including the cost reasonably incurred by the Authority of making other arrangements for the supply of the Product and any additional expenditure incurred by the Authority throughout the remainder of the Term; or

20.9.2 recover in full from the Supplier any other loss sustained by the Authority in consequence of any breach of Clause 20.8

21 ENVIRONMENTAL CONSIDERATIONS

21.1 The Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Product. 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 Invitation to Offer. Without prejudice to the generality of the foregoing, the Supplier shall:

21.1.1 comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Product is supplied;

21.1.2 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 Product;

21.1.3 comply with all obligations imposed on it in relation to the Product 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);

21.1.4 without prejudice to the Supplier's other obligations under this Agreement, label all Units of the Product, and the packaging of those Units, to highlight environmental and safety information as required by applicable UK and EU legislation;

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

21.1.6 where the Product is 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 Product and the packaging which is used for the containment, protection, handling, delivery

and presentation of the Product in addition to any other obligations it may have pursuant to the said Regulations.

21.2 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 21.

22 EQUALITY, NON-DISCRIMINATION AND HUMAN RIGHTS

22.1 The Supplier shall not:

22.1.1 engage in any prohibited conduct as defined in part 2 chapter 2 of the Equality Act 2010 (c.15) (the "**Equality Act**") in relation to any protected characteristic (as defined in section 4 of the Equality Act) where this would contravene any provisions of the Equality Act, including part 3 (goods and services) and part 5 (employment); or

22.1.2 do (or omit to do) anything else that would amount to a contravention of the Equality Act including part 8 (prohibited conduct: ancillary) and chapter 3 part 5 (equality of terms).

22.2 The Supplier shall notify the Authority immediately of any investigation of or proceedings against the Supplier under the Equality Act or any predecessor legislation and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or data required, attending any meetings and providing any information requested.

22.3 The Supplier shall indemnify the Authority against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Authority arising out of or in connection with any investigation conducted or any proceedings brought under any legislation referred to in this Clause 22 due directly or indirectly to any act or omission by the Supplier, its agents, employees or sub-contractors.

22.4 The Supplier shall impose on any sub-contractor obligations substantially similar to those imposed on the Supplier by this Clause 22.

22.5 In addition to its obligations under this Clause 22 relating to Equality Act, the Supplier shall:

22.5.1 ensure that it complies with all other current employment legislation and, in particular, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 (SI 2000/1551), the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002, (SI 2002/2034), any equivalent legislation applicable in Scotland, Northern Ireland and/or Wales or any other relevant legislation relating to discrimination in the employment of employees. The Supplier shall take all reasonable steps (at its own expense) to ensure that any employees employed in the manufacture or supply of the Product do not unlawfully discriminate within the meaning of this Clause 22.5 and shall impose on any sub-contractor obligations substantially similar to those imposed on the Supplier by this Clause 22.5; and

22.5.2 in the management of its affairs and the development of its equality and diversity policies, the Supplier shall co-operate with the Authority in light of the Authority's obligations to comply with its statutory equality duties. The Supplier shall take such 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 any additional equality and diversity requirements applicable in Scotland, Northern Ireland and/or Wales.

22.6 The Supplier shall, and shall use reasonable endeavours to ensure that its employees or agents and/or sub-contractors shall, at all times, act in a way which is compatible with the Convention rights within the meaning of Section 1 of the Human Rights Act 1998 (c.42).

22.7 Subject to Clause 14, the Supplier agrees to indemnify and keep indemnified the Authority against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Supplier of its obligations under Clause 22.6.

23 ENTIRE AGREEMENT

23.1 This Contract together with the Invitation to Tender and the Offer constitutes the entire understanding of the Parties 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 or other documents

referenced in this Clause 23 provided that nothing in this Contract shall exclude liability for any fraudulent misrepresentation. Each Party acknowledges that in entering into this Contract it does not rely on, and shall have no remedies in respect of, any representation or warranty (whether made innocently or negligently) that is not set out in this Contract or the other documents referenced in this Clause 23.

24 VARIATION AND AUTHORISED REPRESENTATIVE

24.1 No variation of this Agreement shall be binding unless it has been agreed in writing and signed by an authorised representative of both Parties. At the date of this Agreement such representatives are **Redacted Under FOIA Section 40, Personal Information** for the Authority and **Redacted Under FOIA Section 40, Personal Information** for the Supplier. The representative of a Party may be varied by that Party by notice in writing to the other Party.

25 RELATIONSHIP BETWEEN THE PARTIES

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

26 PROHIBITED ACTS

26.1 The Supplier warrants and represents that:

26.1.1 it has not committed any offence under the Prevention of Corruption Acts 1889-1916 or the Bribery Act 2010 (c.23) or done any of the following (referred to hereafter as "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 of 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 Agreement paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the Authority.

26.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010 (c.23).

26.2 If the Supplier, its sub-contractors, its employees or agents (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 Prevention of Corruption Acts 1889-1916 or the Bribery Act 2010 (c.23) with or without the knowledge of the Supplier in relation to this or any other agreement with the Authority,

26.2.1 the Authority shall be entitled:

(a) to terminate this Agreement 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; and

26.2.2 any termination under Clause 26.2.1 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the Authority;

27 ASSIGNMENT, NOVATION AND SUBCONTRACTING

27.1 The Supplier:

27.1.1 shall not, except where Clause 27.1.2 applies, assign, sub-contract or in any other way dispose of the whole or any part of this Agreement without the previous consent in writing of the Authority. If with the Authority's consent the Supplier so sub-contracts, every act or omission of the sub-contractor shall for the purposes of this Agreement be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority thereafter as if such act or omission had been committed or omitted by the Supplier itself; and

27.1.2 notwithstanding Clause 27.1.1, may assign to a third party ("the Assignee") the right to receive payment of any sums due and owing to the Supplier under this Agreement for which an invoice has been issued or any part thereof (including any interest which the Authority incurs under Clause 9.4). Any assignment under this Clause 27.1.2 shall be subject to:

(a) the reduction of any sums in respect of which the Authority exercises its right of recovery under Clause 9.5;

(b) all related rights of the Authority in relation to the recovery of sums due but unpaid;

(c) 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;

(d) the provisions of Clause 9 continuing to apply in all other respects after the assignment which shall not be amended without the approval of the Authority in accordance with Clause 24; and

(e) payment to the Assignee being full and complete satisfaction of the Authority's obligation to pay the relevant sums in accordance with this Agreement.

27.2 Any authority given by the Authority for the Supplier to sub-contract any of its obligations hereunder shall not impose any duty on the Authority to enquire as to the competency of any authorised sub-contractor, and 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 Agreement.

27.3 Where the Supplier enters into a sub-contract with a supplier or contractor for the purpose of performing its obligations under the Contract, it shall ensure that a provision is included in such a sub-contract which requires prompt payment to be made of all sums due by the Supplier to the sub-contractor within a reasonable period as specified in the relevant sub-contract. As a general principle, this period should not exceed 30 calendar days from the receipt of a valid invoice unless an alternative acceptable period is agreed with such supplier or contractor (provided such alternative period is not imposed on a supplier or contractor that does not have the same bargaining strength as the Supplier).

27.4 The Authority may at any time as far as it is lawful to do so, transfer, assign, or otherwise dispose of its rights and obligations under this Agreement or any part of this Agreement to anybody:

27.4.1 that performs any of the functions and/or responsibilities that had previously been performed by the Authority; and/or

27.4.2 to whom a material part of the assets or undertaking of the Authority is transferred, including in each case any such body that is:

(a) a new body resulting from a re-organisation, consolidation or merger of the Authority and any Contracting Authority; and/or

(b) a private sector body;

27.5 The Authority shall with the consent of the Supplier, such consent not to be unreasonably withheld or delayed and/or made subject to unreasonable condition(s) and/or restriction(s), be permitted to novate its rights and obligations under this Agreement or any part of this Agreement to anybody:

27.5.1 that performs any of the functions and/or responsibilities that had previously been performed by the Authority; and/or to whom a material part of the assets or undertaking of the Authority is transferred, including in each case any such body that is:

(a) a new body resulting from a re-organisation, consolidation or merger of the Authority and any Contracting Authority; and/or

(b) a private sector body;

27.6 Any change in the legal status of the Authority shall not affect the validity of this Agreement.

28 DISTRIBUTION ARRANGEMENTS DURING A PANDEMIC EVENT OR OTHER EMERGENCY

28.1 The Authority may at its sole discretion, when notified that the supply chain cannot maintain business as usual activities to the NHS, elect to sell some or (in urgent cases, such as but not limited to a Pandemic) all of the Product(s) procured by the Authority from the Supplier pursuant to this Agreement.

28.2 In these urgent circumstances the Authority will appoint one or more Wholesale Distributors, who will be entitled to buy the stockpiled Product(s) from the Authority and distribute the stockpiled Product(s) (on the terms of a separate pre-determined contract). The supply of the stockpiled Product(s) to any such Wholesale Distributor will be limited to those distributors that hold a wholesaler dealer's licence, are full members of the Healthcare Distribution Association UK and operate on a UK wide basis.

28.3 In addition to the circumstances set out in clause 28.2, the Authority reserves the right (at its own discretion and at any time) to donate or sell any of the Product(s) procured by the Authority from the Supplier pursuant to this Agreement for use in an emergency within the UK or overseas.

28.4 The Supplier acknowledges and agrees to the Product(s) being used for the purpose(s) outlined in this clause 28.

29 WAIVER

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

29.2 The failure by the Authority or the Supplier to insist upon the strict performance of any provision, term or condition of this Agreement or to exercise any right or remedy consequent upon the breach thereof shall not

constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.

30 SUPPLY CHAIN RIGHTS AND PROTECTION

30.1 The Supplier shall implement due diligence procedures for subcontractors and other participants in its supply chains, to ensure that there is no slavery or human trafficking in its supply chains.

30.2 The Supplier warrants and undertakes that it shall:

30.2.1 Comply with all relevant law and guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains and;

30.2.2 notify the Authority immediately if it becomes aware of any actual or suspected slavery or human trafficking in a supply chain; and

30.2.3 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 30 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery policy

30.3 If pursuant to section 54 of the Modern Slavery Act the Supplier is required to publish an annual Slavery and Human Trafficking Statement (as defined in the Modern Slavery Act), it shall deliver to the Authority a copy not later than thirty (30) days after the Effective Date and each anniversary of the Effective Date for the duration of the Term of this Agreement.

31 NOTICE

31.1 Any notice to be given under this Agreement by:

31.1.1 the Supplier to the Authority shall be sent for the attention of the authorised representative of the Authority as notified to the Supplier in accordance with Clause 24 and the address for notices or confirmations sent by post shall be the Department of Health and Social Care, 2nd Floor, Rutland House, Runcorn, WA7 2ES;

31.1.2 the Authority to the Supplier shall be sent for the attention of the authorised representative of the Supplier as notified to the Authority in accordance with Clause 24 and the address for

notices or confirmations sent by post shall be B. Braun Medical Limited, Thorncliffe Park, Sheffield, S35 2PW; and

31.1.3 either Party to the other shall be in writing and may be sent by post or by fax. Any notice sent by fax shall be confirmed by post within seven (7) days. A notice shall be deemed to have been served forty-eight (48) hours after the notice is posted or at 9.00am on the next Business Day after the sender receives a successful fax transmission report.

32 SEVERANCE

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

33 MISREPRESENTATION

33.1 The Supplier 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 Agreement and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the Authority for any misrepresentation (whether made carelessly or not) or for breach of any warranty unless the representation relied upon is set out in this Agreement or unless such representation was made fraudulently.

34 COST AND EXPENSES

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

35 RIGHTS AND REMEDIES

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

36 THIRD PARTY RIGHTS

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

36.2 Any Administering Entity or Devolved Administration may enforce any provision of this Agreement which confers a benefit on it. Subject to the foregoing, a person who is not a party to this Agreement shall have no right to enforce any terms of it which confer a benefit on him. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Agreement.

37 PARENT COMPANY GUARANTEES *NOTE: NOT APPLICABLE*

37.1 This Agreement shall be conditional upon receipt of a valid Guarantee from an acceptable Guarantor, on or prior to the execution of this Agreement, and the Supplier shall deliver to the Authority an executed Guarantee in the form set out in Schedule 6 from a Guarantor acceptable to the Authority.

38 GOVERNING LAW AND JURISDICTION

38.1 This Agreement, and any dispute or claim arising out of or in connection with it or its subject matter, shall be governed by, and construed in accordance with, the laws of England.

38.2 Subject to Clause 17, the parties irrevocably agree that the courts of England shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter.

IN WITNESS whereof this Agreement has been entered into the day and year first before written

SIGNED BY: …….....
FOR AND ON BEHALF OF THE AUTHORITY

(NAME) ……...

DATE: ……

SIGNED BY: ……
FOR AND ON BEHALF OF THE SUPPLIER

(NAME) ……..…….

DATE: …….

SCHEDULE 1

Product Specification

[*To be completed at time of award*]

Summary of product characteristics as supplied in your ITO response

Name of Medicinal Product:

Redacted Under FOIA Section 43(2), Commercial Interests

Shelf Life:

Redacted Under FOIA Section 43(2), Commercial Interests

Marketing Authorisation Holder:

- **B. Braun Medical Limited**

Marketing Authorisation Number(s):

Redacted Under FOIA Section 43(2), Commercial Interests

Date of First Authorisation / Renewal of the Authorisation:

Redacted Under FOIA Section 43(2), Commercial Interests

Date of the Revision of the Text:

Redacted Under FOIA Section 43(2), Commercial Interests

Primary and Secondary packaging and Weights and measures information

a) The information in this table has been provided by the Supplier in their ITO response and should reflect the actual product as it is delivered to our warehouse.

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 2

Price

Prices are in £ sterling excluding VAT

Redacted Under FOIA Section 43(2), Commercial Interests

Pack size information used in this table was provided by the Supplier in their ITO response.

SCHEDULE 3

Delivery Schedule

The required Volume by Product and Month is detailed below. This is an indicative forecast based on your offer response; you will be required to provide a more detailed weekly delivery forecast as soon as possible after contract conclusion.

The Authority's preference would be for the supply of complete packs of Product, therefore the Volume has been rounded to your pack size enabling you to supply complete packs.

Redacted Under FOIA Section 43(2), Commercial Interests

The table below illustrates the Volume to be delivered in your pack size. Pack size information used in these tables was provided by the Supplier in their ITO response.

Redacted Under FOIA Section 43(2), Commercial Interests

The table below illustrates the Volume to be delivered in your **pallet** configuration. **Pallet** configuration information used in these tables was provided by the Supplier in their ITO response.

Redacted Under FOIA Section 43(2), Commercial Interests

Summary of total volumes

The table below illustrates the total Volume required by Product in both Unit and Supplier pack size presentations.

Redacted Under FOIA Section 43(2), Commercial Interests

Delivery Point:

Delivery points will be notified on the order which will be sent by the Authority's Authorised Agent upon contract conclusion.

SCHEDULE 4

Supplier's Business Continuity Plan

Redacted Under FOIA Section 43(2), Commercial Interests

SCHEDULE 5

Obligations under the Agreement to be considered material in respect of clause 20.5

As described in the following document(s) submitted as part of the Offer:

SUPPLIER NAME:	B. Braun Medical Limited

Confidential and Commercially Sensitive Information - notes for completion
Offerors attention is drawn to the following clauses in this invitation to offer pack: Terms of Offer - Clause 4 - Freedom of Information Terms of Offer - Clause 5 - Right to Publish Conditions of Contract - Clause 15 - Confidentiality, Freedom of Information and Transparency In particular, this Document should be used to set out any information forming part of the Offeror's offer that is considered by the Offeror to be confidential or commercially sensitive

The Offeror considers that the type of information listed in table A is Confidential Information as defined in the conditions of contract. The Offeror considers that the type of information listed in table B is commerically sensitive information.

Table A

Types of Information that the Offeror considers to be Confidential Information, the reason for the exemption and the section number in the Freedom of Information Act (FOIA) that applies			Period that the Offeror considers applies to this information	
Information provided / name of document / page / paragraph number	**Exempt under FOIA section number:**	**Reason**	**Date From:**	**Date To:**
Please see attached B. Braun - Documents Considered Confidential				

Table B

Types of Information that the Offeror considers to be commercially sensitive information, the reason for the exemption and the section number in the Freedom of Information Act (FOIA) that applies			Period that the Offeror considers applies to this information	
Information provided / name of document / page / paragraph number	**Exempt under FOIA section number:**	**Reason**	**Date From:**	**Date To:**
Please see attached B. Braun - Documents Considered Confidential				
