## TERMS AND CONDITIONS FOR THE SUPPLY OF CENTRALLY PROCURED VACCINES

## **THIS CONTRACT** is made on 7 June 2021 ("Effective Date")

## BETWEEN:

- (1) The Secretary of State for Business, Energy & Industrial Strategy, contracting for and on behalf of the Crown, and whose principal office is at 1 Victoria Street, London SW1H 0ET (the "**Authority**") on the one hand; and
- (2) Pfizer Export B.V., a company established under the laws of the Netherlands with its registered office at (the "**Supplier**").

## BACKGROUND

The Supplier and its Affililates are collaborating in the development of a researchstage, experimental vaccine to address the global COVID-19 pandemic.

Pfizer Limited and the Authority entered into a certain manufacturing and supply agreement dated 12 October 2020, as amended by a deed of amendment dated 29 March 2021, in respect of the supply by Pfizer Limited to the Authority of such vaccine (the "**Original MSA**").

Pursuant to the allocation process operated by The Covid-19 Vaccines Global Access Facility (the "**COVAX Facility**"), and in partnership with the Gavi Alliance, the Authority has been allocated certain doses of the Goods (as defined herein), to be supplied by the Supplier.

The Authority acknowledges and agrees that the Supplier's efforts to develop and manufacture a vaccine are aspirational in nature and subject to significant risks and uncertainties. The Authority acknowledges that the Goods which are the subject of this Contract and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic, and will continue to be studied after provision of the Goods to the Authority under the Contract. Further, the Parties recognize that the vaccine has completed Phase 2b/3 clinical trials but that, despite the efforts of the Supplier in research, development and manufacturing, the vaccine may not be successful due to technical, clinical, regulatory, manufacturing and/or other challenges or failures. Notwithstanding the foregoing, the Parties recognise that events have progressed, in particular the development of the Goods has been successful and an Emergency Use Authorisation from the MHRA under Regulation 174 of the Human Medicines Regulation 2012 has been obtained.

Subject to the above, the Parties are willing to carry out the foregoing pursuant to the terms and conditions set forth in this Contract.

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

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

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

Schedule 1	Key Provisions
Schedule 2	General Terms and Conditions
Schedule 3	Information Provisions
Schedule 4	Definitions and Interpretations
Schedule 5	Specification
Schedule 6	Delivery Schedule
Schedule 7	Proforma Change Control Note
Schedule 8	Approved Sub-contractors
Schedule 9	KPIs

## Schedules

# Signed by the authorised representative of THE AUTHORITY

Name:		Signature:	
Position:	Director General Vaccine Taskforce		

# Signed by the authorised representative of THE SUPPLIER

Name:		Signature:
Position:	Board Member / Dire	ctor

# SCHEDULE 1

## **Key Provisions**

## 1. Application of the Key Provisions

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

## 2. Term

2.1 This Contract shall commence on the Effective Date and shall expire when all of the Goods required to be delivered under this Contract have been delivered to the applicable Authority Facility ("**Term**"). The Term may only be extended by mutual written agreement between the Parties.

### 3. Contract Managers

- 3.1 The Contract Managers at the Effective Date are:
- 3.1.1 for the Authority:



Vaccines Business Unit Lead, Pfizer UK

## 4. Names and addresses for notices

- 4.1 Notices served under this Contract are to be delivered to:
- 4.1.1 for the Authority:

Attention:	Director General of the Vaccine Task Force Secretary of State, Department for Business, Energy and Industrial Strategy 1 Victoria St Westminster London SW1H 0ET
With copy to:	Permanent Secretary, Department for Business, Energy & Industrial Strategy Secretary of State, Department for Business, Energy and Industrial Strategy 1 Victoria St Westminster London SW1H 0ET

## 4.1.2 for the Supplier:

Attention:



With copy to (which shall not constitute notice):



## 5. Management levels for escalation and dispute resolution

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

Level	Authority representative	Supplier representative
1		Contract Manager
2	Deputy Director VTF Commercial	Regional President, Vaccines, International Developed Markets
3	Programme Director VTF	Global President, Vaccines

## 6. Order of precedence

- 6.1 Subject always to Clause 1.1 of Schedule 4, should there be, and only to the extent that there is, a conflict between any of the provisions of this Contract the descending order of priority for construction purposes shall be:
- 6.1.1 the provisions on pages 1 and 2 of this Contract;
- 6.1.2 Schedule 1: Key Provisions and Schedule 2: Clauses 13 and 14;
- 6.1.3 Schedule 5: Specification;
- 6.1.4 Schedule 2: the remainder of the General Terms and Conditions;

- 6.1.5 The provisions of any Purchase Order (subject to Clause 7.4 of this Schedule 1);
- 6.1.6 Schedule 6: Delivery Schedule;
- 6.1.7 Schedule 4: Definitions and Interpretations;
- 6.1.8 Schedule 3: Information Provisions;
- 6.1.9 Schedule 7: Proforma Change Control Note
- 6.1.10 Schedule 8: Approved Sub-contractors
- 6.1.11 Schedule 9: KPIs

## 7. Purchase Orders

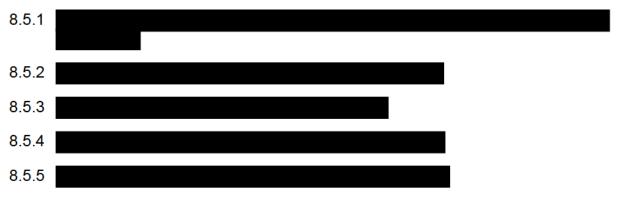
- 7.1 The Authority shall submit legally binding and irrevocable Purchase Orders to the Supplier for the Contracted Doses following the date of this Agreement.
- 7.2
- 7.3 The Purchase Orders shall be provided together with the Authority's order number, VAT number, and invoice address. The Supplier shall confirm acceptance of the Purchase Orders in writing, and the confirmed Purchase Order shall be binding upon the Parties and subject to the terms and conditions set out in this Contract.
- 7.4 The Purchase Orders shall be incorporated into this Contract once accepted by an authorised representative of the Supplier. No additional terms and conditions shall be included within any Purchase Order (or if they are so included, shall not be deemed to form part of this Contract) without the prior written consent of both Parties.

## 8. Supply and Delivery

- 8.1 During the term of this Contract, the Supplier shall supply the Goods to the Authority, and the Authority shall purchase the Goods, subject to and in accordance with the terms and conditions of this Contract.
- 8.2 The Supplier may deliver the Goods by separate instalments and shall use Commercially Reasonable Efforts to deliver the Contracted Doses of the Supplier's acceptance of the relevant Purchase Order, in accordance with Clause 5 of Schedule 2.
- 8.3 Supply of the Goods to the Authority will be made from Supplier sites within the EEA (which shall, throughout this Contract, include the UK irrespective of the UK's withdrawal from the European Union), save with the express prior written approval of the Authority and on the understanding that, if approved by the Authority, Supplier will be responsible for importation of the Goods into the

EEA prior to the supply of such Goods to the Authority to ensure compliance of the Authority with its Wholesale Dealers Licence.

- 8.4 If there are insufficient volumes of the Goods available from the Supplier sites in the EEA to enable the Supplier to deliver the full amount of Goods to the Authority within the agreed timescale while meeting Covid-19 vaccine supply commitments to the Supplier's Affiliates' other customers the Supplier will supply the Authority such volumes of Goods as are
- 8.5 The Authority acknowledges that, as at the execution of this Contract, the Goods are novel and being produced under pandemic conditions, and despite the Commercially Reasonable Efforts of the Supplier, the Supplier's efforts to develop and manufacture a vaccine are aspirational in nature and subject to significant risks and uncertainties due to technical, clinical, regulatory and/or manufacturing challenges and/or failures. The Authority acknowledges that, in such circumstances, the following remedies:



are reasonable and constitute the Authority's sole and exclusive remedies for Supplier's failure to manufacture, supply or deliver the Goods in compliance with this Contract, for whatever reason. Under no circumstances will the Supplier

to the Authority for failure

to manufacture, supply or deliver the Goods in compliance with this Contract, for whatever reason.



8.7 If Supplier fails to deliver the first of the Goods on or before Supplier shall have no obligation to deliver the Goods, the Authority shall have no obligation to purchase the Goods and either Party may terminate this Contract without liability on providing a Termination Notice to the other Party.

- 8.8 Notwithstanding the provisions of Clause 5.19 of Schedule 2, if by the Supplier or BioNTech or one or more of their respective Affiliates are unable to manufacture, or the Supplier is unable to deliver, any Goods from any Facilities for unforeseen reasons beyond their reasonable control, any Party,
- 8.9 If, notwithstanding the obligations set out in this Agreement, the Contracted Doses have not been delivered **Supplier has** (i) generated any changes to the active substance or antigenic characteristics of BNT16b2 encoding a variant or new strain of SARS COV 2 (**"Adapted Vaccine"**) and (ii) agreed relevant terms with the COVAX Facility and/or the Gavi Alliance, then the Parties shall meet to discuss if the Adapted Vaccine should be used for the Contracted Doses and any associated changes which may be needed to this Agreement as a consequence.

## 9. Regulatory and information requirements

- 9.1
- 9.2 Without prejudice to the provisions of Clause 9.3 of this Schedule 1, where the holder of the Authorisation is a third party, any obligation on the Supplier under this Contract shall be taken as a requirement on the Supplier to procure the compliance of the holder of the Authorisation with such obligation to the extent necessary to ensure the relevant obligation is fully met.
- 9.3 Where the Supplier knows or believes there to be any problem with the Authorisation, or its renewal, it shall raise this with the Authority via Governance, within a reasonable timescale.
- 9.4 The Parties agree to discuss the following via Governance:
- 9.4.1 reasonable enquiries and complaints by the Authority relating to the use and effective administration of the Goods;
- 9.4.2 collaborative contract management, including, to the extent relevant, the setting of KPIs;

- 9.4.3 any updates on the Authorisation;
- 9.4.4 an update on progress made in relation to clinical trials and manufacturing;
- 9.4.5 claims brought by third parties relating to the Goods;
- 9.4.6 any material communication from the Licensing Authority arising out of, or in connection with, any concerns relating to the safety or efficacy of the Goods, including any actual or suspected adverse reaction to the Goods which is not described in the Summary of Product Characteristics, and any known health and safety hazard of the Goods; and
- 9.4.7 the progress against actions as set out in any joint deployment plan developed by the Parties.
- 9.5 Without limitation to the warranties contained in Clause 11 of Schedule 2, the Supplier shall, upon written request from the Authority, make available to the Authority evidence of the grant of any required valid Authorisation, and evidence of any other authorisations, labelling, registrations, approvals or documentation required.

## 10. Right to terminate

10.1 Either Party may terminate this Contract by written notice solely in the circumstances expressly provided for in this Contract.

# SCHEDULE 2

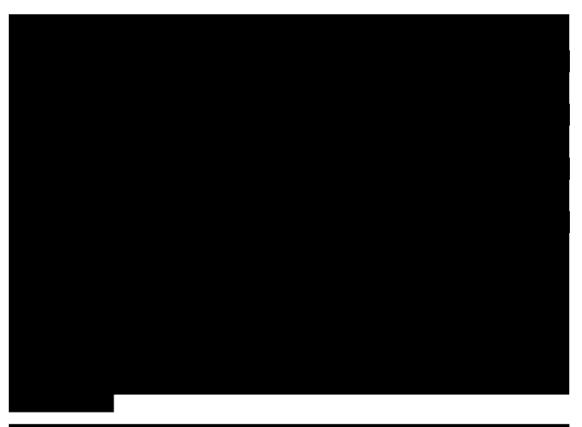
## **General Terms and Conditions**

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### 1. Supply of Goods

- 1.1 The Supplier shall use Commercially Reasonable Efforts to build manufacturing capacity to be capable of manufacturing and supplying the Goods to the Authority in accordance with the provisions of this Contract.
- 1.2 Subject to the terms of this Contract, the Supplier shall manufacture, supply and distribute, and the Authority shall purchase, store, distribute and use the Goods:
- 1.2.1 in accordance with the provisions of this Contract;
- 1.2.2 using reasonable skill and care in their, distribution, storage and use;
- 1.2.3 in accordance with Laws; and
- 1.2.4 in accordance with the Policies.
- 1.3 Subject to the terms of this Contract, the Supplier shall use Commercially Reasonable Efforts to manufacture and supply, and the Authority shall purchase, the Goods:
- 1.3.1 promptly and in any event within any time limits as may be set out in this Contract; and
- 1.3.2 in a professional and courteous manner.
- 1.4 Unless otherwise agreed by the Parties in writing, the Goods shall at the time of delivery to the Authority Facility (as defined in Clause 5 of this Schedule 2) not previously have:
- 1.4.1 left the control of the Supplier or its Sub-contractor or their defined distribution path prior to their receipt by the Authority; or
- 1.4.2 been rejected by any other entity prior to their supply to the Authority under this Contract.
- 1.5 If there are any serious incidents requiring investigation that in any way relate to or involve the use of the Goods by the Authority, the Supplier shall, to the extent permissible by law, cooperate fully with the Authority and shall deal via Governance with any reasonable and proportionate queries, questions and/or requests for information that the Authority may have in this context in relation to the Goods.
- 1.6







## 2. Supply of Additional Goods

Supplier acknowledges and agrees that to the extent the Authority is allocated additional doses of the Goods under the COVAX Facility that the Authority may wish to place an additional binding Purchase Order in the future (the "Additional Order") for additional batches of the Goods, but only upon being advised by the Supplier in writing that

The Additional Order will be subject to the same terms and conditions set forth in this Contract, as applicable and will include a target delivery date to which the provisions of Clause 8 of Schedule 1 shall apply.

### 3. Performance review and delay

- 3.1 The Supplier's performance under this Contract, production plans and business continuity arrangements shall be reviewed via Governance, together with the regulatory approval process.
- 3.2 In the event that the Supplier becomes aware that it is or it may become unable to supply the Goods in accordance with the Delivery Schedule the Supplier shall notify the Authority via Governance within a reasonable time period.

## 4. Quality assurance.

- 4.1 The Supplier shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in-process, bulk finished product and stability (chemical and/or microbial) tests or checks required to assure the quality of the Goods and any tests or checks required by Good Manufacturing Practice.
- 4.2 The Supplier shall not release any Goods for shipment that do not conform to the requirements set forth in this Contract (including Clause 11.1.1 of this Schedule 2) ("Non-conforming Goods").
- 4.3 The Supplier shall not make any significant changes (including without limitation any changes which shall or may have a material impact on the quality or use of the Goods) to the Specification without the relevant Licensing Authority formally approving such change.
- 4.4 The Supplier shall at the Supplier's cost submit sample units of the Goods from each batch to the OMCL(s) named on the Authorisation for quality assessment and batch release prior to delivery of the batch concerned to the Authority.

### 5. Delivery

5.1 The Goods shall be delivered to certain Authority facilities in the UK (each, an "Authority Facility") pre-agreed by the Parties, with the specific shipment volumes notified to Supplier as

which shall be deemed delivery to the Authority notwithstanding certain Authority Facilities may be owned or operated by third parties. As at the Effective Date, the pre-agreed Authority Facilities are listed in the Delivery Schedule. The Parties agree that it may become necessary for subsequent shipments of the Goods to be delivered

may become necessary for subsequent shipments of the Goods to be delivered to other Authority Facilities in the UK instead of or as well as the Authority Facilities initially agreed between the Parties. In such case the Authority shall



- 5.2 The Supplier shall deliver the Goods by separate instalments and shall use Commercially Reasonable Efforts to meet the delivery times set out in Part 2 of the Delivery Schedule.
- 5.3 All deliveries shall be accompanied by the documentation specified in the relevant section of Part 1 of the Delivery Schedule.
- 5.4 The Goods shall be delivered to the unloading point at each Authority Facility in

Goods shall only be made by the Supplier where the

("**Unbroken Cold-Chain**"). Delivery shall be complete at this point and, subject to receipt of an invoice from the Supplier, payment shall become due by the Authority. The Authority shall sign to confirm receipt of delivery at the Authority Facility. The person signing for receipt should ensure the contents of the delivery match the accompanying shipping documentation Proof of Receipt ("**POR**").

Delivery of each box of

- 5.5 Each box delivered is required to be opened and inspected at the Authority Facility within 36 hours of delivery to the Authority Facility, and the specific temperature data logger information confirming the Unbroken Cold-Chain as at the point of delivery at the Authority Facility shall have been electronically provided by the Supplier to the Authority within a six (6) hour period from delivery to the Authority Facility. For the avoidance of doubt, the Authority will not open any of the boxes until it has received such electronic confirmation. The Authority will switch off the temperature data logger on opening of each box.
- 5.6 The Authority shall procure that a duly authorised agent, employee or location representative of the Authority, who has the requisite expertise and training to enable proper handling of the Goods in a safe and lawful manner, (an "Appointee") is at the Authority Facility at the agreed delivery date and time in order to accept such delivery and carry out the inspection referred to in Clause 5.5 of this Schedule 2 within such timescales.
- 5.7 If the temperature data logger information confirms an Unbroken Cold-Chain as at the time of delivery to the Authority Facility, and if the Goods are not, on a visual inspection, clearly non-compliant, the Goods shall be accepted and verified and signed as such by the Authority. If the above conditions are not met,

the Authority must immediately inform the Supplier either directly or via its Appointee and reject the Goods in accordance with the provisions of Clause 7.1 of Schedule 2.

- 5.8 As more data on the Goods becomes available the Parties shall agree in good faith using bona fide efforts the Minimum Shelf-Life to be applicable to the Goods on delivery to the Authority Facility.
- 5.9 The Parties shall actively work together to minimise wastage of the Goods.
- 5.10 The labelling and marking of all packages of the Goods and all relevant information accompanying them shall be in English. The Supplier shall provide the Authority with reasonable notice of any material changes to be made to labelling, instructions and patient information relating to the Goods.
- 5.11 The Supplier shall ensure that a delivery note shall accompany each delivery of the Goods containing the information specified in the relevant section of Part 1 of the Delivery Schedule and shall make available electronically to the Authority such confirmations of conformity with Specification and/or QP release as the Authority may reasonably request pursuant to Clause 9.5 of Schedule 1. The Supplier shall also ensure that information in relation to the handling of the Goods shall be made available electronically to the Authority,
- 5.12 Where any delivery of Goods is less than the ordered quantity, this will not be grounds for the Authority to refuse to accept delivery of the quantity delivered, but the Authority shall promptly notify the Supplier of the shortage and the Supplier shall thereafter notify the Authority if the balance of the Goods will not be delivered within **and the process** for delivering the shortfall shall be addressed via Governance.
- 5.13 Unless otherwise agreed with the Authority in writing, the Supplier shall be responsible for obtaining all export licences for the Goods.

#### Goods.

Without prejudice to clause 8.3 of Schedule 1, in the case of any Goods supplied from outside Belgium, the Supplier shall ensure that accurate information is provided to the Authority in advance as to the country of origin of the Goods.

- 5.14 All third party carriers engaged by the Supplier to deliver the Goods shall at no time be deemed agents of the Authority and accordingly
- 5.15 Following delivery to the Authority Facility, all Goods shall be stored securely by the Authority; and delivered, shipped and distributed by the Authority in a secure manner appropriate to the transportation route and destination, in each case to guard against and deter theft, diversion, tampering or substitution (with, for example, counterfeits). The Authority shall ensure that it and the Appointee and any third party or sub-contractors used on the Authority or Appointee's behalf (as applicable) shall comply with the instructions of the Supplier and provisions in Part 1 of the Delivery Schedule (as such may be updated by the Supplier from time to time) as regards the treatment of Goods (including as to the necessary conditions for their storage, transport and use) and delivery equipment.
- 5.16 The Authority shall promptly notify the Supplier via Governance, providing such reasonable supporting information as the Supplier shall require, if at any time the Authority or its Appointee and any third party or sub-contractors used believes that any of the Goods have been subjected to theft, diversion, abuse, misuse, neglect, negligence, accident, improper testing, improper storage, improper handling, abnormal physical stress, abnormal environmental conditions or use contrary to any instructions issued by the Supplier.
- 5.17 The Supplier anticipates providing the Goods, subject to Authorisation,

to be maintained within that temperature range prior to dosing. The Authority acknowledges that, without prejudice to the right to reject as provided for in Clause 5.7 and Clause 7.1 of this Schedule 2 the Supplier's responsibility for the temperature of the Goods will cease upon delivery to the Authority Facility, and the Authority shall be responsible for monitoring temperature from delivery. The Authority acknowledges that the Supplier shall not permanently store or be required to make available any information response.

5.18 Any provision of this Contract which requires the Authority to do or refrain from doing a thing in relation to the delivery and acceptance of the Goods will be deemed also to refer to it procuring that the Appointee or any third party operating an Authority Facility do or refrain from doing such a thing. The

Appointee and any third party operating an Authority Facility is hereby appointed by the Authority as its agent in relation to the delivery and acceptance of the Goods, provided the Authority remains liable at all times for the acts and omissions of the Appointee or such third party.

5.19 Despite the grant of the Authorization on 2 December 2020, if at any time during the Term the Authorization expires, then the delivery times

("Adjusted Delivery Schedule"). Further, even though the Authorization has been granted prior to the Effective Date, the Supplier

#### 6. Passing of risk and ownership

- 6.1 Without prejudice to the Supplier's obligation under this Agreement to deliver the Goods to the Authority Facilities, ownership of the Goods shall pass to the Authority at the first point of entry of the Goods into the United Kingdom before customs clearance.
- 6.2 Risk in the Goods shall pass to the Authority when the Goods are delivered by the Supplier to the delivery point at the Authority Facility and the Authority shall be responsible for unloading the Goods from the transportation carrier.
- 6.3 For the avoidance of doubt, and subject to the provisions of Clause 7 of this Schedule 2, the Authority shall be responsible for all post-delivery expenses in relation to the Goods after their delivery to the applicable Authority Facility, including, without limitation, post-delivery storage and distribution costs.

### 7. Inspection, rejection, return and recall

- 7.1 The Authority or its Appointee on the Authority's behalf shall visually inspect the Goods at the Authority Facility within the timescales set out in Clause 5.5 of this Schedule 2 and may immediately thereafter by email to Supplier's customer contact centre reject any shipping carton of Goods found to be damaged or any Non-Conforming Goods having followed the process in Clauses 5.4, 5.5, 5.6 and 5.7 of this Schedule 2 ("Rejected Goods"), providing written reasons for the rejection. The whole of any shipping carton of Goods may be rejected if a reasonable sample of the Goods taken indiscriminately from that shipping carton is found to be Non-Conforming Goods.
- 7.2 Upon the rejection of any Goods in accordance with Clauses 7.1 and/or 7.6 of this Schedule 2, the Supplier shall at the Authority's written request:
- 7.2.1 collect the Rejected Goods at the Supplier's risk and expense within twenty (20) Business Days of issue of written notice from the Authority rejecting the Goods; and

- 7.2.2 supply replacements for the Rejected Goods pursuant to Clause 7.7 of this Schedule 2, subject to the provisions of Clause 8.5 of Schedule 1.
- 7.3 If the Supplier requests and the Authority accepts that the Rejected Goods should be disposed of by the Authority, the Authority reserves the right associated with the disposal of the Rejected Goods and the Supplier shall in return for an invoice in such amount. The Authority shall use reasonable endeavours to agree the disposal cost with the Supplier in advance of such disposal.
- 7.4 If Rejected Goods are not collected within **Authority** issuing written notification rejecting the Goods, and the Supplier has not confirmed that such Rejected Goods may be disposed of by the Authority, the Authority or its Appointee on the Authority's behalf may return the Rejected Goods at the Supplier's risk and reasonable expense which for the avoidance of doubt includes the cost of transportation.
- 7.5 Without prejudice to any of the Authority's rights under this Agreement (including under Clause 7.1 of this Schedule 2), the Authority acknowledges that to the extent that the Authority has excess Goods which are not Non-Conforming Goods that the Supplier Returns of Rejected Goods are subject to Clause 7.4.
- 7.6 In addition to the rights under Clause 7.1 of this Schedule 2, the Authority may reject any Non-Conforming Goods at the basis of a non-conformance that could not have been detected by the Authority and/or its Appointee at the time of unloading or visual inspection following the agreed process in Clauses 5.4, 5.5, 5.6 and 5.7 of this Schedule 2. In such case the Authority (directly or via its Appointee) shall provide to the Supplier at the time of rejection a written notice setting out the grounds for rejection by reference to the Contract requirements. The Authority's rights and remedies under this Clause 7.6 of Schedule 2



7.7 The Supplier shall respond to any rejection, defect notice or any quality-related complaint from the Authority in a timely manner. The Supplier shall conduct an analysis of the causes of any such complaint, and shall report to the Authority on any corrective action taken. In the event that Supplier in its discretion determines that such Rejected Goods were Non-Conforming Goods at the time of delivery to the Authority Facility due to no fault of the Authority, the Supplier shall, as the remedy,

- 7.8 All Rejected Goods shall be removed (if applicable) and disposed of by the Supplier in a manner that prevents theft and diversion and in accordance with Laws, Good Distribution Practice and Good Manufacturing Practice. The Supplier shall make all documentation relating to such disposal available to the Authority upon the Authority's request.
- 7.9 Where the Licensing Authority or the Supplier determines that a product recall is required under Laws ("**Requirement to Recall**") in respect of the Goods, the Parties shall comply with all directions of the Licensing Authority in relation to the product recall and keep the other Party informed of the same. The Authority shall provide all reasonable assistance to the Supplier in connection with such product recall.
- 7.10 To the extent that the Requirement to Recall was directly caused by of the Supplier, its Affiliates, or Sub-contractors, the Supplier shall be responsible for all costs of any recall or market withdrawal of the Goods in the United Kingdom, including reasonable costs incurred by or on behalf of the Authority and/or its Appointees. To the extent that such Requirement to Recall arises for any other reason, the Authority shall be responsible for all costs of any recall or market withdrawal of the Goods in the United Kingdom, including reasonable costs incurred by or on behalf of the Supplier its Affiliates or Sub-contractors.

## 8. Business continuity

- 8.1 Each Party shall ensure it has a Business Continuity Plan in place relevant to the supply or use of the Goods. Each Party shall also use Commercially Reasonable Efforts to ensure that its Business Continuity Plan complies on an ongoing basis with any specific business continuity requirements, as may be set out in the Contract. Notwithstanding the foregoing, each Party recognizes that the other Party is operating under pandemic conditions and that compliance with the Business Continuity Plan cannot be guaranteed.
- 8.2 Throughout the term of this Contract, but subject to Clause 24 of Schedule 2, the Supplier will use Commercially Reasonable Efforts and the Authority shall use reasonable endeavours to ensure its Business Continuity Plan provides for continuity during a Business Continuity Event.
- 8.3 Each Party shall test its Business Continuity Plan at reasonable intervals, and in any event no less than once every calendar year (or such other period as may be agreed between the Parties taking into account the critical nature of this Contract to each Party and the size and scope of their respective operations). Each Party shall promptly provide to the other Party, at the other Party's written request, a summary of its Business Continuity Plan, and documentary evidence that that Party tests its Business Continuity Plan in accordance with the requirements of this Clause 8.3 of this Schedule 2.

- 8.4 Should a Business Continuity Event occur at any time, the Supplier shall use Commercially Reasonable Efforts and the Authority shall use reasonable endeavours to implement and comply with its Business Continuity Plan and provide regular written reports to the other Party on such implementation.
- 8.5 During and following a Business Continuity Event, but subject to Clause 24 of Schedule 2, the Supplier shall use Commercially Reasonable Efforts to continue to supply the Goods in accordance with this Contract.
- 8.6 The Authority confirms that Public Health England (and their equivalent in each of Scotland, Wales and Northern Ireland), the Appointee and any party operating the Authority Facilities have and shall maintain in place suitable Business Continuity Plans which address, inter alia, the relevant requirements of vaccination programmes in the United Kingdom.

### 9. Governance and Contract management

- 9.1 The governance and contract management provisions provided for in the Original MSA shall apply to this Contract and shall be utilised by the Parties for the governance and contract management of this Contract.
- 10. Price and payment
- 10.1
- 10.2 The Contract Price:
- 10.2.1 shall remain fixed during the Term; and
- 10.2.2 is the entire price payable by the Authority to the Supplier in respect of the provision of the Goods and includes, without limitation:



- 10.2.3
- 10.3 The Supplier and the Authority acknowledge that in partial consideration of the Contracted Doses,
- 10.4 The Supplier shall invoice the Authority in GBP for the Contract Price for the Contracted Doses delivered to the Authority Facility upon each such delivery pursuant to Clause 5.4 less an apportionment of the Advance Payment based on the number of Contracted Doses in such delivery (the "**Delivered Payment Invoice**"). The Supplier shall apply the Exchange Rate when issuing the Delivered Payment Invoice.
- 10.5 In the third month following the Effective Date, and period thereafter, the Supplier shall undertake a reconciliation of the Delivered Payment Invoice amounts to take account of any Rejected Goods and shall either further invoice or refund the Authority as appropriate. Invoices shall be provided to Department for Business, Energy and Industrial Strategy (BEIS), c/o UK SBS, Queensway House, West Precinct, Billingham, TS23 2NF with emails to . The Supplier shall include the following information on all invoices: the Purchase Order number and billing address; and shall also include, where applicable, the type, description, part number (if any) and quantity of the Goods delivered; the delivery date; the actual date of shipment; the Contract Price
- 10.6 The Contract Price (and the associated Delivered Payment Invoice) is exclusive of VAT, which, if properly chargeable, the Authority shall pay at the prevailing rate subject to receipt from the Supplier of a valid and accurate VAT invoice. Such VAT invoices shall show the VAT calculations as a separate line item.
- 10.7 In the event any payments made pursuant to this Contract become subject to withholding taxes under the Law of any jurisdiction, the Party making such payment shall deduct and withhold the amount of such taxes for the account of the payee to the extent required by Laws and such amounts paid to the payee shall be reduced by the amount of such taxes so deducted and withheld. Any such withholding taxes required under Laws to be paid or withheld shall be an expense of, and borne solely by, the payee. Notwithstanding anything in this Contract to the contrary, if an action (including but not limited to any assignment or sublicense of its rights or obligations under this Contract, or any failure to comply with Laws or filing or record retention requirements) by a Party leads to



- 10.9 The Authority shall verify and pay each valid and undisputed invoice received in accordance with Clause 10.4 of this Schedule 2 in GBP within thirty (30) days of receipt of such invoice at the latest. However, the Authority shall use its reasonable endeavours to pay such undisputed invoices sooner in accordance with any applicable government prompt payment targets. If there is undue delay in verifying the invoice in accordance with this Clause 10.9 of this Schedule 2 the invoices shall be regarded as valid and undisputed for the purposes of this clause after a reasonable time has passed, not to exceed forty-five (45) days from receipt.
- 10.10 Where the Authority raises a query with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within thirty (30) days of the query being raised. If the Parties are unable to agree a resolution within thirty (30) days the query shall be referred to dispute resolution in accordance with the Dispute Resolution Procedure. For the avoidance of doubt, the Authority shall not be in breach of any of any of its payment obligations under this Contract in relation to any queried or disputed invoice sums provided the process referred to in this Clause 10.9 of this Schedule 2 has been followed for such invoice, and until it has been determined that the queried or disputed invoice amount is properly due to the Supplier and the Authority has then failed to pay such sum within a reasonable period following such determination. The Authority will pay any undisputed part of any invoice in accordance with Clause 10.9 of this Schedule 2.
- 10.11 If a Party fails to pay any undisputed sum properly due to the other Party under this Contract, the Party due such sum shall have the right to charge interest on the overdue amount at the applicable rate under the

- 10.12 In addition to all other remedies available under this Contract or otherwise, if the Authority fails to pay any undisputed amounts when due under this Contract, the Supplier may:
- 10.12.1
- 10.12.2

## 11. Warranties

- 11.1 The Supplier warrants and undertakes that:
- 11.1.1 at the time of their delivery to the Authority Facility, the Goods:
  - (a) comply with the Specification and are in accordance with the requirements of the Authorisation, to the extent such compliance is required by Laws; and
  - (b) are approved for release by a Qualified Person as having been manufactured in accordance with current Good Manufacturing Practices and stored, handled and transported in material accordance with Good Distribution Practices;
- 11.1.2 subject to Clause 11.1.7 of this Schedule 2, it has good title to all Goods supplied to the Authority pursuant to this Contract and shall pass such title to the Authority free and clear of any security interests, liens, or other encumbrances;
- 11.1.3 its execution, delivery and performance of this Contract will not violate any agreement or instrument to which it is a party;
- 11.1.4 it has not and will not in the performance of this Contract directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value or improperly or corruptly seek to influence any Government official or any other Person in order to gain an improper business advantage, and, has not accepted, and will not accept in the future, such a payment;
- 11.1.5 as at the Effective Date, it has, or the manufacturer of the Goods has, taken Commercially Reasonable Efforts to obtain manufacturing and warehousing capacity sufficient to comply with its obligations under this Contract;
- 11.1.6 where there is any instruction information that accompanies the Goods, it shall promptly provide updated copies should the instruction information change at any time during the term of this Contract;

- 11.1.7 receipt of the Goods by or on behalf of the Authority and use of the Goods or of any other item or information supplied, or made available, to the Authority will not infringe
- 11.1.8 it has and shall as relevant maintain all rights, consents, authorisations, licences and accreditations (other than those provided for pursuant to Clause 11.1.7 of this Schedule 2) required to manufacture and supply the Goods;
- 11.1.9 it will comply with all Laws and Policies (the latter in all material respects only) relevant to the supply of the Goods. Without prejudice to this obligation, as the Goods are medicinal products, the Supplier warrants and undertakes that it will comply with any such Laws in relation to such medicinal products. In particular, but without limitation, the Supplier warrants that at the point such Goods are delivered to the Authority Facility, all such Goods which are medicinal products shall have a valid Authorisation as required by Laws in order to supply the Goods to the Authority and that all relevant authorisation, labelling, registration, approval and documentation requirements as required to be provided by a manufacturer and supplier under Laws relating to the sale, manufacture, importation, storage, distribution, supply or delivery of such Goods shall have been complied with;
- 11.1.10 it will promptly notify the Authority of any significant health and safety hazard which has arisen at the manufacturing facility for the Goods in Puurs, Belgium;
- 11.1.11 it shall: (i) comply with all Laws to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;
- 11.1.12 it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority as set out in the Contract 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 11.1.12 of Schedule 2 and/or as may be reasonably requested or otherwise required by the Authority in accordance with its anti-slavery Policy;
- 11.1.13 it will promptly respond to reasonable information requests relating to the subject matter of this Contract from the Authority;
- 11.1.14 it is a properly constituted entity and it is fully empowered by the terms of its constitutional documents to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;
- 11.1.15 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;

- 11.1.16 as at the Effective Date, 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;
- 11.1.17 as at the Effective Date, there are no material agreements existing to which the Supplier is a party which prevent the Supplier from entering into or complying with this Contract;
- 11.1.18 it has, and will continue to have, the capacity, funding and cash flow to meet all its obligations under this Contract;
- 11.1.19 it acknowledges the existence of the Supplier Code of Conduct; and
- 11.1.20 it has used Commercially Reasonable Efforts to satisfy itself as to the nature and extent of the risks assumed by it under this Contract and to gather all information necessary to perform its obligations under this Contract.
- 11.2 The Authority warrants and undertakes that:
- 11.2.1 the execution, delivery and performance of this Contract will not violate any agreement or instrument to which it is a party;
- 11.2.2 it is fully empowered by executive powers and/or the terms of its constitution to enter into and to carry out its obligations under this Contract and the documents referred to in this Contract;
- 11.2.3 all necessary actions to authorise the execution of and performance of its obligations under this Contract have been taken before such execution;
- 11.2.4 it has complied with the Public Contracts Regulations 2015 and all other Laws relating to the procurement of the Goods, and will continue to comply with all Laws relevant to this Contract;
- 11.2.5 as at the Effective Date, 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 Authority;
- 11.2.6 it will promptly respond to reasonable information requests relating to the subject matter of this Contract from the Supplier; and
- 11.2.7 as at the Effective Date, there are no material agreements existing to which the Authority is a party which prevent the Authority from entering into or complying with this Contract.
- 11.3 For the avoidance of doubt all warranties whether as set out in this Clause 11 of this Schedule 2 or elsewhere in this Contract shall be without prejudice to indemnity and limitation of liability provisions under Schedule 2 Clauses 13 and 14.

11.4 In the event of any breach of any of the Supplier's warranties and undertakings relating to the Goods,



- 11.5 Except to the extent set out expressly in this Contract, all conditions, warranties or other terms which might have effect between the Parties or be implied or incorporated into this Contract (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by Laws.
- 11.6 The Supplier warrants and undertakes to the Authority that, as at the Effective Date, If, at any point during the term of this Contract, an Occasion of Tax

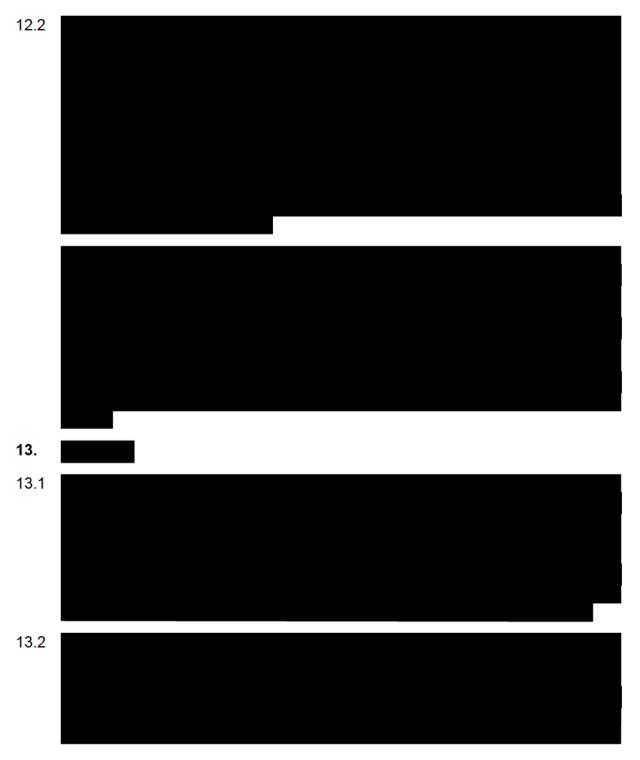
Non-Compliance occurs, the Supplier shall:

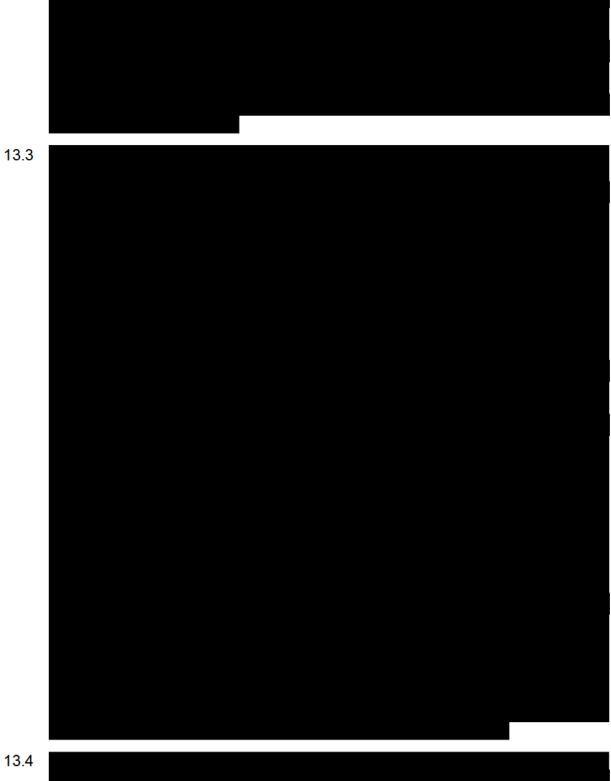
- 11.6.1 notify the Authority in writing of such fact within five (5) Business Days of its occurrence; and
- 11.6.2 promptly provide to the Authority:
  - details of the steps which the Supplier is taking to address the Occasion of Tax Non-Compliance and to prevent the same from recurring, together with any mitigating factors that it considers relevant; and
  - (b) such other information in relation to the Occasion of Tax Non-Compliance as the Authority may reasonably require.
- 11.7 Each Party warrants and undertakes to the other Party that it will inform the other Party in writing promptly upon becoming aware that any of the warranties set out in Clause 11 of this Schedule 2 have been breached or there is a material risk that any warranties may be breached.
- 11.8 Any warranties provided under this Contract are both independent and cumulative and may be enforced independently or collectively at the sole discretion of the enforcing Party.

### 12. Intellectual property

12.1 Neither Party will gain any rights of ownership to or use of any property or Intellectual Property owned by the other (whether by virtue of this Contract, by implication or otherwise). The Supplier hereby grants to the Authority, for the life of the use of Goods by the Authority, an irrevocable, royalty-free, non-exclusive

licence of any Intellectual Property Rights controlled by Supplier required for the purposes of receiving and using, and to the extent necessary to receive and use, the Goods (to include any associated technical or other documentation and information supplied or made accessible to the Authority in any media) in accordance with this Contract.







### 16. Term and termination

- 16.1 This Contract shall commence on the Effective Date and, unless terminated earlier in accordance with the terms of this Contract or the general law, shall continue until the end of the Term in accordance with Schedule 1.
- 16.2 Subject to Clause 16.3 of Schedule 2, in the case of a material breach of any of the terms of this Contract by either Party that is capable of remedy (including, without limitation, subject to Clause 10.9 of this Schedule 2, any breach of any payment obligations, under this Contract) the non-breaching Party may, without prejudice to its other rights and remedies under this Contract, issue a Breach Notice and shall allow the Party in breach the opportunity to remedy such breach in the first instance via a remedial proposal put forward by the Party in breach ("**Remedial Proposal**") before exercising any right to terminate this Contract in accordance with Clause 16.4.1(b) of this Schedule 2. Such Remedial Proposal must be agreed with the non-breaching Party (such agreement not to be unreasonably withheld or delayed) and must be implemented by the Party in breach in accordance with the timescales referred to in the agreed Remedial Proposal. Once agreed, any changes to a Remedial Proposal must be approved by the Parties in writing. Any failure by the Party in breach to:
- 16.2.1 put forward and agree a Remedial Proposal with the non-breaching Party in relation to the relevant default or breach within a period of ten (10) Business Days (or such other period as the non-breaching Party may agree in writing) from written notification of the relevant default or breach from the non-breaching Party; and
- 16.2.2 comply with such Remedial Proposal (including, without limitation, as to its timescales for implementation, which shall be thirty (30) days unless otherwise agreed between the Parties); and/or
- 16.2.3 remedy the default or breach notwithstanding the implementation of such Remedial Proposal in accordance with the agreed timescales for implementation, shall be deemed, for the purposes of Clause 16.4.1(b) of this Schedule 2, a material breach of this Contract by the Party in breach not remedied in accordance with an agreed Remedial Proposal.
- 16.3
- 16.4 Either Party may terminate this Contract upon written notice to the other Party:
- 16.4.1 if the other Party commits a material breach of this Contract which is:-
  - (a) not capable of remedy; or

(b) in the case of a breach capable of remedy, which is not remedied in accordance with a Remedial Proposal;



- 16.4.3 if the Goods are otherwise withdrawn by the Supplier from the UK market for safety, quality or lack of efficacy or other protective effects rendering the benefit-risk balance of the Goods no longer favourable; or
- 16.4.4 in the circumstances specified in Clauses 8.6, 8.7 and 8.8 of Schedule 1 and 24.8 and 26.4 of Schedule 2.
- 16.5 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier if:
- 16.5.1 the Supplier, or any third party guaranteeing the obligations of the Supplier under this Contract, ceases or threatens to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Laws to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
- 16.5.2 within 60 days of the Supplier undergoing a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intragroup change of control), where the party obtaining control is an Unacceptable Party;
- 16.5.3 the Supplier purports to assign, Sub-contract, novate, create a trust in or otherwise transfer or dispose of this Contract in material breach of Clause 29.1 of this Schedule 2;
- 16.5.4 the warranty given by the Supplier pursuant to Clause 11.6 of this Schedule 2 is materially untrue, the Supplier commits a material breach of its obligation to notify the Authority of any Occasion of Tax Non-Compliance as required by Clause 11.6 of this Schedule 2, or the Supplier fails to provide details of

proposed mitigating factors as required by Clause 11.6 of this Schedule 2 that in the reasonable opinion of the Authority are acceptable; or

- 16.5.5 the warranties given by the Supplier pursuant to Clauses 11.1.11 and 11.1.12 are materially untrue and where the Authority demonstrates to the Supplier that this has caused the Authority significant reputational harm.
- 16.6 The Authority may terminate this Contract by issuing a Termination Notice to the Supplier where:
- 16.6.1 the Contract has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
- 16.6.2 the Authority has become aware that the Supplier should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Contract;
- 16.6.3 the Contract should not have been awarded to the Supplier in view of a serious infringement of obligations under European law declared by the Court of Justice of the European Union under Article 258 of the Treaty on the Functioning of the EU; or
- 16.6.4 there has been a failure by the Supplier and/or one of its Sub-contractors to materially comply with legal obligations in the fields of environmental, social or labour Law in such a manner that the Authority demonstrates to the Supplier causes the Authority significant reputational harm. Where the failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by one of the Supplier's Sub-contractors, the Authority
- 16.7 The Supplier may terminate this Contract by issuing a Termination Notice to the Authority in the circumstances as provided for in Clause 11.4 of this Schedule 2.
- 16.8 If the Authority novates this Contract to any body that is not a Contracting Authority, from the effective date of such novation, the rights of the Authority to terminate this Contract in accordance with Clause 16.5.1 of this Schedule 2 shall be deemed mutual termination rights and the Supplier may terminate this Contract by issuing a Termination Notice to the entity assuming the position of the Authority if any of the circumstances referred to in such Clause apply to the entity assuming the position of the Authority.

## 17. Consequences of expiry or early termination of this Contract

17.1 Upon expiry or earlier termination of this Contract, the Authority agrees to pay the Supplier for the Goods which have been supplied and delivered by the Supplier and not rejected or found defective by the Authority in accordance with this

Contract or ordered to be withdrawn by the Licensing Authority prior to expiry or earlier termination of this Contract.

17.2 In the event of termination in accordance with Clauses 16.4.2 to 16.4.4 of this Schedule 2, with effect from the date of the expiry or termination of this Contract:



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

### 18. Post expiry/termination provisions

- 18.1 The Authority and any Central Government Body will not disclose the Contract Price to any Administering Entity (which for the purposes of this Clause 18.1 of this Schedule 2 shall not include a Health Service Board constituted under section 2 of the National Health Service (Scotland) Act 1978, a Special Health Board constituted under that section, the NHS Wales or any statutory successors to such entities) without the Supplier's written consent (such consent not to be unreasonably withheld, delayed or conditioned).
- 18.2 Upon expiry or termination of this Contract for any reason this Clause 18 of this Schedule 2 and the following Clauses shall survive the expiry or termination for any reason of this Contract: Schedule 1 (Key Provisions) Clauses 4 (Names and addresses for notices), 5 (Management levels for escalation and dispute resolution), 6 (Order of precedence), 8 (Supply and Delivery) and 9.1 (Regulatory and information requirements), Schedule 2 (General Terms and Conditions) Clauses 5.15, 5.16 and 5.17 (Delivery), 7 (Inspection, rejection, return and recall), 10 (Price and Payment), 11.4 (Warranties), 12 (Intellectual property), 13 (Indemnity), 14 (Limitation of liability),17 (Consequences of expiry or early termination of this Contract), 23 (Dispute Resolution), 24.9 and 24.10 (Force majeure), 25 (Records retention and right of audit), 28 (Notices), 31 (General), Schedule 3 (Information Provisions), Clauses 1 (Confidentiality) and 2 (Freedom

of Information and Transparency), Schedule 4 (Definitions and Interpretations) and any Clauses and/or Schedules which are expressly or by implication intended to continue.

### 19. Packaging, identification and end of use

- 19.1 The Supplier shall comply with any packaging and labelling requirements in respect of the Goods: (a) specified in Part 1 of the Delivery Schedule; or (b) otherwise notified to the Authority prior to delivery of the Goods.
- 19.2 Unless otherwise set out in Part 1 of the Delivery Schedule or agreed with the Authority in writing,



- 19.3 Without prejudice to the Supplier's obligation to comply with all Laws, the Supplier shall comply in all material respects with applicable environmental laws and regulations in force from time to time in relation to the Goods. Without prejudice to the generality of the foregoing, the Supplier shall:
- 19.3.1 use Commercially Reasonable Efforts to comply with all reasonable stipulations of the Authority aimed at minimising the packaging in which the Goods are supplied;
- 19.3.2 promptly provide such data as may reasonably be requested by the Authority from time to time regarding the weight and type of packaging according to material types used in relation to the Goods;
- 19.3.3 comply with all obligations imposed on it in relation to the Goods by the Producer Responsibility Obligations (Packaging Waste) Regulations 2007 (SI 2007/871) (or any other equivalent legislation giving effect in any part of the European Economic Area to the Packaging and Packaging Waste Directive 94/62/EC as amended); and
- 19.3.4 without prejudice to the Supplier's other obligations under this Contract, label all units of the Goods, and the packaging of those units, to highlight environmental and safety information as required by Laws.
- 19.4 The Supplier shall meet all reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 19 of this Schedule 2.

#### 20. Sustainable development

- 20.1 The Supplier shall comply in all material respects with all Laws, including applicable environmental and social and labour Law requirements in force during the term of this Contract. Without prejudice to the generality of the foregoing, the Supplier shall:
- 20.1.1 comply with all policies and/or procedures and requirements set out in Supplier's standards and policies in relation to environmental and social and labour requirements, characteristics and impacts of the Goods and the Supplier's supply chain;
- 20.1.2 maintain relevant policy statements documenting the Supplier's significant labour, social and environmental aspects as relevant to the Goods being supplied and as proportionate to the nature and scale of the Supplier's business operations; and
- 20.1.3 maintain plans and procedures that support the commitments made as part of the Supplier's significant labour, social and environmental policies, as referred to at Clause 20.1.2 of this Schedule 2.
- 20.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 20 of this Schedule 2.

### 21. Electronic product information

Not Used

### 22. Change Control

22.1 Any variation to this Contract shall only be binding once it has been agreed in writing and signed by an authorised representative of both Parties, the Parties having used good contract management practices and using the Pro Forma Change Control request.

### 23. Dispute resolution

- 23.1 During any Dispute, including a Dispute as to the validity of this Contract, it is agreed that the Supplier shall continue its performance of the provisions of the Contract (unless the Authority requests in writing that the Supplier does not do so).
- 23.2 In the case of a Dispute arising out of or in connection with this Contract the Supplier and the Authority shall make every reasonable effort to communicate and cooperate with each other with a view to resolving the Dispute and follow the procedure set out in Clause 23.3 of this Schedule 2 as the first stage in the Dispute Resolution Procedure.

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

If the procedure set out in Clause 23.3 of this Schedule 2 above has been exhausted and fails to resolve such Dispute, as part of the Dispute Resolution Procedure, the Dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce, which Rules are deemed to be incorporated by reference into this Clause, by three arbitrators appointed in accordance with said Rules. The claimant shall nominate an arbitrator in its request for arbitration. The respondent shall nominate an arbitrator within thirty (30) days of the receipt of the request for arbitration. The two (2) arbitrators nominated by the Parties shall nominate a third arbitrator, in consultation with the Parties, within thirty (30) days after the confirmation of the later-nominated arbitrator. The third arbitrator shall act as chair of the tribunal. If any of the three (3) arbitrators are not nominated within the time prescribed above, then the International Chamber of Commerce shall appoint the arbitrator(s). The seat, or legal place, of arbitration shall be London, UK.

The language to be used in the arbitral proceedings shall be English. The governing law shall be the law of England and Wales. The Parties agree to keep confidential the existence of the arbitration, the arbitral proceedings, the submissions made by the Parties and the decisions made by the arbitral tribunal, including its awards, except as required by Law and to the extent not already in the public domain. The costs of the arbitration, including the Parties' reasonable legal fees, shall be borne by the unsuccessful Party or Parties. However, the arbitral tribunal may apportion such costs between the Parties if it determines that apportionment is reasonable, taking into account the circumstances of the case. The arbitration award shall be final and binding on the Parties, and the parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.

23.4 Nothing in this Contract shall prevent either Party seeking from any court any interim or provisional relief that may be necessary to protect the rights or property of that Party or that relates to the safety of patients or the security of Confidential Information, pending resolution of the relevant Dispute in accordance with the Dispute Resolution Procedure.

23.5 This Clause 23 of this Schedule 2 shall survive the expiry of or earlier termination of this Contract for any reason.

#### 24. Force majeure

- 24.1 Subject to Clause 24.2 of this Schedule 2 neither Party shall be liable to the other for any delay to or failure to perform all or any of its obligations under this Contract nor liable to the other Party for any loss or damage arising out of such delay or failure to perform its obligations to the extent that such performance is affected by a Force Majeure Event.
- 24.2 Each Party shall only be entitled to rely on a Force Majeure Event and the relief set out in this Clause 24 of this Schedule 2 and will not be considered to be in default or liable for breach of any obligations under this Contract if:
- 24.2.1 in the case of the Supplier, it has fulfilled its obligations pursuant to Clause 8 of this Schedule 2, or in the case of the Authority, it has taken reasonable steps to implement a business continuity plan, to the extent these obligations have not been affected by the Force Majeure Event;
- 24.2.2 the Force Majeure Event does not arise directly or indirectly as a result of any wilful or negligent act or default of that Party; and
- 24.2.3 that Party has complied with the procedural requirements set out in this Clause 24 of this Schedule 2.
- 24.3 Where a Party is (or claims to be) affected by a Force Majeure Event it shall use (for the Authority) reasonable endeavours or (for the Supplier) Commercially Reasonable Efforts to mitigate the consequences of such a Force Majeure Event upon the performance of its obligations under this Contract and to resume the performance of its obligations affected by the Force Majeure Event as soon as practicable.
- 24.4 Where the Force Majeure Event affects the Supplier's ability to perform part of its obligations under the Contract the Supplier shall fulfil all such contractual obligations that are not so affected and shall not be relieved from its liability to do so.
- 24.5 If either Party is prevented or delayed in the performance of its obligations under this Contract by a Force Majeure Event, that Party shall as soon as reasonably practicable serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to its failure to perform or any anticipated delay in performance of its obligations.
- 24.6 Subject to service of such notice, the Party affected by such circumstances shall have no liability for its failure to perform or for any delay in performance of its obligations affected by the Force Majeure Event only for so long as such circumstances continue and for such time after they cease as is necessary for

that Party, using (for the Authority) reasonable endeavours or (for the Supplier) Commercially Reasonable Efforts, to recommence its affected operations in order for it to perform its obligations.

- 24.7 The Party claiming relief shall notify the other in writing as soon as the consequences of the Force Majeure Event have ceased and of when performance of its affected obligations can be resumed.
- 24.8 If either Party is prevented from performance of its obligations as a result of a Force Majeure Event, the other Party may at any time if the Force Majeure Event subsists for for a former or more, terminate this Contract by issuing a Termination Notice to the affected Party, save where the Force Majeure Event has arisen by virtue of the
- 24.9 Following such termination in accordance with Clause 24.8 of this Schedule 2 and subject to Clause 24.10 of this Schedule 2,
- 24.10

### 25. Records retention and right of audit

- 25.1 Subject to any statutory requirement and Clause 25.2 of this Schedule 2, the Supplier and the Authority shall keep secure and maintain for the term of this Contract and seven (7) years afterwards, or such longer period as may be agreed between the Parties, full and accurate records of all matters relating to this Contract.
- 25.2 Where any records could be relevant to a claim for personal injury such records shall be kept secure by the Supplier and by the Authority and maintained for a period of twenty one (21) years from the date of expiry or earlier termination of this Contract.
- 25.3 The Authority shall have the right to audit the Supplier's compliance with this Contract. The Supplier shall permit or procure permission for the Authority during normal business hours having given advance written notice of no less than five (5) Business Days, reasonable access to the Supplier's business premises and facilities, in each case as are used in relation to this Contract, together with books and records reasonably required to audit the Supplier's compliance with its obligations under this Contract. Any such access will be subject to the Authority agreeing to comply with reasonable security measures of the Supplier.
- 25.4 Should the Supplier Sub-contract any of its material obligations under this Contract, the Authority shall have the right to audit and inspect such third party.

The Supplier shall use Commercially Reasonable Efforts to procure permission for the Authority or its authorised representatives during normal business hours no more than once in any twelve (12) months, having given advance written notice of no less than five (5) Business Days, reasonable access to any premises and facilities, books and records used in the performance of the Supplier's obligations under this Contract that are Sub-contracted to such third party. The Supplier shall cooperate with such audit and inspection and accompany the Authority or its authorised representative if requested. Any such access will be subject to the Authority agreeing to comply with reasonable security measures of the Sub-contractor.

- 25.5 The Supplier shall grant to the Authority or its authorised representative, such access to those records as they may reasonably require in order to check the Supplier's compliance with this Contract for the purposes of:
- 25.5.1 the examination and certification of the Authority's accounts; or
- 25.5.2 any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the Authority has used its resources.
- 25.6 The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned, held or otherwise within the control of the Supplier and may require the Supplier to provide such oral and/or written explanations as they consider necessary. This Clause 25 of this Schedule 2 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Supplier under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
- 25.7 The Supplier shall provide reasonable cooperation to the Authority its authorised representatives or any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Contract.
- 25.8 The Supplier shall provide all reasonable information as may be reasonably requested by the Authority to evidence the Supplier's compliance with the requirements of this Contract.
- 25.9 The reference to "authorised representatives" for the purposes of this Clause 25 of this Schedule 2 shall be to any members of staff of the Authority or a Contracting Authority only, and shall not to avoid doubt include any other third party.

#### 26. Conflicts of interest and the prevention of fraud

26.1 Each Party shall take appropriate steps to ensure that neither that Party nor any Staff (or in the Authority's case, its staff) are placed in a position where, in the reasonable opinion of the other Party, there is or may be an actual conflict, or a

potential conflict, between the pecuniary or personal interests of the first Party and the duties owed to the other Party under the provisions of this Contract. Each Party will disclose to the other Party full particulars of any such conflict of interest which may arise.

- 26.2 In the event there is a conflict or potential conflict as detailed at Clause 26.1, the Parties shall work together in order to address and resolve it.
- 26.3 Both Parties shall take all reasonable steps to prevent Fraud by Staff and themselves (including its owners, members and directors). Each Party shall notify the other immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.
- 26.4 If a Party or its Staff commits a material Fraud that causes significant and demonstrable reputational harm to the other Party, then the other Party may terminate this Contract forthwith on providing written notice.

## 27. Equality and human rights

- 27.1 The Supplier shall:
- 27.1.1 ensure that (a) it does not, whether as employer or as supplier of the Goods and any associated services, engage in any act or omission that would contravene the Equality Legislation, and (b) it complies with all its obligations as an employer or supplier of the Goods and any associated services as set out in the Equality Legislation and take reasonable endeavours to ensure its Staff do not unlawfully discriminate within the meaning of the Equality Legislation;
- 27.1.2 in the management of its affairs and the development of its equality and diversity policies, cooperate with the Authority in light of the Authority's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Supplier shall take such reasonable and proportionate steps as the Authority considers appropriate to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age; and
- 27.1.3 impose on all its Sub-contractors and suppliers, obligations substantially similar to those imposed on the Supplier by this Clause 27 of this Schedule 2.
- 27.2 The Supplier shall meet reasonable requests by the Authority for information evidencing the Supplier's compliance with the provisions of this Clause 27 of this Schedule 2.

#### 28. Notice

28.1 Any notice required to be given by either Party under this Contract shall be in writing quoting the date of the Contract and shall be delivered by hand or sent by prepaid first class recorded delivery or by email to the person referred to in the

Key Provisions or such other person as one Party may inform the other Party in writing from time to time.

- 28.2 A notice shall be treated as having been received:
- 28.2.1 if delivered by hand within normal business hours when so delivered or, if delivered by hand outside normal business hours, at the next start of normal business hours; or
- 28.2.2 if sent by first class recorded delivery mail on a normal Business Day, at 9.00 am on the second Business Day subsequent to the day of posting, or, if the notice was not posted on a Business Day, at 9.00 am on the third Business Day subsequent to the day of posting; or
- 28.2.3 if sent by email, if sent within normal business hours when so sent or, if sent outside normal business hours, at the next start of normal business hours provided the sender has either received an electronic confirmation of delivery or has telephoned the recipient to inform the recipient that the email has been sent.

### 29. Assignment, novation and Sub-contracting

- 29.1 Except as set out in Clause 29.2 of this Schedule 2, the Supplier shall not assign, Sub-contract, novate, create a trust in, or in any other way dispose of the whole or any part of this Contract to any party, other than its Affiliates (provided such Affiliates have the necessary resources, finances, qualifications, licences, consents and permissions to fulfil the Supplier's obligations hereunder), without the prior consent in writing of the Authority, such consent not to be unreasonably withheld or delayed. Notwithstanding any consent given by the Authority in accordance with this Clause 29.1 of this Schedule 2, if the Supplier Subcontracts any of its obligations under this Contract, every act or omission of the Sub-contractor shall for the purposes of this Contract be deemed to be the act or omission of the Supplier and the Supplier shall be liable to the Authority as if such act or omission had been committed or omitted by the Supplier itself.
- 29.2 Notwithstanding Clause 29.1 of this Schedule 2, the Supplier may Sub-contract to the parties set out in Schedule 8, and may further Sub-contract to any third party on written notification to the Authority provided such third party is not an Unacceptable Party. Whether the third party to which the Supplier Sub-contracts is pre-approved and set out in Schedule 8, or is notified to the Authority in accordance with this Clause 29.2 of this Schedule 2, the Supplier's liability to the Authority for the acts or omissions of its Sub-contractor shall be as set out in Clause 29.1 of this Schedule 2.

## 30. Prohibited Acts

30.1 Each Party warrants and represents that in relation to this Contract:

- 30.1.1 it has not committed any offence under the Bribery Act 2010 or done any of the following ("**Prohibited Acts**"):
  - (a) offered, given or agreed to give any officer or employee of the other Party any gift or consideration of any kind as an inducement or reward for doing or not doing or for having done or not having done any act in relation to the obtaining or performance of this or any other agreement with the other Party or for showing or not showing favour or disfavour to any person in relation to this or any other agreement with the other Party; or
  - (b) in connection with this Contract paid or agreed to pay any commission other than a payment, particulars of which (including the terms and conditions of the agreement for its payment) have been disclosed in writing to the other Party; and
- 30.1.2 it has in place adequate procedures to prevent bribery and corruption, as contemplated by section 7 of the Bribery Act 2010.
- 30.2 If either Party or any of their Staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the other Party in relation to this or any other agreement between the Parties, the non-breaching Party may terminate this Contract for material breach in accordance with Clause 16.4.1.

#### 31. General

- 31.1 Each of the Parties is independent of the other and nothing contained in this Contract shall be construed to imply that there is any relationship between the Parties of partnership or of principal/agent or of employer/employee nor are the Parties hereby engaging in a joint venture and accordingly neither of the Parties shall have any right or authority to act on behalf of the other nor to bind the other by agreement or otherwise, unless expressly permitted by the terms of this Contract.
- 31.2 Failure or delay by either Party to exercise an option or right conferred by this Contract shall not of itself constitute a waiver of such option or right.
- 31.3 The delay or failure by either Party to insist upon the strict performance of any provision, term or condition of this Contract or to exercise any right or remedy consequent upon such breach shall not constitute a waiver of any such breach or any subsequent breach of such provision, term or condition.
- 31.4 Any provision of this Contract which is held to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability without invalidating or rendering unenforceable the remaining provisions of this

Contract and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provisions in any other jurisdiction.

- 31.5 Each Party acknowledges and agrees that it has not relied on any representation, warranty or undertaking (whether written or oral) in relation to the subject matter of this Contract and therefore irrevocably and unconditionally waives any rights it may have to claim damages against the other Party for any misrepresentation or undertaking (whether made carelessly or not) or for breach of any warranty unless the representation, undertaking or warranty relied upon is set out in this Contract or unless such representation, undertaking or warranty was made fraudulently.
- 31.6 Each Party shall bear its own expenses in relation to the preparation and execution of this Contract including all costs, legal fees and other expenses so incurred.
- 31.7 This Contract is not exclusive and accordingly the Authority shall not be restricted from purchasing any products whatsoever including any products that are equivalent to or substitutable for the Goods from other parties.
- 31.8 The rights and remedies provided in this Contract are independent, cumulative and not, other than where expressly stated to be the sole remedy, exclusive of any rights or remedies provided by general law, any rights or remedies provided elsewhere under this Contract or by any other contract or document. In this Clause 31.8 of this Schedule 2, right includes any power, privilege, remedy, or proprietary or security interest.



- 31.10 A person who is not a party to this Contract shall have no right to enforce any terms of it which confer a benefit on such person, including pursuant to the Contracts (Rights of Third Parties) Act 1999. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.
- 31.11 This Contract, any variation in writing signed by an authorised representative of each Party and any document referred to (explicitly or by implication) in this

Contract or any variation to this Contract, contain the entire understanding between the Supplier and the Authority relating to the supply of the Goods to the exclusion of all previous agreements, confirmations and understandings and there are no promises, terms, conditions or obligations whether oral or written, express or implied other than those contained or referred to in this Contract. Nothing in this Contract seeks to exclude either Party's liability for Fraud.

- 31.12 This Contract, and any Dispute or claim arising out of or in connection with it or its subject matter (including any non-contractual claims), shall be governed by, and construed in accordance with, the laws of England and Wales.
- 31.13 Subject to Clause 23 of this Schedule 2, the Parties irrevocably agree that the courts of England and Wales shall have non-exclusive jurisdiction to settle any Dispute or claim that arises out of or in connection with this Contract or its subject matter.
- 31.14 All written and oral communications and all written material referred to under this Contract shall be in English.
- 31.15 This Contract may be executed in any number of counterparts, each of which when executed and delivered shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.
- 31.16 Transmission of the executed signature page of a counterpart of this Contract by email in PDF format shall take effect as delivery of an executed counterpart of this Contract.
- 31.17 No counterpart shall be effective until each party has executed and delivered at least one counterpart.

## SCHEDULE 3

#### **Information Provisions**

## 1. Confidentiality

- 1.1 In respect of any Confidential Information it may receive directly or indirectly from the other Party ("**Discloser**") and subject always to the remainder of this Clause 1 of this Schedule 3, each Party ("**Recipient**") undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party without the Discloser's prior written consent, and use such Confidential Information only for the purpose of this Contract, provided that:
- 1.1.1 the Recipient shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the Effective Date;
- 1.1.2 the provisions of this Clause 1 of this Schedule 3 shall not apply to any Confidential Information:
  - (a) which is in or enters the public domain other than by breach of this Contract or other act or omissions of the Recipient, and in clarification of the foregoing, a general disclosure in the public domain will not cause more specific (but related) information to be covered under this exception; similarly, a combination of several pieces of information, which individually would be deemed covered by this exception, will not be deemed covered by this exception unless the combination itself is in the public domain;
  - (b) which is obtained from a third party who is lawfully authorised to disclose such information without any obligation of confidentiality;
  - (c) which is authorised for disclosure by the prior written consent of the Discloser;
  - (d) which the Recipient can demonstrate was in its possession without any obligation of confidentiality prior to receipt of the Confidential Information from the Discloser; or
  - (e) which the Recipient is required to disclose purely to the extent to comply with the requirements of any relevant stock exchange.
- 1.2 Nothing in this Clause 1 of this Schedule 3 shall prevent the Recipient from disclosing Confidential Information where it is required to do so by judicial, administrative, governmental or regulatory process in connection with any action, suit, proceedings or claim or otherwise by Laws, including the Freedom of Information Act 2000 ("FOIA"), Codes of Practice on Access to Government Information, on the Discharge of Public Authorities' Functions or on the Management of Records ("Codes of Practice") or the Environmental Information

Regulations 2004 ("**Environmental Regulations**"), provided that the Recipient shall: (i) notify the Discloser of any such disclosure requirement or request as soon as practicable; (ii) cooperate and reasonably assist with the Discloser (at the Discloser's cost) if the Discloser seeks a protective order or other remedy in respect of any such disclosure and (iii) furnish only that portion of the Confidential Information which, in the opinion of Recipient's legal counsel, is responsive to such requirement or request.

- 1.3 The Authority may disclose the Supplier's Confidential Information:
- 1.3.1 on a confidential basis, to any Contracting Authority (the Parties agree that all Contracting Authorities receiving such Confidential Information shall be entitled to further disclose the Confidential Information to other Contracting Authorities on the basis that the information is confidential and is not to be disclosed to a third party which is not part of any Contracting Authority);
- 1.3.2 on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 1.3.1 of this Schedule 3 (including any benchmarking organisation) on a need to know basis for any purpose relating to or connected with this Contract, provided no disclosure may be made to any competitor of the Supplier pursuant to this Clause;
- 1.3.3 on a confidential basis, to any consultant, contractor or other person engaged by the Authority and/or the Contracting Authority receiving such information, on a need to know basis for any purpose relating to or connected with this Contract, provided no disclosure may be made to any competitor of the Supplier pursuant to this Clause;
- 1.3.4 to any relevant party for the purpose of the examination and certification of the Authority's accounts;
- 1.3.5 to any relevant party for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;
- 1.3.6 to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements; or
- 1.3.7 on a confidential basis, to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Contract,

and for the purposes of this Contract, references to disclosure "on a confidential basis" shall mean the Authority making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Laws or this Clause 1.3 of this Schedule 3, and where disclosure is made pursuant to Clause 1.3.2 or 1.3.3 of this Schedule 3, the Authority may only disclose subject to entering into a non-disclosure

agreement with confidentiality provisions equivalent to this Contract in respect of such disclosure with the third party.

- 1.4 The Supplier may only disclose the Authority's Confidential Information, and any other information provided to the Supplier by the Authority in relation to this Contract, to the Supplier's Staff or professional advisors who are directly involved in the performance of or advising on the Supplier's obligations under this Contract. The Supplier shall ensure that such Staff or professional advisors are aware of and shall comply with the obligations in this Clause 1 of this Schedule 3 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the Authority's written discretion, destroyed securely or returned to the Authority when it is no longer required. The Supplier shall not, and shall ensure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of performing the Supplier's obligations in this Contract.
- 1.5 For the avoidance of doubt, save as required by Laws or as otherwise set out in this Schedule 3, neither Party shall, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), announce or issue any press release in relation to this Contract or its subject matter.
- 1.6 This Clause 1 of this Schedule 3 shall remain in force:
- 1.6.1 without limit in time in respect of Confidential Information which comprises Personal Data or which relates to national security; and
- 1.6.2 for all other Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.

## 2. Freedom of Information and Transparency

- 2.1 The Parties acknowledge the duties of Contracting Authorities under the FOIA, Codes of Practice and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties.
- 2.2 The Supplier shall assist and cooperate with the Authority to enable it to comply with its disclosure obligations under the FOIA, Codes of Practice and Environmental Regulations. The Supplier agrees:
- 2.2.1 that this Contract and any recorded information held by the Supplier on the Authority's behalf for the purposes of this Contract are subject to the obligations and commitments of the Authority under the FOIA, Codes of Practice and Environmental Regulations;
- 2.2.2 that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the

FOIA, Codes of Practice and Environmental Regulations is a decision solely for the Authority;

- 2.2.3 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier itself is subject to the FOIA, Codes of Practice and Environmental Regulations it will liaise with the Authority as to the contents of any response before a response to a request is issued and will promptly (and in any event within two (2) Business Days) provide a copy of the request and any response to the Authority;
- 2.2.4 that where the Supplier receives a request for information under the FOIA, Codes of Practice and Environmental Regulations and the Supplier is not itself subject to the FOIA, Codes of Practice and Environmental Regulations, it will not respond to that request (unless directed to do so by the Authority) and will promptly (and in any event within two (2) Business Days) transfer the request to the Authority;
- 2.2.5 that the Authority, acting in accordance with the Codes of Practice issued and revised from time to time under both section 45 of FOIA, and regulation 16 of the Environmental Regulations, may disclose information concerning the Supplier and this Contract; and
- 2.2.6 to assist the Authority in responding to a request for information, by processing information or environmental information (as the same are defined in FOIA and the Environmental Regulations) in accordance with a records management system that complies with all applicable records management recommendations and codes of conduct issued under section 46 of FOIA, and providing copies of all information requested by the Authority within five (5) Business Days of that request and without charge.
- 2.3 Notwithstanding any other term of this Contract, the Supplier consents to the publication of this Contract in its entirety (including variations), subject only to the redaction of information relating to the second and any other information that is exempt from disclosure in accordance with the provisions of the FOIA, Codes of Practice and Environmental Regulations.
- 2.4 In preparing any disclosure under Clause 2 of this Schedule 3 or a copy of this Contract for publication under Clause 2.3 of this Schedule 3, the Authority shall give the Supplier as much notice as is reasonably practical of any request made for disclosure, and shall consult with the Supplier and give it a reasonable period to make representations to inform decision making regarding any redactions but the final decision in relation to the redaction of information will be at the Authority's absolute discretion.
- 2.5 The Supplier acknowledges that the Authority is subject to the transparency obligations set out in the Crown Commercial Services' Procurement Policy Note 02/17 (as amended or replaced from time time) and shall assist and cooperate

with the Authority to enable and facilitate the Authority to comply with its obligations thereunder including but not limited to publishing this Contract, subject to the provisions of Clause 2.3 of this Schedule 3.

2.6 Where any information is held by any Sub-contractor of the Supplier in connection with this Contract, the Supplier shall procure that such Sub-contractor shall comply with the relevant obligations set out in this Clause 2 of this Schedule 3, as if such Sub-contractor were the Supplier.

#### 3. Information Security

- 3.1 Without limitation to any other information governance requirements set out in this Schedule 3, the Supplier shall:
- 3.1.1 notify the Authority forthwith of any material information security breaches to the extent any such breach affects the Authority's Confidential Information or has a material impact on the Supplier's ability to perform this Contract; and
- 3.1.2 provide reasonable cooperation with any audits or investigations relating to information security, provided that the cost of these shall be borne by the Authority, and providing the Authority provides a written request for such cooperation giving at least 30 days' notice.

## 4. Data Protection

"**Controller**" means an entity which, alone or jointly with others, determines the purposes and means of the Processing of Personal Data;

**"Data Protection Laws**" means any laws applicable to the Parties in relation to the Processing of Personal Data under this Contract, including, but not limited to: (i) the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016) and any consequential national data protection legislation; and (ii) any guidance and/or codes of practice issued by the UK Information Commissioner's Office or other relevant supervisory authority, including without limitation the European Data Protection Board, in each case as amended, supplemented or replaced from time to time;

"**Personal Data**" means any information relating to an identified or identifiable natural person;

"**Processing**" means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

- 4.1 The Parties acknowledge and agree that they will each be acting as independent Controllers of Personal Data transferred between the Parties in relation to this Contract.
- 4.2 Each Party shall be responsible for complying with the obligations imposed on a Controller by the Data Protection Laws, including to maintain or make any registrations and/or obtain any authorisations and comply with other duties required by Data Protection Laws with respect to the Personal Data under this Contract.

## SCHEDULE 4

## **Definitions and Interpretations**

## 1. Definitions

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

"Administering Entity"	means any body administering the Goods including all Health Service Bodies;
"Affiliate"	means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
"Authorisation"	means a Conditional Approval, Emergency Use authorisation from the MHRA under Regulation 174 of the Human Medicines Regulation 2012 and/or Marketing Authorisation that permits the Goods to be put on the market in the United Kingdom;
"Authority"	means the authority named on the form of Contract on page 1;
"BioNTech"	means BioNTech SE, a company organized and existing under the laws of Germany with offices at An der Goldgrube 12, 55131 Mainz, Germany;
"Breach Notice"	means a written notice of breach given by one Party to the other, notifying the Party receiving the notice of its breach of this Contract;
"Business Continuity Event"	means any event or issue that could impact on the operations of the Supplier or the Authority (or any party operating on their behalf) and its or their ability to supply or use the Goods including, without limitation, an influenza pandemic and any Force Majeure Event;
"Business Continuity Plan"	means a business continuity plan which includes its plans for continuity of the supply or use of the Goods during a Business Continuity Event;
"Business Day"	means any day other than a Saturday, Sunday or bank holiday in England;
"Central Government Body"	means a body listed in one of the following sub- categories of the Central Government classification of the Public Sector Classification Guide, as

	published and amended from time to time by the Office for National Statistics:
	(a) Government Department;
	(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);
	(c) Non-Ministerial Department; or
	(d) Executive Agency;
"Change"	means any change to this Contract;
"Change Control Note"	means the written record of a Change agreed or to be agreed by the Parties pursuant to the procedure set out in Clause 22 of Schedule 2;
"Codes of Practice"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Commercially Reasonable Efforts"	

"Confidential Information"	means all confidential or proprietary information in any form concerning this Contract, its conclusion and/or operation, including any procurement process, which is directly or indirectly disclosed by or on behalf of the Discloser or its Affiliates to the Recipient or its representatives pursuant to this Contract, regardless of the manner in which it is disclosed, delivered, furnished, learned or observed, either marked "Confidential" or, if oral, declared to be confidential when disclosed and confirmed in writing within thirty (30) days of disclosure. Failure to mark Confidential Information disclosed in writing hereunder as "Confidential" shall not cause the information to be considered non-confidential, with the burden on the Discloser, to prove such information clearly should have been known by a reasonable person with expertise on the subject matter, based on the nature of the information and the circumstances of its disclosure, to be Confidential Information, provided that the Discloser has otherwise made good faith efforts to clearly mark Confidential Information as such.
"Conditional Approval"	means a conditional Marketing Authorisation for the Product granted by the European Commission pursuant to Article 14a of Regulation (EC) No 726/2004, or by the Medicines and Healthcare products Regulatory Agency ("MHRA"), acting on behalf of the Licensing Authority of the United Kingdom under regulation 49(1) of Human Medicines Regulations 2012 (SI 2012 No. 1916) in accordance with regulation 58F of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 775), that allows the Goods to be placed on the market in the UK.

"Contracted Doses"	means 539,370 doses of the Goods, allocated to the Authority under the COVAX Facility;
"Contract"	means the agreement between the Parties in the form of contract at the front of this document and all schedules attached to the form of contract, together with any Purchase Orders which have been accepted by the Supplier;
"Contracting Authority"	means any contracting authority as defined in regulation 2 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"Contract Manager"	means for the Authority and for the Supplier the individuals specified in the Key Provisions or such other person notified by a Party to the other Party from time to time in accordance with the terms of this Agreement;
"Contract Price"	
"Control"	means the possession by person or entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person (whether through the ownership of
	voting shares, by contract or otherwise) and "Controls" and "Controlled" shall be interpreted accordingly;
"COVAX Facility"	"Controls" and "Controlled" shall be interpreted
"COVAX Facility" "Crown"	"Controls" and "Controlled" shall be interpreted accordingly;
	<ul> <li>"Controls" and "Controlled" shall be interpreted accordingly;</li> <li>has the meaning given on page 1 of this Contract;</li> <li>means the government of the United Kingdom (including the governments of Northern Ireland, Scotland, and Wales), including, but not limited to, government ministers, government departments,</li> </ul>

"Devolved Administration"	means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly);
"Directive 2001/83"	means Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (and any amended and/or successor legislation applicable to the UK);
"Directive 2003/94"	means Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (and any amended and/or successor legislation applicable to the UK);
"Dispute(s)"	means any dispute, difference or question of interpretation or construction arising out of or in connection with this Contract, including any dispute, difference or question of interpretation relating to the Goods, any matters of contractual construction and interpretation relating to the Contract, or any matter where this Contract directs the Parties to resolve an issue by reference to the Dispute Resolution Procedure;
"Dispute Notice"	means a written notice served by one Party to the other stating that the Party serving the notice believes there is a Dispute;
"Dispute Resolution Procedure"	means the process for resolving Disputes as set out in Clause 23 of Schedule 2;
"DOTAS"	means the Disclosure of Tax Avoidance Schemes rules which require a promoter of tax schemes to tell HM Revenue and Customs of any specified notifiable arrangements or proposals and to provide prescribed information on those arrangements or proposals within set time limits as contained in Part 7 of the Finance Act 2004 and in secondary legislation made under vires contained in Part 7 of the Finance Act 2004 and as extended to National Insurance Contributions by the National Insurance Contributions (Application of Part 7 of the Finance Act 2004) Regulations 2012, SI

	2012/1868 made under s.132A Social Security Administration Act 1992;
"Effective Date"	has the meaning given on page 1 of this Contract;
"Electronic Trading System(s)"	means such electronic data interchange system and/or world wide web application and/or other application with such message standards and protocols as the Authority may specify from time to time;
"EMA"	means the European Medicines Agency (or any statutory successor);
"Environmental Regulations"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Equality Legislation"	means any and all Laws relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including, but not limited to, the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998;
"Exchange Rate"	means the Bank of England's spot rate for the purchase of Pounds Sterling on the day before the Effective Date, provided that if any additional doses are allocated to the Authority under the COVAX Facility the Parties shall update the Exchange Rate to reflect the prevailing spot rate on the day of the corresponding amendment to this Agreement;
"FOIA"	shall have the meaning given to the term in Clause 1.2 of Schedule 3;
"Force Majeure Event"	means any event beyond the reasonable control of the Party in question to include, without limitation:
	(a) war including civil war (whether declared or undeclared), riot, civil commotion or armed conflict materially affecting either Party's ability to perform its obligations under this Contract;

(b) the impact on a Party of an outbreak of any disease or an epidemic or pandemic,
(c) acts of terrorism;
(d) flood, storm, extreme weather conditions or other natural disasters;
(e) fire;
(f) unavailability of public utilities and/or access to transport networks to the extent no diligent supplier could reasonably have planned for such unavailability as part of its business continuity planning;
(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 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 applicable outside of England and Wales that could not have been reasonably foreseen;
(i) industrial action which affects the ability of the Supplier to supply the Goods, but which is not confined to the workforce of the Supplier or the workforce of any Sub-contractor of the Supplier;
(j) the impact of the withdrawal of the United Kingdom from the European Union to the extent this impact could not have been reasonably foreseen or prepared for by the Party; and
(k) a failure in the Supplier's and/or Authority's supply chain to the extent that such failure is due to any event suffered by a member of such supply chain, which would also qualify as a Force Majeure Event in accordance with this definition had it been suffered by one of the Parties;

	but excluding, for the avoidance of doubt, the ability to pay amounts due under this Contract;
"Fraud"	means any offence under any law in respect of fraud in relation to this Contract or defrauding or attempting to defraud or conspiring to defraud the government, parliament or any Contracting Authority;
"GDPR"	means the General Data Protection Regulation (Regulation (EU) 2016/679);
"General Anti-Abuse Rule"	means the legislation in Part 5 of the Finance Act 2013;
"Good Distribution Practice"	means the principles of good distribution of human medicines as set for in European Commission Directive 2001/82/EC and 2001/83/EC together with the European Commission guidance set forth in "Guidance on GDP of medicinal products for human use" and as embodied in UK law and described in the guidance of the MHRA;
"Good Manufacturing Practice"	means the principles of good manufacturing practice and standards contained in Laws, including without limitation Directive 2003/94, Directive 2001/83/EC and those published by the European Commission in Volume IV of "The Rules Governing Medical Products in the European Community" and ICH Q7 Guideline, The Rules Governing Medicinal Products in the European Union, Volume 4, Part II, as they apply to the manufacturing of the Goods from time to time.
"Goods"	means the vaccine that the Supplier has agreed to supply to the Authority under the terms of this Contract and confirmed Purchase Orders.
"Governance"	means the process described in Clause 9 of Schedule 2;
"Halifax Abuse Principle"	means the principle explained in the CJEU Case C-255/02 Halifax and others;
"Health Service Bodies"	means: (a) the Department of Health and Social Care

	and all divisions and agencies thereof and any independent NHS board or similar body that may be established including regional agencies of such board;
	(b) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not));
	(c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41);
	(d) the Secretary of State for Health and Social Care;
	(e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41);
	(f) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service act 2006 (c.41);
	(g) any body replacing or providing similar or equivalent services to any of the above in any area of the United Kingdom including any bodies established pursuant to the Health and Social Care Act 2012, including but not limited to NHS England; and
	(h) any statutory successor to any of the above;
"Intellectual Property Rights"	means all patents, copyright, design rights, registered designs, trade marks, know-how, database rights, confidential formulae and any other intellectual property rights and the rights to apply for patents and trade marks and registered designs;
"Key Provisions"	means the key provisions set out in Schedule 1;
"Law"	means any applicable legal requirements including, without limitation:
	(a) any applicable statute or proclamation, delegated or subordinate legislation, bye-

		law, order, regulation or instrument as applicable in England and Wales including the Sanctions Guidelines, and any other rules having the force of law;
	(b)	to the extent binding under UK law, any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye- law, order, regulation or instrument);
	(c)	to the extent in force in the UK, any enforceable community right within the meaning of section 2(1) European Communities Act 1972;
	(d)	any applicable judgment of a relevant court of law which is a binding precedent in England and Wales;
	(e)	binding requirements set by any regulatory body as applicable in England and Wales;
	(f)	any relevant binding code of practice as applicable in England and Wales; and
	(g)	any relevant collective agreement and/or international law provisions (to include, without limitation, as referred to in (a) to (f) above);
"Licensing Authority"	of the and/o	is the MHRA and/or European mission/EMA as the case may be (in the case e latter, to the extent that any Authorisation or Manufacturing Licence issued by such is valid in the UK);
"Manufacturing Licence"		is the manufacturing licence in respect of the s granted by the Licensing Authority;
"Marketing Authorisation"		s the marketing authorisation in respect of Goods granted by the Licensing Authority as

	amended or varied by the Licensing Authority from time to time;
"MHRA"	means the Medicines and Healthcare products Regulatory Agency;
"Minimum Shelf-Life"	
"Non-Conforming Goods"	has the meaning given in Schedule 2, Clause 4.2
"Occasion of Tax Non- Compliance"	
	(ii)

	(b)
"OMCL"	means the Official Medicines Control Laboratory;
"Party"	means the Authority or the Supplier as appropriate and Parties means both the Authority and the Supplier;
"Personal Data"	shall have the same meaning as set out in the GDPR;
"Policies"	means the policies, rules and procedures of the Authority as notified to the Supplier in writing in advance of the Effective Date, as amended from time to time via agreement of the Parties under the Change procedure;
"Purchase Order"	means the purchase order required by the Authority's financial systems, if a purchase order is referred to in the Key Provisions, which shall become part of the Contract once accepted and confirmed by the Supplier;
"Qualified Person"	means the person defined as such in Article 49 of Directive 2001/83/EC;
"Rejected Goods"	has the meaning given under Clause 7.1 of Schedule 2;
"Relevant Tax Authority"	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which the Supplier is established;
"Remedial Proposal"	has the meaning given under Clause 16.2 of Schedule 2;
"Requirement to Recall"	has the meaning given under Clause 7.9 of Schedule 2;

"Responsible Person"	means the individual that each holder of a WDA (H) is required under GDP to appoint:-
	<ul> <li>to ensure that the provisions of the WDA(H) are observed</li> </ul>
	• to ensure that the operations do not compromise the quality of medicines
	• to ensure that an adequate quality system is established and maintained
	• to oversee audit of the quality system and to carry out independent audits
	<ul> <li>to ensure that adequate records are maintained</li> </ul>
	• to ensure that all personnel are trained
	• to ensure full and prompt cooperation with product licence holders in the event of recalls.
"Sanctions Guidelines"	means the UK Government's financial sanctions guidelines under the Sanctions and Anti-Money Laundering Act 2018, as amended from time to time;
"Specification"	means the document set out in Schedule 5 as amended and/or updated in accordance with this Contract;
"Staff"	means all persons employed or engaged by the Supplier to perform its obligations under this Contract including any Sub-contractors and person employed or engaged by such Sub-contractors;
"Sub-contract"	means a contract between two or more suppliers, at any stage of remoteness from the Supplier in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Contract;
"Sub-contractor"	means a party to a Sub-contract other than the

	Supplier;
"Summary of Product Characteristics"	means the summary of product characteristics approved by the Licensing Authority for the Authorisation;
"Supplier"	means the supplier named on the form of Contract on page 1;
"Term"	means the Term as set out in the Key Provisions and any extension to this made in accordance with the terms of this Contract;
"Termination Notice"	means a written notice of termination given by one Party to the other notifying the Party receiving the notice of the intention of the Party giving the notice to terminate this Contract on a specified date and setting out the grounds for termination;
"VAT"	means value added tax chargeable under the Value Added Tax Act 1994 or any similar, replacement or extra tax; and
"Unacceptable Party"	means a third party to which the provisions of Regulation 57(1) or (2) of the Public Contracts Regulations 2015 applies;
"Unbroken Cold-Chain"	has the meaning given in Clause 5.4 of Schedule 2;
"Volume"	means the total quantity of the Goods to be delivered during the Term.

- 1.2 References to any Law shall be deemed to include a reference to that Law as amended, extended, consolidated, re-enacted, restated, implemented or transposed from time to time.
- 1.3 References to any legal entity shall include any body that takes over responsibility for the functions of such entity.
- 1.4 References in this Contract to a "Schedule", "Appendix", "Paragraph" or to a "Clause" are to schedules, appendices, paragraphs and clauses of this Contract.
- 1.5 References in this Contract to a day or to the calculation of time frames are references to a calendar day unless expressly specified as a Business Day.

- 1.6 Unless set out in the this Contract as a chargeable item and subject to Clause 31.6 of Schedule 2, the Supplier shall bear the cost of complying with its obligations under this Contract.
- 1.7 The headings are for convenience only and shall not affect the interpretation of this Contract.
- 1.8 Words denoting the singular shall include the plural and vice versa.
- 1.9 Where a term of this Contract provides for a list of one or more items following the word "including" or "includes" then such list is not to be interpreted as an exhaustive list. Any such list shall not be treated as excluding any item that might have been included in such list having regard to the context of the contractual term in question. General words are not to be given a restrictive meaning where they are followed by examples intended to be included within the general words.
- 1.10 Where a document is required under this Contract, the Parties may agree in writing that this shall be in electronic format only.
- 1.11 Unless expressly stated otherwise, any obligation under the Contract where one Party is obliged to provide assistance to the other Party shall be interpreted on the basis that such request must be reasonable, and that the obligation to meet that request will be met by the other Party if it provides reasonable assistance.
- 1.12 Any Breach Notice issued by a Party in connection with this Contract shall not be invalid due to it containing insufficient information. A Party receiving a Breach Notice ("**Receiving Party**") may ask the Party that issued the Breach Notice ("**Issuing Party**") to provide any further information in relation to the subject matter of the Breach Notice that it may reasonably require to enable it to understand the Breach Notice and/or to remedy the breach. The Issuing Party shall not unreasonably withhold or delay the provision of such further information as referred to above as may be requested by the Receiving Party but no such withholding or delay shall invalidate the Breach Notice.
- 1.13 Any terms defined as part of a Schedule or other document forming part of this Contract shall have the meaning as defined in such Schedule or document.
- 1.14 Any reference to a Party "procuring" another person to act or omit to act in a certain manner shall mean that the Party so procuring shall be liable for any default on the part of the person acting or omitting to act in that manner.
- 1.15 In this Contract the Authority is acting as part of the Crown.

Schedule 5









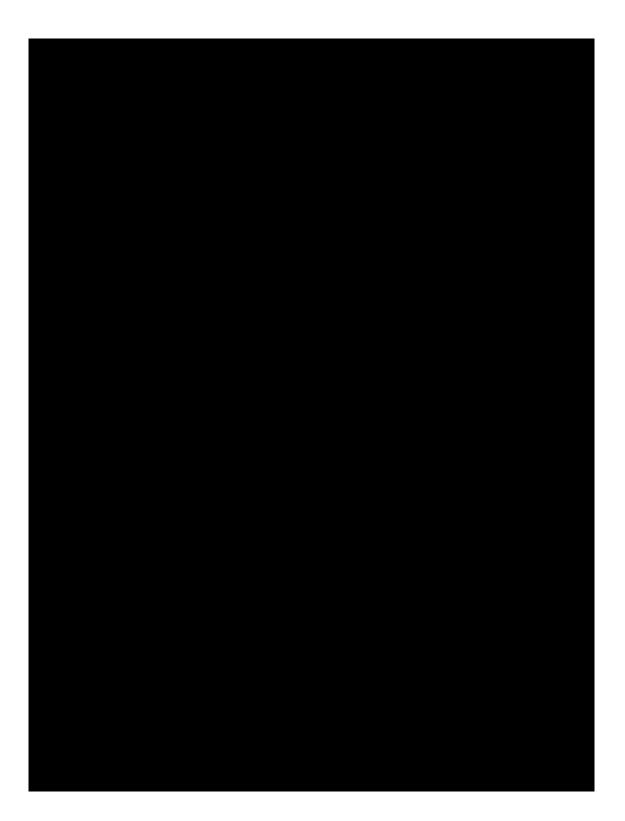


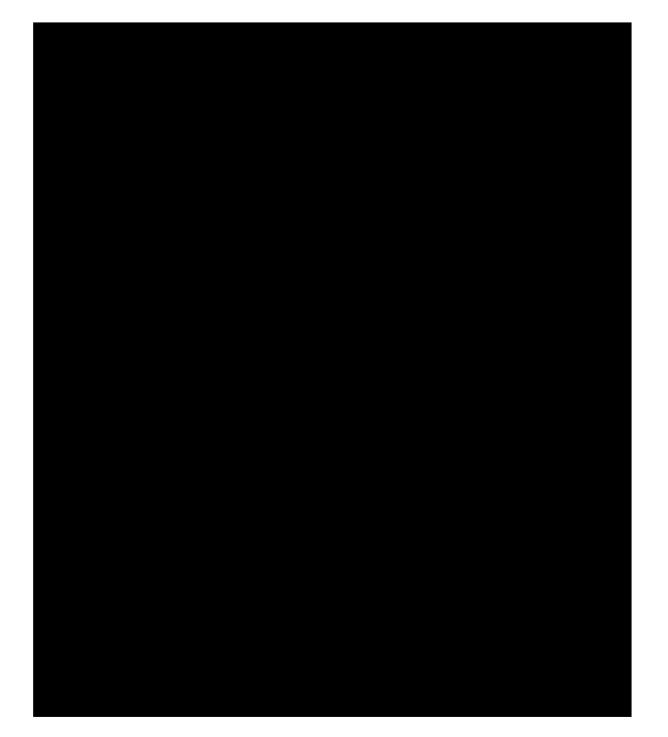






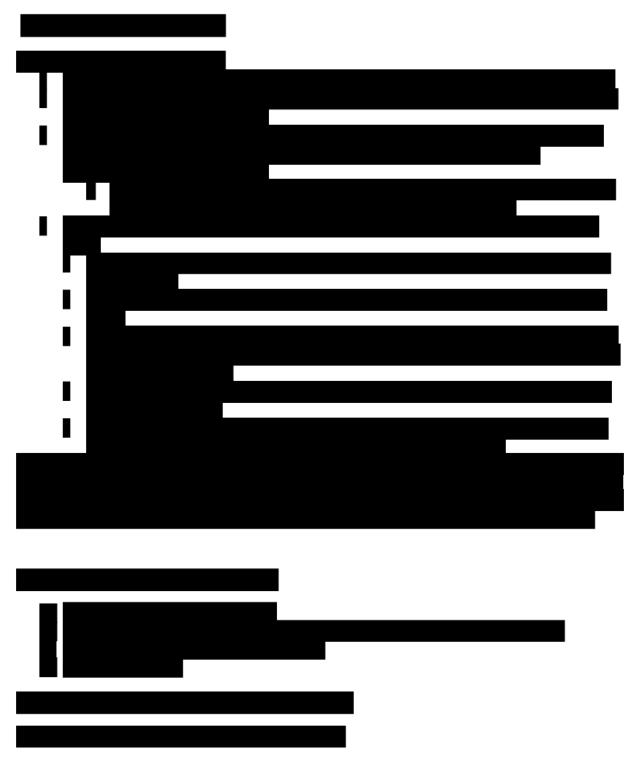






# SCHEDULE 6

# **Delivery Schedule**



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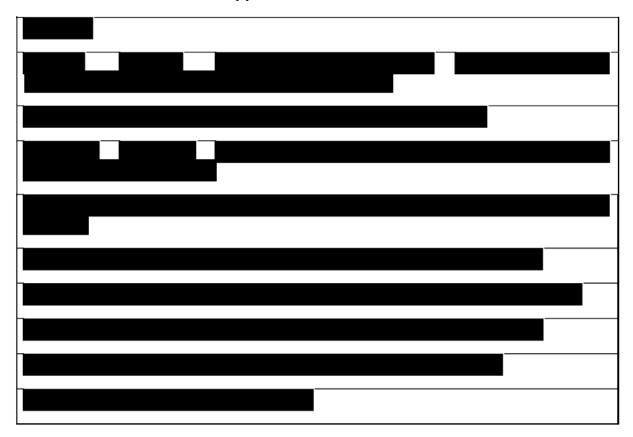
# SCHEDULE 7

# Proforma Change Control Note

CCN No:	Contract:	Effective date of Change:			
Initiated by:		· · · · · · · · · · · · · · · · · · ·			
Change requested by [Supplier <b>OR</b> Authority]					
Date of request:					
Period of validity:					
This Change Control Note i	s valid for acceptance	until [DATE].			
Reason for Change:					
Description and impact of the Change (including to delivery and performance):					
Required amendments to wording of Contract or Schedules:					
Adjustment to Contract P	rice resulting from C	hange:			
Additional one-off charges and means of determining these (for example, fixed price basis):					
Supporting or additional	information:				
Please confirm all Changes relating to procurement, shipment (delivery) and storage have been reviewed and approved by the Authority Responsible Person (Y:N)					
SIGNED ON BEHALF OF AUTHORITY	THE SIGNE SUPPL	D ON BEHALF OF THE JIER			
Signature:	Signatu	lre:			
Name:	Name:				
Position:	Position	Position:			
Date: Date:					

# **SCHEDULE 8**

### Approved Sub-contractors



# **SCHEDULE 9**

#### **KPIs**

