Department for Environment Food & Rural Affairs

www.gov.uk/defra

(1) THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

- and -

(2) MERIAL SAS

AGREEMENT FOR THE PROVISION OF A FOOT AND MOUTH DISEASE VACCINE BANK

This document/publication is also available on our website at:
www.gov.uk/government/organisations/department-for-environment-food-rural-affairs
procurement@defra.gsi.gov.uk

January 2019

SECTION 1
FORM OF CONTRACT

PARTIES:

(1) THE SECRETARY OF STATE FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS of Nobel House, 17 Smith Square, London, SW1P 3JR (the "**Authority**");

AND

(2) Merial SAS [redacted]

(each a "**Party**" and together the "**Parties**").

WHEREAS

A On 23rd August 2018 the Authority advertised in the Official Journal of European Union a call for competition, inviting prospective suppliers to submit proposals for provision of an antigen, storage and production of foot and mouth vaccines.

B Following the conclusion of negotiations, conducted under the OJEU procurement procedure (open procedure), the Parties have agreed to contract with each other in accordance with the terms and conditions set out below.

NOW IT IS HEREBY AGREED as follows:

1. TERMS OF CONTRACT

1.1 The "**Contract**" comprises the following:

Section 1:	Form of Contract
Section 2:	Terms and Conditions
Schedule 1:	Specification
Schedule 2:	Pricing
Schedule 3:	Change Control
Schedule 4:	Commercially Sensitive Information
Schedule 5:	Non-Disclosure Contract
Schedule 6:	Implementation Plan
Schedule 7:	Security Requirements, Policy and Plan
Schedule 8:	Supplier's Business Continuity Plan
Schedule 9:	Processing, Personal Data And Data Subjects

1.2 Execution of the Contract is carried out in accordance with EU Directive 99/93 (Community framework for electronic signatures) and the Electronic Communications Act 2000. The Contract is formed on the date on which both Parties communicate acceptance of its terms on the Authority's electronic contract management system ("**Bravo**").

1.3 The Contract starts on the date of signature of this Contract (the "**Commencement Date**") and ends on the expiry of the period of five (5) years from the date the Authority issues the Antigen Delivery Milestone Achievement Certificate in accordance with clause B1.2(c) (the "**End Date**") unless it is terminated early or extended in accordance with the Contract.

1.4 The Authority may extend the term of the Contract for subsequent periods of one (1) year each (each an "**Extension**") up to a maximum of five (5) Extensions, in each case by executing a CCN to that effect prior to the expiry of the Initial Contract Period or the then-current Extension (as the case may be). The terms of the Contract will apply throughout the period of any Extension.

Contents

SECTION 2
TERMS AND CONDITIONS

CONTENTS

A. GENERAL PROVISIONS

A1 Definitions and Interpretation

Unless the context otherwise requires the following terms shall have the meanings given to them below:

"Acceptance" means that the Authority confirms in writing via an Antigen Delivery Milestone Achievement Certificate, that the Acceptance Criteria has been fully satisfied in respect of the manufacture of the Antigen and **"Accept"** and **"Accepted"** shall be construed accordingly.

"Acceptance Criteria" means the criteria to be satisfied to demonstrate that the Antigen has been manufactured in accordance with this Contract and the Specification.

"Administering Entity" means any body administering the Vaccine including all Veterinary Health Service Bodies.

"**Affected Party**" means the Party seeking to claim relief in respect of a Force Majeure Event.

"**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 with, that body corporate from time to time.

"Antigen" means the strains of antigen specified in the Specification, together with any additional strains as may be included under this Contract pursuant to paragraph 1.7 of the Specification from time to time.

"Antigen Delivery Milestone Achievement Certificate" means a certificate issued by the Authority confirming that satisfactory completion of the manufacture of the Dedicated Minimum

Viable Stock of Antigen in accordance with the Antigen Manufacturing Schedule and the provisions of this Contract has been achieved.

"Antigen Manufacturing Fee" means the one-off fee for the manufacture of the Dedicated Minimum Viable Stock of Antigen to be paid by the Authority to the Supplier as specified in part 1 of Schedule 2.

"Antigen Manufacturing Schedule" means the manufacturing schedule setting out the timeline for the manufacture of the Dedicated Minimum Viable Stock of Antigen as set out in the Supplier's implementation plan submitted as part of its Tender and included at Schedule 6.

"Antigen Storage Fee" means the recurring fee for the storage of the Dedicated Minimum Viable Stock of Antigen to be paid by the Authority to the Supplier in the amount specified in part 1 of Schedule 2.

"**Approval**" and "**Approved**" means the prior written consent of the Authority.

"**Authorised Representative**" means any Authority representative authorised and appointed by the Authority as notified to the Supplier in writing or, where applicable, named in the CCN as authorised to approve agreed Variations.

"**Authority Data**" means:

(a) the data, text, drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, and which are: (i) supplied to the Supplier by or on behalf of the Authority; or (ii) which the Supplier is required to generate, process, store or transmit pursuant to the Contract; or

(b) any Personal Data for which the Authority is the Data Controller.

"**Authority Software**" means software which is owned by or licensed to the Authority (other than under or pursuant to the Contract) and which is or will be used by the Supplier for the purposes of providing the Goods.

"**Authority System**" means the Authority's computing environment (consisting of hardware, software and/or telecommunications networks or equipment) used by the Authority or the Supplier in connection with the Contract which is owned by or licensed to the Authority by a third party and which interfaces with the Supplier System or which is necessary for the Authority to receive the Goods.

"**Bravo**" has the meaning given in paragraph 1.2 of the Form of Contract.

"Business Continuity Event" means any event or issue that could impact on the operations of the Supplier and its ability to supply the Vaccines including, without limitation, any Force Majeure event.

"Business Continuity Plan" means the Supplier's business contingency plan which includes continuity in the event of a Business Continuity Event and an executive summary of the current such plan is attached at Schedule 8.

"**CCN**" means a change control notice in the form set out in Schedule 3.

"**Commencement Date**" means the date set out in paragraph 1.3 of the Form of Contract.

"**Commercially Sensitive Information**" means the information listed in Schedule 4 comprising the information of a commercially sensitive nature relating to:

(a) the Price;

(b) details of the Supplier's Intellectual Property Rights; and

(c) the Supplier's business and investment plans

which the Supplier has indicated to the Authority that, if disclosed by the Authority, would cause the Supplier significant commercial disadvantage or material financial loss.

"**Confidential Information**" means any information which has been designated as confidential by either Party in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) including information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person or trade secrets or Intellectual Property Rights of either Party and all personal data and sensitive personal data within the meaning of the DPA. Confidential Information shall not include information which:

(a) was public knowledge at the time of disclosure otherwise than by breach of clause E5;

(b) was in the possession of the receiving Party, without restriction as to its disclosure, before receiving it from the disclosing Party;

(c) is received from a third party (who lawfully acquired it) without restriction as to its disclosure; or

(d) is independently developed without access to the Confidential Information.

"**Contract**" has the meaning given in paragraph 1.1 of the Form of Contract.

"**Contract Manager**" has the meaning given to it in paragraph 1.2 of the Specification.

"**Contract Period**" means the period from the Commencement Date to:

(a) the End Date; or

(b) following an Extension, the end date of the Extension

or such earlier date of termination or partial termination of the Contract in accordance with the Law or the Contract.

"**Contracting Authority**" means any contracting authority (other than the Authority) as defined in regulation 3 of the Regulations.

"**Supplier Software**" means software which is proprietary to the Supplier, including software which is or will be used by the Supplier for the purposes of providing the Goods.

"**Supplier System**" means the information and communications technology system used by the Supplier in providing the Goods including the Software, the Supplier Equipment and related cabling (but excluding the Authority System).

"**Control**" means that a person possesses, directly or indirectly, 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.

"**Controller**" has the meaning given in the GDPR.

"**Copyright**" means as defined in s.1 of Part 1 of Chapter 1 of the Copyright, Designs and Patents Act 1988.

"**Crown**" means the government of the United Kingdom (including the Northern Ireland Executive Committee and Northern Ireland Departments, the Scottish Executive and the National Assembly for Wales), including, but not limited to, government ministers, government departments, government offices and government agencies and "**Crown Body**" is an emanation of the foregoing.

"**Data Loss Event**" means any event that results, or may result, in unauthorised access to Personal Data held by the Supplier under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach.

"**Data Protection Impact Assessment**" means an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data.

"**Data Protection Legislation**" means (i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the DPA 2018 to the extent that it relates to processing of personal data and privacy; and (iii) all applicable Law about the processing of personal data and privacy.

"**Data Protection Officer**" has the meaning given in the GDPR.

"**Data Subject**" has the meaning given in the GDPR.

"**Data Subject Request**" means a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

"**Database Rights**" means rights in databases as defined in s.3A of Part 1 Chapter 1 of the Copyright, Designs and Patents Act 1988.

"Dedicated Minimum Viable Stock" means the level of stock of Antigen (or any one of them, as the case may be) that the Supplier must manufacture and store in a separate and designated area on behalf of the Authority, as specified in the Specification.

"**Default**" means any breach of the obligations of the relevant Party (including abandonment of the Contract in breach of its terms, repudiatory breach or breach of a fundamental term) or any other default, act, omission, negligence or statement of the relevant Party or the Staff in connection with the subject-matter of the Contract and in respect of which such Party is liable to the other.

"Defective Vaccine" means any vial of the Vaccine supplied under this Contract which does not conform to or is not produced in accordance with Good Manufacturing Practice, the Specification or the Marketing Authorisation, or which otherwise fails to conform to the requirements of this Contract relating to the safety and efficacy of the Vaccine (including, without limitation, such requirements set out in Clauses B4.1(c), B4.13, G2.2 and G2.3).

"Delivered" and **"Delivery"** shall have the meaning given in Clause B4.1(b);

"Delivery Order" has the meaning given to it in Clause B1.4.

"Devolved Administrations" means the devolved administrations of Scotland, Wales and Northern Ireland (the Scottish Parliament, the Welsh Assembly and the Northern Ireland Assembly).

"**DOTAS**" means the Disclosure of Tax Avoidance Schemes rules which require a promotor of tax schemes to tell HMRC 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 and as extended to NICs by the National Insurance (Application of Part 7 of the Finance Act 2004) regulations 2012, SI 2012/1868 made under section 132A of the Social Security Administration Act 1992.

"**DPA 2018**" means the Data Protection Act 2018 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.

"**EIR**" means the Environmental Information Regulations 2004 (SI 2004/3391) and any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such regulations.

"**End Date**" means the date set out in paragraph 1.3 of the Form of Contract.

"**Extension**" has the meaning given in paragraph 1.4 of the Form of Contract.

"**FOIA**" means the Freedom of Information Act 2000 and any subordinate legislation made under that Act from time to time together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.

"**Force Majeure Event**" means any event outside the reasonable control of either Party affecting its performance of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control and which are not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party, including acts of God, riots, war or armed conflict, acts of terrorism, acts of government, local government or regulatory bodies, for flood, storm or earthquake, or disaster but excluding any industrial dispute relating to the Supplier or the Staff or any other failure in the Supplier's supply chain.

"**Form of Contract**" means Section 1 of the Contract.

"GB Storage Facility" has the meaning given to it in paragraph 1.10 of the Specification.

"**GDPR**" means the General Data Protection Regulation (Regulation (EU) 2016/679) as may be amended or superseded from time to time.

"**General Anti-Abuse Rule**" means:

(a) the legislation in Part 5 of the Finance Act 2013; and

(b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid NICs;

"**Good Industry Practice**" means standards, practices, methods and procedures conforming to the Law and the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged in a similar type of undertaking under the same or similar circumstances.

"Good Laboratory Practice" shall have the meaning set out in Directives 2004/9/EC and 2004/10/EC.

"Good Manufacturing Practice" shall have the meaning set out in Directive 91/412/EEC.

"**Goods**" means any Antigens and/or Vaccines (as the case may be) supplied by the Supplier (or by a Sub-Contractor) under the Contract as specified in the Specification including any modified or alternative goods.

"**Halifax Abuse Principle**" means the principle explained in the CJEU Case C-255/02 Halifax and others.

"**Security Policy Framework**" means the HMG Security Policy Framework (available from the Cabinet Office's Government Security Secretariat) as updated from time to time. Further detail can be found at: https://www.gov.uk/government/publications/security-policy-framework.

"**HMRC**" means HM Revenue & Customs.

"**ICT Environment**" means the Authority System and the Supplier System.

"**Information**" has the meaning given under section 84 of the FOIA.

"**Initial Contract Period**" means the period from the Commencement Date to the End Date.

"**Intellectual Property Rights**" means patents, utility models, inventions, trademarks, service marks, logos, design rights (whether registrable or otherwise), applications for any of the foregoing, copyright, database rights, domain names, plant variety rights, Know-How, trade or business names, moral rights and other similar rights or obligations whether registrable or not in any country (including but not limited to the United Kingdom) and the right to sue for passing off.

"Invitation to Tender" means the invitation to tender despatched on 23rd August 2018 by the Authority via the Bravo Solutions portal.

"**ITEPA**" means the Income Tax (Earnings and Pensions) Act 2003.

"**Know-How**" means all information not in the public domain held in any form (including without limitation that comprised in or derived from drawings, data formulae, patterns, specifications, notes, samples, chemical compounds, biological materials, computer software, component lists, instructions, manuals, brochures, catalogues and process descriptions and scientific approaches and methods).

"**Law**" means law, statute, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of section 2 of the European Communities Act 1972, regulation, order, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any Regulatory Body with which the Supplier is bound to comply.

"**LED**" means Law Enforcement Directive (Directive (EU) 2016/680).

"Licensing Authority" means VMD, MHRA or EMA or such other licensing body as the case may be.

"Loss Costs" means to the extent that the Authority and/or Administering Entity and/or Devolved Administration has taken all reasonable steps to mitigate such losses:

(a) all costs in connection with receiving and storing Defective Vaccines;

(b) where the Defective Vaccine has been despatched by or on behalf of the Authority or Devolved Administration, the costs of recalling the Defective Vaccine;

(c) all wasted administrative and personnel costs of the Authority and/or any Administering Entity and/or Devolved Administration relating to a Defective Vaccine;

(d) where livestock is required to be given further treatments of the Vaccine because their initial course was a Defective Vaccine, the costs of providing such further treatments of the Vaccine to such livestock;

(e) all costs in excess of the price paid or payable by the Authority for Rejected Vaccines incurred in sourcing alternative products from third parties; and

(f) all costs associated with advising, screening, testing, treating or otherwise providing healthcare to livestock in relation to a Defective Vaccine.

"Manufacturing Authorisation" means manufacturing authorisation number 08327/4162 in respect of the manufacture of the Antigen and Vaccine granted by the Licensing Authority.

"Marketing Authorisation" means marketing authorisation number 08327/4162 in respect of the Antigen and Vaccine granted by the Licensing Authority as amended or varied by the Licensing Authority from time to time.

"MHRA" means Medicines and Healthcare products Regulatory Agency.

"**Malicious Software**" means any software program or code intended to destroy, interfere with, corrupt, or cause undesired effects on program files, data or other information, executable code or application software macros, whether or not its operation is immediate or delayed, and whether the malicious software is introduced wilfully, negligently or without knowledge of its existence.

"**Material Breach**" means a breach (including an anticipatory breach) that is serious in the widest sense of having a serious effect on the benefit which the Authority would otherwise derive from:

(a) a substantial portion of the Contract; or

(b) any of the obligations set out in clauses A6, D1, E1, E2, E4, E5, E8 or E10.

"**Month**" means calendar month.

"**NICs**" means National Insurance Contributions.

"**Occasion of Tax Non-Compliance**" means:

(a) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 which is found on or after 1 April 2013 to be incorrect as a result of:

i) a Relevant Tax Authority successfully challenging the Supplier under the General Anti-Abuse Rule or the Halifax Abuse principle or under any tax rules or legislation that have an effect equivalent or similar to the General Anti-Abuse Rule or the Halifax Abuse Principle;

ii) the failure of an avoidance scheme which the Supplier was involved in, and which was, or should have been, notified to the Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or

(b) any tax return of the Supplier submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise on or after 1 April 2013 to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Commencement Date or to a civil penalty for fraud or evasion.

"**Personal Data**" has the meaning given in the GDPR.

"**Personal Data Breach**" has the meaning given in the GDPR.

"**Price**" means the price (excluding any applicable VAT) payable to the Supplier by the Authority under the Contract, as set out in Schedules 1 and 2 for the full and proper performance by the Supplier of its obligations under the Contract.

"**Processor**" has the meaning given in the GDPR.

"**Prohibited Act**" means:

(a) to directly or indirectly offer, promise or give any person working for or engaged by the Authority a financial or other advantage to:

i) induce that person to perform improperly a relevant function or activity; or

ii) reward that person for improper performance of a relevant function or activity;

(b) to directly or indirectly request, agree to receive or accept any financial or other advantage as an inducement or a reward for improper performance of a relevant function or activity in connection with the Contract;

(c) an offence:

i) under the Bribery Act 2010 (or any legislation repealed or revoked by such Act;

ii) under legislation or common law concerning fraudulent acts; or

iii) the defrauding, attempting to defraud or conspiring to defraud the Authority;

(d) any activity, practice or conduct which would constitute one of the offences listed under (c) above if such activity, practice or conduct has been carried out in the UK.

"**Protective Measures**" means appropriate technical and organisational measures which may include: pseudonymising and encrypting Personal Data, ensuring confidentiality, integrity, availability and resilience of systems and services, ensuring that availability of and access to Personal Data can be restored in a timely manner after an incident, and regularly assessing and evaluating the effectiveness of the such measures adopted by it including those outlined in Schedule 7.

"**Quality Standards**" means the quality standards published by BSI British Standards, the National Standards Body of the United Kingdom, the International Organisation for Standardization or other reputable or equivalent body (and their successor bodies) that a skilled and experienced operator in the same type of industry or business sector as the Supplier would reasonably and ordinarily be expected to comply with, and as may be further detailed in the Specification, together with the quality standards set out in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) and the European Pharmacopoeia monographs and guidelines.

"**Receipt**" means the physical or electronic arrival of the invoice at the address specified in clause A4.4 or at any other address given by the Authority to the Supplier for the submission of invoices from time to time.

"**Regulations**" means the Public Contract Regulations 2015 (SI 2015/102).

"**Regulatory Body**" means a government department and regulatory, statutory and other entities, committees, ombudsmen and bodies which, whether under statute, rules, regulations, codes of practice or otherwise, are entitled to regulate, investigate, or influence the matters dealt with in the Contract or any other affairs of the Authority.

"Rejected Vaccine" means any Defective Vaccines rejected by the Authority pursuant to Clause B7.2 or Clause B7.3.

"**Relevant Requirements**" means all applicable Law relating to bribery, corruption and fraud, including the Bribery Act 2010 and any guidance issued by the Secretary of State for Justice pursuant to section 9 of the Bribery Act 2010.

"**Relevant Tax Authority**" means HMRC or, if applicable, a tax authority in the jurisdiction in which the Supplier is established.

"**Replacement Supplier**" means any third party supplier appointed by the Authority to supply any goods which are substantially similar to any of the Goods in substitution for any of the Goods following the expiry, termination or partial termination of the Contract.

"**Request for Information**" means a request for information under the FOIA or the EIR.

"**Results**" means any guidance, specifications, reports, studies, instructions, toolkits, plans, data, drawings, databases, patents, patterns, models, designs or other material which is:

a) prepared by or for the Supplier for use in relation to the performance of its obligations under the Contract; or

b) the result of any work done by the Supplier, the Staff or any Sub-Contractor in relation to the provision of the Goods.

"**Specification**" means the description of the Goods to be supplied under the Contract as set out in Schedule 1 including, where appropriate, the Quality Standards.

"**SSCBA**" means the Social Security Contributions and Benefits Act 1992.

"**Staff**" means all persons employed by the Supplier to perform its obligations under the Contract together with the Supplier's servants, agents, suppliers and Sub-Contractors used in the performance of its obligations under the Contract.

"Storage Fees" means the Antigen Storage Fee and/or the Vaccine Storage Fee as the context requires.

"Summary of Vaccine Characteristics" means the summary of product characteristics approved by the Licensing Authority for the Marketing Authorisation.

"**Sub–Contract**" means a contract between 2 or more suppliers, at any stage of remoteness from the Authority in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of the Contract and "**Sub-Contractor**" shall be construed accordingly.

"**Sub-processor**" means any third party appointed to process Personal Data on behalf of the Supplier related to this Contract.

"**Tender**" means the document submitted by the Supplier to the Authority in response to the Authority's invitation to suppliers for formal offers to supply the Goods.

"**TFEU**" means the Treaty on the Functioning of the European Union.

“**Third Party Software**” means software which is proprietary to any third party which is or will be used by the Supplier to provide the Goods.

“**Treaties**” means the Treaty on European Union and the TFEU.

“**TUPE**” means the Transfer of Undertakings (Protection of Employment) Regulations 2006.

"Use" means use in any activities carried out by or on behalf of the Authority or any Administering Entity or Devolved Administration in relation to the Vaccine following Delivery to the Authority including storage and distribution of the Vaccine and the carrying out of a vaccination programme as well as the supply, resale or donation of the Vaccine to any third party (including without limitation to any or all of the Devolved Administrations and **“Used”** shall have an equivalent meaning.

"**Vaccine**" has the meaning given to it in clause B1.1.

"Vaccine Storage Fee" means the recurring fee for the storage of the Vaccine to be paid by the Authority to the Supplier in the amount specified in part 1 of Schedule 2.

“**Valid Invoice**” means an invoice containing the information set out in clause C2.5.

“**Variation**” means a change in the Specification, the Price or any of the terms or conditions of the Contract.

“**VAT**” means value added tax charged or regulated in accordance with the provisions of the Value Added Tax Act 1994.

"Veterinary Health Service Body" means the Authority's vaccine delivery agents and/or veterinarians who will administer the Vaccine to cloven-hooved mammals.

"VMD" means Veterinary Medicines Directorate.

"Volume" means Units of the Vaccine to be Delivered during the Contract Period.

“**Working Day**” means a day (other than a Saturday or Sunday) on which banks are open for general business in the City of London.

In the Contract, unless the context implies otherwise:

(a) the singular includes the plural and vice versa;

(b) words importing the masculine include the feminine and the neuter;

(c) reference to a clause is a reference to the whole of that clause unless stated otherwise;

(d) references to a person include an individual, company, body corporate, corporation, unincorporated association, firm, partnership or other legal entity or central Government body;

(e) the words "other", "in particular", "for example", "including" and similar words shall not limit the generality of the preceding words and shall be construed as if they were immediately followed by the words "without limitation";

(f) headings are included for ease of reference only and shall not affect the interpretation or construction of the Contract;

(g) a reference to any Law includes a reference to that Law as amended, extended, consolidated or re-enacted from time to time; and

(h) references to the Contract are references to the Contract as amended from time to time.

A2 The Authority's Obligations

A2.1 Save as otherwise expressly provided, the obligations of the Authority under the Contract are obligations of the Authority in its capacity as a contracting counterparty and nothing in the Contract shall operate as an obligation upon, or in any other way fetter or constrain the Authority in any other capacity, and the exercise by the Authority of its duties and powers in any other capacity shall not lead to any liability (howsoever arising) on the part of the Authority to the Supplier.

A3 Supplier's Status

A3.1 The Supplier shall be an independent contractor and nothing in the Contract shall create a contract of employment, a relationship of agency or partnership or a joint venture between the Parties and accordingly neither Party shall be authorised to act in the name of, or on behalf of, or otherwise bind the other Party save as expressly permitted by the terms of the Contract.

A3.2 The Supplier shall not (and shall ensure that any other person engaged in relation to the Contract shall not) say or do anything that might lead any other person to believe that the Supplier is acting as the agent or employee of the Authority.

A4 Notices and Communications

A4.1 Subject to clause A4.3, where the Contract states that a notice or communication between the Parties must be "written" or "in writing" it is not valid unless it is made by letter (sent by hand, first class post, recorded delivery or special delivery) or by email or by communication via Bravo.

A4.2 If it is not returned as undelivered a notice served:

(a) in a letter is deemed to have been received 2 Working Days after the day it was sent; and

(b) in an email is deemed to have been received 4 hours after the time it was sent provided it was sent on a Working Day

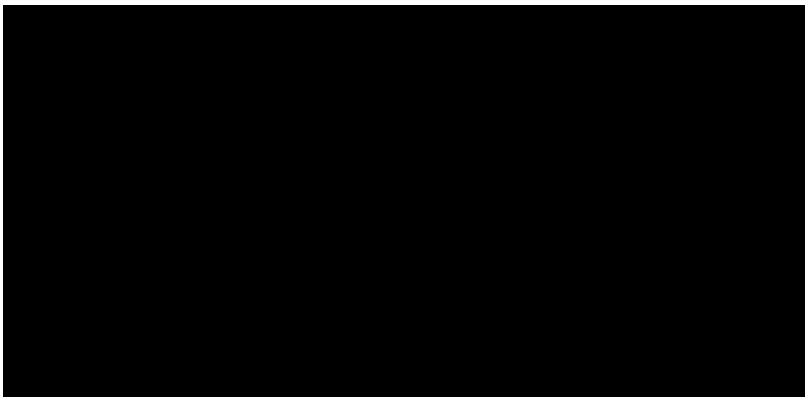
or when the other Party acknowledges receipt, whichever is the earlier.

A4.3 Notices pursuant to clauses G3 (Force Majeure), I2 (Dispute Resolution) or to terminate the Contract or any part of the Goods are valid only if served in a letter by hand, recorded delivery or special delivery.

A4.4 Notices shall be sent to the addresses set out below or at such other address as the relevant Party may give notice to the other Party for the purpose of service of notices under the Contract:

(a) For the Authority:

(b) For the Supplier:



A5 Mistakes in Information

A5.1 The Supplier is responsible for the accuracy of all drawings, documentation and information supplied to the Authority by the Supplier in connection with the Goods and shall pay the Authority any extra costs occasioned by any discrepancies, errors or omissions therein.

A6 Conflicts of Interest

A6.1 The Supplier shall take appropriate steps to ensure that neither the Supplier nor any Staff is placed in a position where, in the reasonable opinion of the Authority, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of the Contract. The Supplier will notify the Authority without delay giving full particulars of any such conflict of interest which may arise.

A6.2 The Authority may terminate the Contract immediately by notice and/or take or require the Supplier to take such other steps it deems necessary if, in the Authority's reasonable

opinion, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Supplier and the duties owed to the Authority under the provisions of the Contract. The actions of the Authority pursuant to this clause A6 shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Authority.

B. THE GOODS

B1 Specification

B1.1 The Supplier shall manufacture and store the Dedicated Minimum Viable Stock of Antigen on behalf of the Authority and, where required by the Authority, develop the Antigen into a vaccine (**"Vaccine"**) and supply the required Volume to the Authority, in accordance with this Contract, including the Specification, the Antigen Manufacturing Schedule, all Delivery Orders, the Invitation to Tender and the Tender at the Price set out in Schedule 2. In the event of any inconsistency between the Specification and the Tender the former shall prevail.

B1.2 With regards the manufacture of Antigen by the Supplier:

(a) the parties will use all reasonable endeavours to agree the Acceptance Criteria within ten (10) Working Days of the Commencement Date;

(b) in the absence of any agreement by the end of the timescales identified above in clause B1.2(a), the Acceptance Criteria will be reasonably determined by the Authority so as to assess the Supplier's compliance with the requirements of the Contract in respect of the manufacture of the Antigen;

(c) the Authority shall issue an Antigen Delivery Milestone Achievement Certificate when the Supplier has satisfied the relevant Acceptance Criteria in respect of the manufacture of the Antigen and such Antigen Delivery Milestone Achievement Certificate shall indicate that Acceptance of the Antigen has been achieved;

(d) if the Supplier fails to achieve Acceptance of the Antigen on or before the date for Acceptance as specified in the Antigen Manufacturing Schedule, then the provisions of paragraphs 13 and 14 of the Specification shall apply; and

(e) Acceptance operates without prejudice to any rights and remedies that the Authrority may have in relation to the performance by the Supplier of its obligations under the Contract. Acceptance by the Customer does not operate as a waiver of any of its accrued rights.

B1.3 Title in the stocks of Antigen shall pass to the Authority on payment of the Antigen Manufacturing Fee, but risk shall remain with the Supplier until: (i) the Antigen is developed into a Vaccine; and (ii) risk in that Vaccine passes to the Authority in accordance with Clause B5.1.

B1.4 The Authority may (but shall not be obliged to) place orders for the Delivery of vials of the Vaccine in a Volume to be specified by the Authority using the pro forma set out in part 2 of Schedule 2 (**"Delivery Order"**). Each Delivery Order shall be provided to the Supplier in writing and shall carry an authorised purchase order number which the Supplier shall quote on all correspondence relating to such Delivery Order. The Supplier shall manufacture and supply to the Authority the vials of the Vaccine requested in any Delivery Order to the extent that such order does not exceed the Dedicated Minimum Viable Stock of the Antigen. Where the Authority places a Delivery Order which exceeds the Dedicated Minimum Viable Stock of the Antigen, the Supplier shall use all reasonable endeavours to

obtain additional stocks of the Antigen to enable it to meet the Delivery Order at a price to be agreed between the parties (acting reasonably and in good faith).

B1.5 The prices for all vials of the Vaccine ordered by the Authority in any Delivery Order shall be as set out in part 1 of Schedule 2.

B1.6 The Supplier shall ensure that all vials of the Vaccine supplied to the Authority under this Contract:

(a) comply fully with the Specification and the Marketing Authorisation;

(b) are supplied in the numbers set out in the relevant Delivery Order;

(c) have the shelf life set out in the Specification (Schedule 1) paragraph 3.6 less any period relating to the release of the Vaccine provided that such release period shall not reduce the shelf life of the Vaccine by more than one (1) month;

(d) conform in all respects with all applicable Laws; and

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

B1.7 Throughout the duration of the Contract, and for a period of three (3) months thereafter, the Authority may exercise its rights pursuant to paragraph 4 of the Specification in respect of unused Antigen and/or Vaccine.

B1.8 The Supplier shall:

(a) ensure manufacturing capacity sufficient to comply with its obligations under this Contract including Clauses B1.1 and B1.4;

(b) keep the production facilities used in the manufacture of the Goods in a state and condition necessary to enable the Supplier to comply with its obligations to supply the Vaccine to the Authority in accordance with this Contract; and

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

B1.9 This Contract is not exclusive and accordingly the Authority shall not be restricted from purchasing any products whatsoever including products that are equivalent to or substitutable for the Goods from other parties.

B1.10 Where and insofar as expressly stated in writing by the Authority, the Authority may appoint its Authorised Representative to act on the Authority's behalf in relation to part or all of this Contract. The Supplier shall work and co-operate fully with the Authorised Representative.

B2 Samples

B2.1 The provisions of paragraph 7 of the Specification shall apply in respect of sampling of the Goods.

B2.2 The Supplier acknowledges that the Authority relies on the skill and judgment of the Supplier in the supply of the Goods and the performance of the Supplier's obligations under the Contract.

B3 Storage

B3.1 In return for the payment by the Authority of the Antigen Storage Fee in accordance with the provisions of Clause C1.1(b), and (where applicable) the Vaccine Storage Fee in accordance with Clause C1.1(c), the Supplier shall store all stocks of Antigen and vials of Vaccine (if any):

(a) in a good and proper manner, in accordance with all applicable Laws and recommended storage instructions;

(b) under Good Manufacturing Practice conditions with the appropriate documentation and security; and

(c) in accordance with the Specification.

B4 Delivery

B4.1 The Supplier shall:

(a) store all vials of the Vaccine when manufactured in a good and proper manner;

(b) deliver all vials of the Vaccine in accordance with the Specification. The Supplier shall be deemed to have delivered vials of the Vaccine to the Authority upon collection of the same by the Authority or an Authorised Representative from the GB Storage Facility and once the Vaccines are loaded onto the Authority's or Authorised Representative's vehicle(s) and all relevant paperwork has been provided to the Authority or Authorised Representative at the relevant location (**"Delivered"** and **"Delivery"** shall be construed accordingly); and

(c) transport and deliver the Vaccine in such manner necessary to ensure that it is Delivered in good and usable condition.

B4.2 The Supplier shall be responsible for all transport and all related costs associated with the delivery of the Vaccine up to the point of collection by the Authority or an Authorised Representative in accordance with Clause B4.1(b). The Supplier shall be responsible for ensuring that the Vaccine is made available for collection by the Authority or an Authorised Representative from the loading bay of the GB Storage Facility and will cooperate in the loading of the Vaccines with the Authority or its Authorised Representative as may be appropriate.

B4.3 All third party carriers engaged to Deliver the Vaccine shall at no time be an agent of the Authority and accordingly the Supplier shall be liable to the Authority for the acts and omissions of all third party carriers engaged to Deliver the Vaccine to the Authority.

B4.4 The Authority shall be under no obligation to accept or pay for any Vaccines supplied earlier than the date for Delivery stated in the relevant Delivery Order.

B4.5 The Authority is under no obligation to accept or pay for any Vaccines Delivered in excess of the quantity ordered. If the Authority elects not to accept such over-Delivered Vaccines it shall give notice to the Supplier to remove them within 5 Working Days and to refund to the Authority any expenses incurred by it as a result of such over-Delivery (including but not limited to the costs of moving and storing the Vaccines), failing which the Authority may dispose of such Vaccines and charge the Supplier for the costs of such disposal. The risk in any over-Delivered Vaccines shall remain with the Supplier unless they are accepted by the Authority.

B4.6 Unless expressly agreed to the contrary, the Authority shall not accept Delivery by instalments. If, however, the Authority does specify or agree to Delivery by instalments, Delivery of any instalment later than the date specified or agreed for its Delivery shall, without prejudice to any other rights or remedies of the Authority, entitle the Authority to terminate the whole or any unfulfilled part of the Contract without further liability to the Authority.

B4.7 The Authority may inspect and examine the manner in which the Supplier supplies and stores the Goods at its premises during normal business hours on reasonable notice. The Supplier shall provide free of charge all such facilities as the Authority may reasonably require for such inspection and examination. In this clause B4, Goods include planning or preliminary work in connection with the supply of the Goods.

B4.8 If reasonably requested to do so by the Authority, the Supplier shall co-ordinate its activities in supplying the Goods with the activities of the Authority and other suppliers engaged by the Authority.

B4.9 Timely supply of all vials of the Vaccine as specified in any Delivery Order shall be of the essence and without prejudice to any other right or remedy of the Authority, should the Supplier not Deliver and make available the vials of the Vaccine in accordance with the applicable Delivery Order (provided that minor variances to the Delivery Order due to the unpredictable nature of the Vaccine manufacturing process shall be permitted so long as agreed with the Authority prior to Delivery) and other than where such failure to Deliver is due to the default of the Authority or its agents, the Authority shall:

(a) be entitled to refuse or cancel Delivery of any such vials of the Vaccine not Delivered in accordance with the applicable Delivery Order;

(b) cease to have any liability to pay for any such vials of the Vaccine not Delivered in accordance with the applicable Delivery Order where such vials have been refused Delivery or had their Delivery cancelled in accordance with Clause B4.9(a);

(c) be entitled to charge the Supplier for any costs incurred by the Authority or an Administering Entity or Devolved Administration as a result of such failure to Deliver (such costs to include, without limitation, all costs incurred in sourcing alternative products from third parties in excess of what would have been paid to the Supplier for such vials of the Vaccine). The Supplier shall pay such costs due to the Authority under this Clause B4.9(c) within 30 days of the date of the Authority's invoice for the same;

(d) be entitled to the payments calculated and payable by the Supplier in accordance with paragraphs 13 and 14 of the Specification; and / or

(e) be entitled to terminate this Contract.

B4.10 The Supplier shall perform its obligations under the Contract:

(a) with appropriately experienced, qualified and trained personnel with all due skill, care and diligence;

(b) in accordance with Good Industry Practice; and

(c) in compliance with all applicable Laws.

B4.11 The Supplier shall at all times comply with the Quality Standards and, where applicable, shall maintain accreditation with the relevant Quality Standards authorisation body. To the extent that the standard of the Goods has not been specified in the Contract, the Supplier

shall agree the relevant standard of the Goods with the Authority prior to the supply of the Goods and, in any event, the Supplier shall perform its obligations under the Contract in accordance with the Law and Good Industry Practice.

B4.12 The Supplier shall ensure that all Staff supplying the Goods do so with all due skill, care and diligence and shall possess such qualifications, skills and experience as are necessary for the proper supply of the Goods. The Supplier shall ensure that those Staff are properly managed and supervised.

B4.13 The Supplier shall provide complete and accurate temperature records for each Delivery of the Vaccine to the Authority during the period of transport of the Vaccine from the Supplier's manufacturing facilities to the GB Storage Facility and during the period of storage at the GB Storage Facility until collection by the Authority or an Authorised Representative.

B5 Risk and Ownership

B5.1 Subject to clauses B4.4 and B4.5 and B7.8 and without prejudice to any other rights or remedies of the Authority (including the Authority's rights and remedies under clause F1 (Failure to meet Requirements)), risk in all vials of the Vaccine shall pass to the Authority upon completion of Delivery, in accordance with Clause B4.1(b), of the relevant vials and ownership of all vials of the Vaccine shall pass to the Authority upon the earlier of Delivery or the time of any payment being made by or on behalf of the Authority.

B6 Labelling and Packaging

B6.1 The Supplier shall Deliver all vials of the Vaccine securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

(a) a description of the Vaccine using the Supplier's brand name and/or generic drug name;

(b) the quantity in the package;

(c) special directions for storage (if any);

(d) expiry date for the Vaccine in the package;

(e) batch number;

(f) name of Supplier; and

(g) any other labelling and packaging details as required by the Specification; and

(h) any other information required by the Licensing Authority to be provided.

B6.2 The Supplier shall comply with the Packaging & Packaging Waste Directive (94/62/EC), implemented in the UK by the Packaging (Essential Requirements) Regulations 2003. Each Delivery of the Vaccine shall be accompanied by an advice note stating the full description, weight, quantity, measure, order number, batch number and expiry date. All ancillary paperwork and literature (including invoices) shall include the same information. Any and all containers of hazardous goods (and all documents relating thereto) shall bear prominent and adequate warnings.

B6.3 The labelling and marking of all packages of the Vaccine and all relevant information accompanying them shall be in English. The Supplier shall discuss and, other than to the

extent required by the Licensing Authority, agree with the Authority any changes to be made to labelling, instructions and patient information relating to the Vaccine.

B6.4 The Supplier shall:

(a) use packaging capable of easy recovery for further use or recycling. Packaging materials shall be easily separable by hand into recyclable parts consisting of one material (e.g. cardboard, paper, plastic, textile);

(b) reuse the packaging and, where reuse is not practicable, recycle the materials in the manufacture of crates, pallets, boxes, cartons, cushioning and other forms of packaging, where these fulfil other packaging specifications;

(c) make maximum use of materials taken from renewable sources, if recycled materials are not suitable or not readily available;

(d) if using wooden pallets or timber derived products for the packaging and supply of Goods, comply with the Authority's timber procurement policy (further detail of which can be found at: https://www.gov.uk/guidance/timber-procurement-policy-tpp-prove-legality-and-sustainablity);

(e) review packaging specifications periodically to ensure that no unnecessary limitations on the use of recycled materials exist; and

(f) if requested to do so, provide the Authority with a description of the product packaging and evidence to satisfy the Authority that it is reusing, recycling and reviewing its use of packaging. The evidence should provide proof of compliance with BS EN 13430 on recyclability or BS EN 13429 on reusability, or equivalent.

B7 Inspection and Rejection of Vaccines

B7.1 Without prejudice to the Authority's rights under Clauses B7.3 and B7.4, the Authority shall carry out a visual inspection of the Vaccine promptly and in any event within 7 calendar days of the date of Delivery to the Authority in accordance with Clause B4.1(b). Such visual inspection shall cover checking the relevant batches of Vaccine to ensure there is no obvious damage, checking batch numbers and expiry dates in accordance with delivery documents, and quantity. The Authority shall notify the Supplier of any issues arising from such inspection promptly and in any event within 7 Working Days of the date of Delivery to the Authority in accordance with Clause B4.1(b).

B7.2 The Authority may reject any vials of the Vaccine:

(a) where such visual inspection reveals such vials or their packaging to be damaged and/or to have batch numbers and/or expiry dates which do not correspond to the relevant delivery documents and/or the provisions of this Contract;

(b) in respect of which the Supplier fails to provide complete and accurate temperature records in accordance with Clause B4.13 on the date of Delivery.

B7.3 The Authority may at any time by written notice to the Supplier reject any Defective Vaccines. Where the Authority discovers more than one Defective Vaccine in any given batch of the Vaccine, the Authority shall be entitled to reject the entire batch provided always that the Authority shall take due account of all relevant guidance received from the Licensing Authority.

B7.4 Without prejudice to any other right or remedy of the Authority:

(a) the Authority may by written notice to the Supplier require the Supplier to replace Rejected Vaccines with vials of the Vaccine that are in compliance with this Contract; or

(b) the Authority may choose to source the Vaccine or any substitute product from a third party.

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

B7.5 No failure to make a complaint at the time of the Delivery nor any other act or omission of the Authority including in particular taking Delivery, keeping a sample, inspection of or payment for any vials of the Vaccine by the Authority shall constitute acceptance, waiver or approval of the Vaccine or limit the Authority's right subsequently to reject vials of the Vaccine should such vials be Defective Vaccines.

B7.6 Rejected Vaccines shall be removed by the Supplier at its own expense within fourteen (14) days from the date of notification of rejection. If the Supplier fails to remove Rejected Vaccines within such period the Authority may return such Rejected Vaccines at the Supplier's risk and expense.

B7.7 The Authority shall be entitled to charge the Supplier for any Loss Costs incurred by the Authority and/or any Administering Entity and/or Devolved Administration as a result of rejection of any vials of the Vaccine in accordance with this Contract provided that the Authority and/or the Administering Entity and/or Devolved Administration, as appropriate, shall use its/their reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within 30 days of the date of the Authority's invoice for the same.

B7.8 Subject to Clause B7.6, risk in and title to Rejected Vaccines shall remain with the Authority whilst such Rejected Vaccines are in its possession until collection by the Supplier or its agent from the premises of the Authority or its nominee when risk and title shall pass to the Supplier.

B8 Delay

B8.1 In the event that the Supplier becomes aware that it is or it may become unable to supply the Vaccine in accordance with any Delivery Order the Supplier shall promptly (and in any event within twelve (12) hours) notify the Authority.

B9 Regulatory and Information Requirements

B9.1 The Supplier shall maintain, and no later than any date on which it would otherwise expire, obtain a renewal of the Marketing Authorisation in accordance with the provisions of all applicable Laws and regulations. This obligation shall continue to apply after the expiry or termination of this Contract until such time as the Authority notifies the Supplier in writing that it has used or disposed of all vials of the Vaccine supplied under this Contract.

B9.2 The Supplier shall promptly and in any event within seven (7) days inform the Authority in writing if it knows or believes there to be any delay or other problem with the Marketing Authorisation or its renewal. If the Marketing Authorisation is:

(a) withdrawn by the Licensing Authority;

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

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

in each case for reasons relating to the safety or efficacy of the Vaccine or deficiencies in any application made by the Supplier to the Licensing Authority, then the Authority shall be entitled to terminate this Contract upon written notice to the Supplier and the provisions of Clause H5.7 shall apply.

B9.3 The Supplier shall:

(a) reply promptly (and in any event within forty eight (48) hours to all enquiries and complaints by the Authority relating to the Use, effective administration, quality, performance and durability of the Vaccine;

(b) to the extent relevant to the performance of this Contract, ensure that the Authority is kept aware at regular intervals (and in any event not less than every six (6) months) of all material data or information obtained by the Supplier whether in clinical trials, from other customers of the Supplier, or otherwise or any other matters in each case relating to the safety and/or efficacy of the Vaccine including the balance of risk and benefits of using the Vaccine. The Supplier will provide reasonable cooperation with the Authority and the Licensing Authority in investigating such data, information or other matters and shall keep the Authority up to date as to the outcome of such investigations;

(c) promptly and in any event within 7 days of becoming aware of the same inform the Authority and provide full details of any claim brought by any third party in relation to the Vaccine;

(d) without prejudice to Clause B9.3(b), should the Supplier become aware of an actual or suspected adverse reaction to the Vaccine which is not described in the Summary of Vaccine Characteristics, promptly inform the Authority in writing and in any event within 7 days of becoming aware of the same; and

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

B10 Quality Assurance

B10.1 The Supplier shall comply with its quality control monitoring system details of which are included in the Marketing Authorisation and the Manufacturing Authorisation. The Supplier shall manufacture and test the Goods in accordance with the Specification and Good Manufacturing Practice. The Supplier shall provide a copy of its valid Good Manufacturing Practice certificate to the Authority upon request.

B10.2 The Supplier shall maintain the Manufacturing Authorisation and all other authorisations/licences necessary for the manufacture of the Goods during the Contract Period and shall not make any significant changes (including without limitation any

changes which shall or may have an impact on the quality or use of the Goods) to the same or to the Specification or the Supplier's quality control monitoring system in relation to the Goods without:

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

(b) the Licensing Authority formally approving such change.

Any non-conformity identified during an inspection of the Supplier's manufacturing and/or storage site(s) by the Licensing Authority or any other regulatory body shall be notified to the Authority without delay, including detailed information of the impact (if any) on the quality, safety and efficacy of the Goods. The Supplier shall remedy any such non-conformity promptly and to the satisfaction of the Authority and the Licensing Authority or other regulatory body (as applicable).

B10.3 The Supplier shall ensure that its laboratory/production facility(ies) and storage facility(ies) (including the GB Storage Facility) hold suitable UK/EU accreditations and quality standards (including, in respect of the GB Storage Facility, a wholesale dealer authorisation (WDA) granted by the Licensing Authority (where the GB Storage Facility is not covered by the Manufacturing Authorisation)) to assure the safety, consistency, efficacy and quality of vaccine production and storage.

B10.4 The Supplier shall comply with the provisions of paragraphs 6.6 and 6.7 of the Specification in respect of assuring the quality of the Goods during storage.

B11 Due Diligence

Save as the Authority may otherwise direct, the Supplier is deemed to have completed due diligence before submitting its Tender in relation to all matters connected with the performance of its obligations under the Contract.

B12 Business Continuity

B12.1 Throughout the duration of this Contract, the Supplier will ensure its Business Continuity Plan provides for continuity during a Business Continuity Event. The Supplier confirms and agrees that such Business Continuity Plan details and will continue to detail robust arrangements the Supplier has and will retain in place with third parties regarding continuity of supply of raw materials and utilities and Delivery of the Vaccine during a Business Continuity Event. The Supplier shall test its Business Continuity Plan at reasonable intervals and shall provide to the Authority, at the Authority's written request, copies of its Business Continuity Plan, any updated or revised Business Continuity Plan, evidence that the Supplier tests its Business Continuity Plan at least once each year and information regarding the outcome of such tests.

B12.2 In the event of a Business Continuity Event, the Supplier shall implement and comply with its Business Continuity Plan and report to the Authority on such implementation.

B12.3 In the event of a Business Continuity Event, the Parties may agree as appropriate a revised schedule in respect of any then-current Delivery Orders and review and update this at weekly intervals.

B12.4 During a Business Continuity Event, the Supplier shall use all reasonable endeavours to fulfil its obligations to supply the required Volume in accordance with any then-current Delivery Orders and the provisions of this Contract (including, without limitation, the price for the Vaccines set out at part 1 of Schedule 2) shall apply equally to all vials of the Vaccine supplied by the Supplier in accordance with this Clause B12.4.

B13 Purchase of Vaccines in an Emergency

B13.1 In cases of emergency, the provisions of paragraph 3.15 of the Specification shall apply.

C. PAYMENT

C1 Price

C1.1 In consideration of the Supplier's performance of its obligations under the Contract, the Authority shall pay:

(a) the Antigen Manufacturing Fee following the Supplier's receipt of the Antigen Delivery Milestone Achievement Certificate from the Authority;

(b) the Antigen Storage Fee on a six-monthly basis commencing on the date of the Supplier's receipt of the Antigen Delivery Milestone Achievement Certificate from the Authority until the end of the Contract Period or such shorter period where the Supplier ceases to store Antigen on behalf of the Authority prior to the end of the Contract Period; and

(c) the Vaccine Storage Fee on a six-monthly basis for the duration of any period(s) during which the Supplier is storing vials of the Vaccine at the GB Storage Facility prior to Delivery of such Vaccines to the Authority; and

(d) the charges in respect of any Vaccine Delivered under this Contract, calculated in accordance with Clause C1.2,

payable in accordance with Clause C2.

C1.2 The prices to be paid by the Authority to the Supplier for the Vaccine Delivered to the Authority under this Contract shall be as shown in part 1 of Schedule 2. These prices will remain fixed during the Contract Period and are inclusive of any royalties, licence fees, packaging and testing by the Supplier and the cost of Delivery to the Authority, or similar expenses in connection with the Vaccine but excluding the Vaccine Storage Fee. All prices set out in this Contract are stated exclusive of any applicable VAT. For the avoidance of doubt, these prices shall apply to any Delivery Order requested by the Authority in accordance with Clause B1.4 unless Schedule 2 expressly provides otherwise.

C2 Payment and VAT

C2.1 The Supplier shall submit invoices to the Authority in accordance with paragraph 12 of the Specification.

C2.2 The Authority shall, in addition to the Price and following Receipt of a Valid Invoice, pay the Supplier a sum equal to the VAT chargeable on the value of the Goods supplied in accordance with the Contract.

C2.3 The Supplier shall add VAT to the Price at the prevailing rate as applicable and shall show the amount of VAT payable separately on all invoices as an extra charge. If the Supplier fails to show VAT on an invoice, the Authority will not, at any later date, be liable to pay the Supplier any additional VAT.

C2.4 All Supplier invoices shall be expressed in GBP sterling.

C2.5 Valid Invoices shall include:

(a) the Supplier's full name, address and title of the Contract;

(b) the name and quantity of the Goods delivered including batch numbers; and

(c) the purchase order number.

C2.6 If the Authority pays the Supplier prior to the submission of a Valid Invoice this payment shall be on account of and deductible from the next payment to be made.

C2.7 If any overpayment has been made or the payment or any part is not supported by a Valid Invoice the Authority may recover this payment against future invoices raised or directly from the Supplier. All payments made by the Authority to the Supplier shall be on an interim basis pending final resolution of an account with the Supplier in accordance with the terms of this clause C2.

C2.8 The Authority shall pay all sums due to the Supplier within 30 days of Receipt of a Valid Invoice. Valid Invoices should be submitted for payment to the following address:

ssd.ap Accounts-Payable.def@defra.gsi.gov.uk (the Authority's preferred option); or
SSCL AP, Defra, PO Box 790, Newport Gwent, NP10 8FZ.

C2.9 If a payment of an undisputed amount is not made by the Authority by the due date, then the Authority shall pay the Supplier interest at the interest rate specified in the Late Payment of Commercial Debts (Interest) Act 1998.

C2.10 The Supplier shall ensure that a provision is included in all Sub-Contracts which requires payment to be made of all sums due to Sub-Contractors within 30 days from the receipt of a valid invoice.

C2.11 The Supplier shall indemnify the Authority on a continuing basis against any liability, including any interest, penalties or costs incurred, which is levied, demanded or assessed on the Authority at any time in respect of the Supplier's failure to account for or to pay any VAT relating to payments made to the Supplier under the Contract. Any amounts due under this clause C2.11 shall be paid by the Supplier to the Authority not less than 5 Working Days before the date upon which the tax or other liability is payable by the Authority.

C2.12 The Supplier shall not suspend supply of the Goods unless the Supplier is entitled to terminate the Contract under clause H2.3 for failure to pay undisputed sums of money.

C2.13 The Authority shall not pay an invoice which is not Valid Invoice. In respect of any Rejected Vaccines, no payment shall be due whatsoever.

C3 Recovery of Sums Due

C3.1 If under the Contract any sum of money is recoverable from or payable by the Supplier to the Authority (including any sum which the Supplier is liable to pay to the Authority in respect of any breach of the Contract), the Authority may unilaterally deduct that sum from any sum then due, or which at any later time may become due to the Supplier from the Authority under the Contract or under any other agreement with the Authority or the Crown.

C3.2 Any overpayment by either Party, whether of the Price or of VAT or otherwise, shall be a sum of money recoverable by the Party who made the overpayment from the Party in receipt of the overpayment.

C3.3 The Supplier shall make all payments due to the Authority without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise unless the Supplier has a valid court order requiring an amount equal to such deduction to be paid by the Authority to the Supplier.

C3.4 All payments due shall be made within a reasonable time unless otherwise specified in the Contract, in cleared funds, to such bank or building society account as the recipient Party may from time to time direct.

C4 Price During Extension

C4.1 Subject to Schedule 2 and clause F6 (Variation), the Price shall apply for the Initial Contract Period and until the end date of any Extension or such earlier date of termination or partial termination of the Contract in accordance with the Law or the Contract.

D. STATUTORY OBLIGATIONS

D1 Prevention of Fraud and Bribery

D1.1 The Supplier represents and warrants that neither it, nor to the best of its knowledge any Staff, have at any time prior to the Commencement Date:

(a) committed a Prohibited Act or been formally notified that it is subject to an investigation or prosecution which relates to an alleged Prohibited Act; and/or

(b) been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act.

D1.2 The Supplier shall not during the Contract Period:

(a) commit a Prohibited Act; and/or

(b) do or suffer anything to be done which would cause the Authority or any of its employees, consultants, suppliers/contractors, sub-contractors or agents to contravene any of the Relevant Requirements or otherwise incur any liability in relation to the Relevant Requirements.

D1.3 The Supplier shall, during the Contract Period:

(a) establish, maintain and enforce, and require that its Sub-Contractors establish, maintain and enforce, policies and procedures which are adequate to ensure compliance with the Relevant Requirements and prevent the occurrence of a Prohibited Act; and

(b) keep appropriate records of its compliance with its obligations under clause D1.3(a) and make such records available to the Authority on request.

D1.4 The Supplier shall immediately notify the Authority in writing if it becomes aware of any breach of clauses D1.1 and/or D1.2, or has reason to believe that it has or any of the Staff have:

(a) been subject to an investigation or prosecution which relates to an alleged Prohibited Act;

(b) been listed by any government department or agency as being debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for participation in government procurement programmes or contracts on the grounds of a Prohibited Act; and/or

(c) received a request or demand for any undue financial or other advantage of any kind in connection with the performance of the Contract or otherwise suspects that any person directly or indirectly connected with the Contract has committed or attempted to commit a Prohibited Act.

D1.5 If the Supplier notifies the Authority pursuant to clause D1.4, the Supplier shall respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to Audit any books, records and/or any other relevant documentation.

D1.6 If the Supplier is in Default under clauses D1.1 and/or D1.2, the Authority may by notice:

(a) require the Supplier to remove from performance of the Contract any Staff whose acts or omissions have caused the Default; or

(b) immediately terminate the Contract.

D1.7 Any notice served by the Authority under clause D1.6 shall specify the nature of the Prohibited Act, the identity of the party who the Authority believes has committed the Prohibited Act and the action that the Authority has taken (including, where relevant, the date on which the Contract shall terminate).

D2 Discrimination

D2.1 The Supplier shall:

(a) perform its obligations under the Contract in accordance with:

i) all applicable equality Law (whether in relation to race, sex, gender reassignment, age, disability, sexual orientation, religion or belief, pregnancy maternity or otherwise);

ii) the Authority's equality and diversity policy as given to the Supplier from time to time;

iii) any other requirements and instructions which the Authority reasonably imposes in connection with any equality obligations imposed on the Authority at any time under applicable equality Law; and

(b) take all necessary steps and inform the Authority of the steps taken to prevent unlawful discrimination designated as such by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation).

D3 Rights of Third Parties

D3.1 The Supplier acknowledges that the Authority has entered into this Contract in the context of the exercise of performance of the duties of the Secretary of State for Environmental, Food and Rural Affairs, and on behalf of the Devolved Administrations. Accordingly, for the purpose of assessing the extent of any liability of the Supplier to the Authority any relevant loss or damage or any liability incurred by any Administering Entity or Devolved Administration shall be deemed to be loss or damage or liability incurred by the Authority.

D3.2 Any Administering Entity or Devolved Administration may enforce any provision of this Contract which confers a benefit on it. Subject to the foregoing, 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 him. No such person shall be entitled to object to or be required to consent to any amendment to the provisions of this Contract.

D4 Health and Safety

D4.1 The Supplier shall perform its obligations under the Contract in accordance with:

(a) all applicable Law regarding health and safety; and

(b) the Supplier's health and safety policy at the Supplier's premises.

D4.2 Each Party shall notify the other as soon as practicable of any health and safety incidents or material health and safety hazards at the Supplier's premises of which it becomes aware and which relate to or arise in connection with the performance of the Contract. The Supplier shall instruct Staff to adopt any necessary associated safety measures in order to manage any such material health and safety hazards.

D5 Environmental Requirements

D5.1 The Supplier shall in the performance of the Contract have due regard to the Authority's environmental, sustainable and ethical procurement policies ("**Environmental Policies**") which require the Authority through its procurement and management of suppliers to:

(a) conserve energy, water, wood, paper and other resources and reduce waste;

(b) phase out the use of ozone depleting substances;

(c) minimise the release of greenhouse gases, volatile organic compounds and other substances damaging to health and the environment;

(d) minimise the use of products harmful to health and the environment such as hazardous substances and solvents, replacing them with more benign substances where feasible and, where such substances are necessary, to ensure that they are stored in properly labelled containers, used and disposed of in compliance with legal and regulatory requirements and any instructions from the Authority;

(e) reduce fuel emissions wherever possible;

(f) maximise the use of recovered materials and, if recycled materials are not suitable or not readily available, to maximise the use of materials taken from renewable sources; and

(g) promote the design of products that are capable of reuse or remanufacture or easily separable into recyclable parts consisting of one material (e.g. steel, plastic, textile).

D5.2 The Supplier shall ensure that any equipment and materials used in the supply of the Goods do not contain:

(a) ozone depleting substances such as hydrochlorofluorocarbons (HCFCs), halons, carbon tetrachloride, 111 trichoroethane, bromochloromethane or any other damaging substances; and/or

(b) HFCs and other gaseous and non-gaseous substances with a high global warming potential;

unless given written permission by the Authority to do so.

D5.3 The Supplier shall conserve energy and water; reduce carbon emissions and other greenhouse gases; minimise the use of substances damaging or hazardous to health and the environment and reduce waste by, for example, using resources more efficiently and reusing, recycling and composting and respecting biodiversity.

D5.4 If required by the Authority the Supplier shall provide the Authority with information about its compliance with its obligations under clause D5.3.

D5.5 The Supplier shall ensure that its Staff are aware of the Authority's Environmental Policies.

D5.6 The Supplier shall comply with the minimum environmental mandatory standards in the "Government Buying Standards" and in addition where required by the Authority, comply with any relevant "Best Practice" and "Class Leader" standards in relation to any goods on that list which are supplied to the Authority by or on behalf of the Supplier under the Contract.

D5.7 The Supplier shall:

(a) identify any risks arising from climate change and variable weather such as higher temperatures, droughts, flooding, sea and river level rises, coastal and riparian erosion, water scarcity, and loss of water quality which may disrupt and/or affect the supply of the Goods; and

(b) if such risks have been identified, enhance the resilience of its organisation to enable it to adapt and deal with the effects of such extreme events, including by having the necessary awareness-raising, evaluation, preventive, preparatory, recovery measures and support systems in place in order to minimise any disruption to the supply of the Goods.

D6 Personnel Issues

D6.1 Due to the nature of this Contract it is not anticipated that TUPE will apply, whether as a result of the termination of this Contract, or any part of it, or otherwise.

D6.2 Notwithstanding clause D6.1 above, in the event that any person or persons employed by the Supplier or any subcontractor of the Supplier transfers or alleges that they have transferred from the employment of the Supplier or any subcontractor of the Supplier into

the employment of the Authority (or any Replacement Supplier) (whether pursuant to TUPE or otherwise), the Authority shall be entitled to terminate the employment of such person or persons immediately and the Supplier shall indemnify the Authority (both for itself and on behalf of any Replacement Supplier) in full for and against all claims, costs, expenses or liabilities whatsoever and howsoever arising incurred or suffered by the Authority in respect of such transfer and/or termination, including without limitation all legal expenses and other professional fees (together with any VAT thereon).

E. PROTECTION OF INFORMATION

E1 Authority Data

E1.1 The Supplier shall not delete or remove any proprietary notices contained within or relating to the Authority Data.

E1.2 The Supplier shall not store, copy, disclose, or use the Authority Data except as necessary for the performance by the Supplier of its obligations under this Contract or as otherwise expressly authorised in writing by the Authority.

E1.3 To the extent that Authority Data is held and/or processed by the Supplier, the Supplier shall supply Authority Data to the Authority as requested by the Authority in the format specified in the Specification.

E1.4 The Supplier shall preserve the integrity of Authority Data and prevent the corruption or loss of Authority Data.

E1.5 The Supplier shall perform secure back-ups of all Authority Data and shall ensure that up-to-date back-ups are stored securely off-site. The Supplier shall ensure that such back-ups are made available to the Authority immediately upon request.

E1.6 The Supplier shall ensure that any system on which the Supplier holds any Authority Data, including back-up data, is a secure system that complies with the Security Policy Framework.

E1.7 If Authority Data is corrupted, lost or sufficiently degraded as a result of the Supplier's Default so as to be unusable, the Authority may:

(a) require the Supplier (at the Supplier's expense) to restore or procure the restoration of Authority Data and the Supplier shall do so promptly (and in any event within ten (10) days); and/or

(b) itself restore or procure the restoration of Authority Data, and shall be repaid by the Supplier any reasonable expenses incurred in doing so.

E1.8 If at any time the Supplier suspects or has reason to believe that Authority Data has or may become corrupted, lost or sufficiently degraded in any way for any reason, then the Supplier shall notify the Authority immediately and inform the Authority of the remedial action the Supplier proposes to take, such actions to be agreed and supplemented (if required) by the Authority, acting reasonably. The Supplier shall implement the agreed remedial action plan without delay.

E2 Data Protection

E2.1 The Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority is the Controller and the Supplier is the Processor unless otherwise specified in

Schedule 9. The only processing that the Supplier is authorised to do is listed in Schedule 9 by the Authority and may not be determined by the Supplier.

E2.2 The Supplier shall notify the Authority immediately if it considers that any of the Authority's instructions infringe the Data Protection Legislation.

E2.3 The Supplier shall provide all reasonable assistance to the Authority in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may, at the discretion of the Authority, include:

(a) a systematic description of the envisaged processing operations and the purpose of the processing;

(b) an assessment of the necessity and proportionality of the processing operations in relation to the Services;

(c) an assessment of the risks to the rights and freedoms of Data Subjects; and

(d) the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

E2.4 The Supplier shall, in relation to any Personal Data processed in connection with its obligations under this Contract:

(a) process that Personal Data only in accordance with Schedule 9 unless the Supplier is required to do otherwise by Law. If it is so required the Supplier shall promptly notify the Authority before processing the Personal Data unless prohibited by Law;

(b) ensure that it has in place Protective Measures which are appropriate to protect against a Data Loss Event, which the Authority may reasonably reject (but failure to reject shall not amount to approval by the Authority of the adequacy of the Protective Measures), having taken account of the:

i) nature of the data to be protected;

ii) harm that might result from a Data Loss Event;

iii) state of technological development; and

iv) cost of implementing any measures;

(c) ensure that :

i) the Staff do not process Personal Data except in accordance with this Contract (and in particular Schedule 9);

ii) it takes all reasonable steps to ensure the reliability and integrity of any Staff who have access to the Personal Data and ensure that they:

(A) are aware of and comply with the Supplier's duties under this clause;

(B) are subject to appropriate confidentiality undertakings with the Supplier or any Sub-processor;

(C) are informed of the confidential nature of the Personal Data and do not publish, disclose or divulge any of the Personal Data to any third party unless directed in writing to do so by the Authority or as

otherwise permitted by this Contract; and

(D) have undergone adequate training in the use, care, protection and handling of Personal Data; and

(d) not transfer Personal Data outside of the European Union unless the prior written consent of the Authority has been obtained and the following conditions are fulfilled:

i) the Authority or the Supplier has provided appropriate safeguards in relation to the transfer (whether in accordance with the GDPR Article 46 or LED Article 37) as determined by the Authority;

ii) the Data Subject has enforceable rights and effective legal remedies;

iii) the Supplier complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Authority in meeting its obligations); and

iv) the Supplier complies with any reasonable instructions notified to it in advance by the Authority with respect to the processing of the Personal Data;

(e) at the written direction of the Authority, delete or return Personal Data (and any copies of it) to the Authority on termination of the Contract unless the Supplier is required by Law to retain the Personal Data.

E2.5 Subject to clause E2.6 the Supplier shall notify the Authority immediately if, in relation to any Personal Data processed in connection with its obligations under this Contract, it:

(a) receives a Data Subject Request (or purported Data Subject Request);

(b) receives a request to rectify, block or erase any Personal Data;

(c) receives any other request, complaint or communication relating to either Party's obligations under the Data Protection Legislation;

(d) receives any communication from the Information Commissioner or any other regulatory authority;

(e) receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by Law; or

(f) becomes aware of a Data Loss Event.

E2.6 The Supplier's obligation to notify under clause E2.5 shall include the provision of further information to the Authority in phases, as details become available.

E2.7 Taking into account the nature of the processing, the Supplier shall provide the Authority with full assistance in relation to either Party's obligations under Data Protection Legislation in relation to any Personal Data processed in connection with its obligations under this Contract and any complaint, communication or request made under Clause E2.5 (and insofar as possible within the timescales reasonably required by the Authority) including by promptly providing:

(a) the Authority with full details and copies of the complaint, communication or request;

(b) such assistance as is reasonably requested by the Authority to enable the Authority to comply with a Data Subject Request within the relevant timescales set out in the Data Protection Legislation;

(c) the Authority, at its request, with any Personal Data it holds in relation to a Data Subject;

(d) assistance as requested by the Authority following any Data Loss Event;

(e) assistance as requested by the Authority with respect to any request from the Information Commissioner's Office, or any consultation by the Authority with the Information Commissioner's Office.

E2.8 The Supplier shall maintain complete and accurate records and information to demonstrate its compliance with this clause. This requirement does not apply where the Supplier employs fewer than 250 staff, unless:

(a) the Authority determines that the processing is not occasional;

(b) the Authority determines the processing includes special categories of data as referred to in Article 9(1) of the GDPR or Personal Data relating to criminal convictions and offences referred to in Article 10 of the GDPR; or

(c) the Authority determines that the processing is likely to result in a risk to the rights and freedoms of Data Subjects.

E2.9 The Supplier shall allow for audits of its Personal Data processing activity by the Authority or the Authority's designated auditor.

E2.10 Each Party shall designate its own Data Protection Officer if required by the Data Protection Legislation.

E2.11 Before allowing any Sub-processor to process any Personal Data related to this Contract, the Supplier must:

(a) notify the Authority in writing of the intended Sub-processor and processing;

(b) obtain the written consent of the Authority;

(c) enter into a written agreement with the Sub-processor which give effect to the terms set out in this clause E2 such that they apply to the Sub-processor; and

(d) provide the Authority with such information regarding the Sub-processor as the Authority may reasonably require.

E2.12 The Supplier shall remain fully liable for all acts or omissions of any of its Sub-processors.

E2.13 The Authority may, at any time on not less than 30 Working Days' notice, revise this clause by replacing it with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Contract).

E2.14 The Parties agree to take account of any non-mandatory guidance issued by the Information Commissioner's Office. The Authority may on not less than 30 Working Days' notice to the Supplier amend this Contract to ensure that it complies with any guidance issued by the Information Commissioner's Officer.

E2.15 This clause E2 shall apply during the Contract Period and indefinitely after its expiry.

E3 Official Secrets Acts and Finance Act

E3.1 The Supplier shall comply with the provisions of:

(a) the Official Secrets Acts 1911 to 1989; and

(b) section 182 of the Finance Act 1989.

E4 Confidential Information

E4.1 Except to the extent set out in this clause E4 or if disclosure or publication is expressly permitted elsewhere in the Contract each Party shall treat all Confidential Information belonging to the other Party as confidential and shall not disclose any Confidential Information belonging to the other Party to any other person without the other party's consent, except to such persons and to such extent as may be necessary for the performance of the Party's obligations under the Contract.

E4.2 The Supplier hereby gives its consent for the Authority to publish the whole Contract (but with any information which is Confidential Information belonging to the Authority redacted) including from time to time agreed changes to the Contract, to the general public, subject to the requirements of Schedule 4.

E4.3 If required by the Authority, the Supplier shall ensure that Staff, professional advisors and consultants sign a non-disclosure agreement prior to commencing any work in connection with the Contract in substantially the form attached in Schedule 5. The Supplier shall maintain a list of the non-disclosure agreements completed in accordance with this clause E4.3.

E4.4 If requested by the Authority, the Supplier shall give the Authority a copy of the list and, subsequently upon request by the Authority, copies of such of the listed non-disclosure agreements as required by the Authority. The Supplier shall ensure that its Staff, professional advisors and consultants are aware of the Supplier's confidentiality obligations under the Contract.

E4.5 The Supplier may only disclose the Authority's Confidential Information to the Staff who are directly involved in the provision of the Services and who need to know the information, and shall ensure that such Staff are aware of and shall comply with these obligations as to confidentiality.

E4.6 The Supplier shall not, and shall procure that the Staff do not, use any of the Authority's Confidential Information received otherwise than for the purposes of this Contract.

E4.7 Clause E4.1 shall not apply to the extent that:

(a) such disclosure is a requirement of Law placed upon the Party making the disclosure, including any requirements for disclosure under the FOIA or the EIR;

(b) such information was in the possession of the Party making the disclosure without obligation of confidentiality prior to its disclosure by the information owner;

(c) such information was obtained from a third party without obligation of confidentiality;

(d) such information was already in the public domain at the time of disclosure otherwise than by a breach of the Contract; or

(e) it is independently developed without access to the other Party's Confidential Information.

E4.8 Nothing in clause E4.1 shall prevent the Authority disclosing any Confidential Information obtained from the Supplier:

(a) for the purpose of the examination and certification of the Authority's accounts;

(b) for the purpose of 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;

(c) to any Crown Body or any Contracting Authority and the Supplier hereby acknowledges that all government departments or Contracting Authorities receiving such Confidential Information may further disclose the Confidential Information to other government departments or 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 government department or any Contracting Authority;

(d) to any consultant, contractor or other person engaged by the Authority

provided that in disclosing information under clauses E4.8(c) and (d) the Authority discloses only the information which is necessary for the purpose concerned and requests that the information is treated in confidence and that a confidentiality undertaking is given where appropriate.

E4.9 Nothing in clauses E4.1 to E4.6 shall prevent either Party from using any techniques, ideas or Know-How gained during the performance of its obligations under the Contract in the course of its normal business, to the extent that this does not result in a disclosure of the other Party's Confidential Information or an infringement of the other Party's Intellectual Property Rights.

E4.10 The Authority shall use all reasonable endeavours to ensure that any government department, Contracting Authority, employee, third party or Sub-Contractor to whom the Supplier's Confidential Information is disclosed pursuant to clause E4.6 is made aware of the Authority's obligations of confidentiality.

E4.11 If the Supplier does not comply with clauses E4.1 to E4.6 the Authority may terminate the Contract immediately on written notice to the Supplier.

E4.12 In order to ensure that no unauthorised person gains access to any Confidential Information or any data obtained in the supply of the Goods, the Supplier shall maintain adequate security arrangements that meet the requirements of professional standards and best practice.

E4.13 The Supplier will immediately notify the Authority of any breach of security in relation to Confidential Information and all data obtained in the supply of the Goods and will keep a record of such breaches. The Supplier will use its best endeavours to recover such Confidential Information or data however it may be recorded. The Supplier will co-operate with the Authority in any investigation as a result of any breach of security in relation to Confidential Information or data.

E4.14 The Supplier shall, at its own expense, alter any security systems at any time during the Contract Period at the Authority's request if the Authority reasonably believes the Supplier has failed to comply with clause E4.12.

E5 Freedom of Information

E5.1 The Supplier acknowledges that the Authority is subject to the requirements of the FOIA and the EIR.

E5.2 The Supplier shall transfer to the Authority all Requests for Information that it receives as soon as practicable and in any event within 2 Working Days of receipt:

(a) give the Authority a copy of all Information in its possession or control relating to the Contract in the form that the Authority requires within 5 Working Days (or such other period as the Authority may specify) of the Authority's request;

(b) provide all necessary assistance as reasonably requested by the Authority to enable the Authority to comply with its obligations under the FOIA and EIR; and

(c) not respond to directly to a Request for Information unless authorised to do so in writing by the Authority.

E5.3 The Authority shall determine in its absolute discretion and notwithstanding any other provision in the Contract or any other agreement whether the Commercially Sensitive Information and any other Information is exempt from disclosure in accordance with the provisions of the FOIA and/or the EIR.

E6 Publicity, Media and Official Enquiries

E6.1 Without prejudice to the Authority's obligations under the FOIA, the EIR or any obligations under the Regulations, or any policy requirements as to transparency, neither Party shall make any press announcement or publicise the Contract or any part thereof in any way, except with the written consent of the other Party.

E6.2 The Supplier shall use its reasonable endeavours to ensure that its Staff, professional advisors and consultants comply with clause E6.1.

E7 Security

E7.1 The Supplier shall, as an enduring obligation during the Contract Period, use the latest versions of anti-virus definitions available from an industry accepted anti-virus software vendor to check for and delete Malicious Software from the ICT Environment.

E7.2 Notwithstanding clause E7.1, if Malicious Software is found, the Parties shall co-operate to reduce the effect of the Malicious Software and, particularly if Malicious Software causes loss of operational efficiency or loss or corruption of the Authority Data, assist each other to mitigate any losses and to restore the supply of Goods.

E7.3 Any cost arising out of the actions of the Parties taken in compliance with clause E7.2 shall be borne by the Parties as follows:

(a) by the Supplier where the Malicious Software originates from the Supplier Software, the Third Party Software or the Authority Data (whilst the Authority Data was under the control of the Supplier); and

(b) by the Authority if the Malicious Software originates from the Authority Software or Authority Data (whilst the Authority Data was under the control of the Authority).

E8 Intellectual Property Rights

E8.1 The Supplier warrants, represents and undertakes to the Authority that either it is the sole proprietor and legal and beneficial owner of all Intellectual Property Rights in the Goods or it is licensed by the relevant owners to supply the Goods in accordance with this Contract and shall use best endeavours to ensure that it remains the owner and / or licensee (as applicable) of the Intellectual Property Rights in the Goods throughout the Contract Period.

E8.2 The Supplier warrants and represents that any receipt and Use of the Goods by the Authority or any Administrating Entity or Devolved Administration in accordance with this Contract shall not infringe any Intellectual Property Rights of any third party.

E8.3 The Supplier shall indemnify and hold harmless the Authority and any Administering Entity or Devolved Administration against all claims, liabilities, losses, damages, costs (including legal costs) and expenses incurred in connection with any claim by any party that its Intellectual Property Rights in the Goods have been infringed as a result of the supply of the Goods under this Contract or the Use of the Goods.

E9 Audit

E9.1 The Supplier shall keep and maintain until 6 years after the end of the Contract Period, or as long a period as may be agreed between the Parties, full and accurate records of the Contract including the Goods supplied under it, all expenditure reimbursed by the Authority, and all payments made by the Authority. The Supplier shall on request afford the Authority or the Authority's representatives such access to those records and processes as may be requested by the Authority in connection with the Contract.

E9.2 The Supplier agrees to make available to the Authority, free of charge, whenever requested, copies of audit reports obtained by the Supplier in relation to the Goods.

E9.3 The Supplier shall permit duly authorised representatives of the Authority and/or the National Audit Office to examine the Supplier's records and documents relating to the Contract and to provide such copies and oral or written explanations as may reasonably be required.

E9.4 The Supplier (and its agents) shall permit the Comptroller and Auditor General (and his appointed representatives) access free of charge during normal business hours on reasonable notice to all such documents (including computerised documents and data) and other information as the Comptroller and Auditor General may reasonably require for the purposes of his financial audit of the Authority and for carrying out examinations into the economy, efficiency and effectiveness with which the Authority has used its resources. The Supplier shall provide such explanations as are reasonably required for these purposes.

E10 Tax Compliance

E10.1 If, during the Contract Period, an Occasion of Tax Non-Compliance occurs, the Supplier shall:

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

(b) promptly give the Authority:

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

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

E10.2 If the Supplier or any Staff are liable to be taxed in the UK or to pay NICs in respect of consideration received under the Contract, the Supplier shall:

(a) at all times comply with ITEPA and all other statutes and regulations relating to income tax, and SSCBA and all other statutes and regulations relating to NICs, in respect of that consideration; and

(b) indemnify the Authority against any income tax, NICs and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made in connection with the supply of the Goods by the Supplier or any Staff.

F. CONTROL OF THE CONTRACT

F1 Failure to meet Requirements

F1.1 If the Authority informs the Supplier in writing that the Authority reasonably believes that any part of the Goods do not meet the requirements of the Contract or differs in any way from those requirements, and this is not as a result of a default by the Authority, the Supplier shall at its own expense re-schedule and supply the Goods in accordance with the requirements of the Contract within such reasonable time as may be specified by the Authority.

F1.2 The Authority may by notice to the Supplier reject any of the Goods which fail to conform to the approved sample or fail to meet the Specification. Such notice shall be given within a reasonable time after delivery to the Authority of such Goods. If the Authority rejects any of the Goods pursuant to this clause the Authority may (without prejudice to its other rights and remedies) either:

(a) where the Supplier has the Antigen in stock, have such Goods promptly, free of charge and in any event within ten (10) days, replaced by the Supplier with Goods which conform in all respects with the approved sample or with the Specification and due delivery shall not be deemed to have taken place until such replacement has occurred; or

(b) where the Supplier does not have the Antigen in stock, discuss and agree with the Supplier (both parties acting reasonably) a timetable for the prompt production of further amounts of the Antigen and provision by the Supplier, free of charge, of replacement Goods which conform in all respects with the approved sample or with the Specification and due delivery shall not be deemed to have taken place until such replacement has occurred; or

(c) treat the Contract as discharged by the Supplier's breach and obtain a refund (if payment for the Goods has already been made) from the Supplier in respect of the Goods concerned together with payment of any additional expenditure reasonably incurred by the Authority in obtaining other goods in replacement.

F1.3 The Authority will be deemed to have accepted the Goods if it expressly states the same in writing or fails to reject the Goods in accordance with clause F1.2.

F1.4 The issue by the Authority of a receipt note for delivery of the Goods shall not constitute any acknowledgement of the condition, quantity or nature of those Goods, or the Authority's acceptance of them.

F1.5 The Supplier hereby guarantees the Goods against faulty materials or workmanship for such period as may be specified in the Specification or, if no period is specified, for a period of 12 months from the date of manufacture. If the Authority shall within such period or within 25 Working Days thereafter give notice to the Supplier of any defect in any of the Goods as may have arisen during such period under proper and normal use, the Supplier shall (without prejudice to any other rights and remedies which the Authority may have) promptly remedy such defects (by replacement) free of charge.

F1.6 Any Goods rejected or returned by the Authority as described in clause F1.2 shall be returned to the Supplier at the Supplier's risk and expense.

F2 Monitoring of Contract Performance

F2.1 The Supplier shall immediately inform the Authority if any of the Goods are not being or are unable to be supplied, the reasons for non-performance, any corrective action and the date by which that action will be completed.

F2.2 At or around six (6) Months from the Commencement Date and each anniversary of the Commencement Date thereafter (each being a "**Review Date**"), the Authority shall carry out a review of the performance of the Supplier (**"Checkpoint Review"**). Without prejudice to the generality of the foregoing, the Authority may in respect of the period under review consider such items as (but not limited to): the Supplier's delivery of the Goods; the Supplier's contribution to innovation in the Authority; whether the Goods provide the Authority with best value for money; consideration of any changes which may need to be made to the Goods; a review of future requirements in relation to the Goods and progress against key milestones.

F2.3 The Supplier shall provide at its own cost any assistance reasonably required by the Authority to perform such Checkpoint Review including the provision of data and information.

F2.4 The Authority may produce a report (a "**Checkpoint Review Report**") of the results of each Checkpoint Review stating any areas of exceptional performance and areas for improvement in the provision of the Goods and where there is any shortfall in any aspect of performance reviewed as against the Authority's expectations and the Supplier's obligations under this Contract.

F2.5 The Authority shall give the Supplier a copy of the Checkpoint Review Report (if applicable). The Authority shall consider any Supplier comments and may produce a revised Checkpoint Review Report.

F2.6 The Supplier shall, within 10 Working Days of receipt of the Checkpoint Review Report (revised as appropriate) provide the Authority with a plan to address resolution of any shortcomings and implementation of improvements identified by the Checkpoint Review Report.

F2.7 Actions required to resolve shortcomings and implement improvements (either as a consequence of the Supplier's failure to meet its obligations under this Contract identified by the Checkpoint Review Report, or those which result from the Supplier's failure to meet the Authority's expectations notified to the Supplier or of which the Supplier ought reasonably to have been aware) shall be implemented at no extra charge to the Authority.

F2.8 In addition the Supplier shall:

(a) as may from time to time be reasonably requested by the Authority, attend further meetings with the Authority or other relevant third parties on an ad hoc basis; and

(b) provide to the Authority the reports described in paragraph 11 of the Specification at the corresponding reporting frequencies as also specified in that paragraph (**"Reports"**).

F3 Remedies for inadequate performance

F3.1 If the Authority reasonably believes the Supplier has committed a Material Breach it may, without prejudice to its rights under clause H2 (Termination on Default), do any of the following:

(a) without terminating the Contract, itself supply or procure the supply of all or part of the Goods until such time as the Supplier has demonstrated to the Authority's reasonable satisfaction that the Supplier will be able to supply the Goods in accordance with the Specification;

(b) without terminating the whole of the Contract, terminate the Contract in respect of some of the Goods only (whereupon a corresponding reduction in the Price shall be made) and thereafter itself supply or procure a third party to supply such part of the Goods;

(c) withhold or reduce payments to the Supplier in such amount as the Authority reasonably deems appropriate in each particular case; and/or

(d) terminate the Contract in accordance with clause H2.

F3.2 Without prejudice to its right under clause C3 (Recovery of Sums Due), the Authority may charge the Supplier for any costs reasonably incurred and any reasonable administration costs in respect of the supply of any part of the Goods by the Authority or a third party to the extent that such costs exceed the payment which would otherwise have been payable to the Supplier for such of the Goods.

F3.3 If the Authority reasonably believes the Supplier has failed to supply all or any part of the Goods in accordance with the Contract, professional or industry practice which could reasonably be expected of a competent and suitably qualified person, or any legislative or regulatory requirement, the Authority may give the Supplier notice specifying the way in which its performance falls short of the requirements of the Contract or is otherwise unsatisfactory.

F3.4 If the Supplier has been notified of a failure in accordance with clause F3.3 the Authority may:

(a) direct the Supplier to identify and remedy the failure within such time as may be specified by the Authority and to apply all such additional resources as are necessary to remedy that failure at no additional charge to the Authority within the specified timescale; and/or

(b) withhold or reduce payments to the Supplier in such amount as the Authority deems appropriate in each particular case until such failure has been remedied to the satisfaction of the Authority.

F3.5 If the Supplier has been notified of a failure in accordance with clause F3.3, it shall:

(a) use its best endeavours to immediately minimise the impact of such failure to the Authority and to prevent such failure from recurring; and

(b) immediately give the Authority such information as the Authority may request regarding what measures are being taken to comply with the obligations in this clause F3.5 and the progress of those measures until resolved to the satisfaction of the Authority.

F3.6 If, having been notified of any failure, the Supplier fails to remedy it in accordance with clauses F3.4 and F3.5 within the time specified by the Authority, the Authority may treat the continuing failure as a Material Breach and may terminate the Contract immediately on notice to the Supplier.

F4 Transfer and Sub-Contracting

F4.1 Except where clauses F4.5 and F4.6 both apply, the Supplier shall not transfer, charge, assign, sub-contract or in any other way dispose of the Contract or any part of it without Approval. All such documents shall be evidenced in writing and shown to the Authority on request. Sub-contracting any part of the Contract shall not relieve the Supplier of any of its obligations or duties under the Contract.

F4.2 The Supplier shall be responsible for the acts and/or omissions of its Sub-Contractors as though they are its own. If it is appropriate, the Supplier shall provide each Sub-Contractor with a copy of the Contract and obtain written confirmation from them that they will provide the Services fully in accordance with the Contract.

F4.3 The Supplier shall ensure that its Sub-Contractors and suppliers retain all records relating to the Services for at least six (6) years from the date of their creation and make them available to the Authority on request in accordance with the provisions of clause E9 (Audit). If any Sub-Contractor or supplier does not allow the Authority access to the records then the Authority shall have no obligation to pay any claim or invoice made by the Supplier on the basis of such documents or work carried out by the Sub-Contractor or supplier.

F4.4 If the Authority has consented to the award of a Sub-Contract, the Supplier shall ensure that:

(a) the Sub-Contract contains a right for the Supplier to terminate the Sub-Contract if the relevant Sub-Contractor does not comply in the performance of its contract with legal obligations in environmental, social or labour law;

(b) the Sub-Contractor includes a provision having the same effect as set out in clause F4.4(a) in any Sub-Contract which it awards; and

(c) copies of each Sub-Contract shall, at the request of the Authority, be sent by the Supplier to the Authority immediately.

F4.5 If the Authority believes there are:

(a) compulsory grounds for excluding a Sub-Contractor pursuant to regulation 57 of the Regulations, the Supplier shall replace or not appoint the Sub-Contractor; or

(b) non-compulsory grounds for excluding a Sub-Contractor pursuant to regulation 57 of the Regulations, the Authority may require the Supplier to replace or not appoint the Sub-Contractor and the Supplier shall comply with such requirement.

F4.6 Notwithstanding clause F4.1, the Supplier may assign to a third party (the "**Assignee**") the right to receive payment of the Price or any part thereof due to the Supplier (including any interest which the Authority incurs under clause C2 (Payment and VAT)). Any assignment under this clause F4.6 shall be subject to:

(a) reduction of any sums in respect of which the Authority exercises its right of recovery under clause C3 (Recovery of Sums Due);

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

(c) the Authority receiving notification under both clauses F4.7 and F4.8.

F4.7 If the Supplier assigns the right to receive the Price under clause F4.6, the Supplier or the Assignee shall notify the Authority in writing of the assignment and the date upon which the assignment becomes effective.

F4.8 The Supplier shall ensure that the Assignee notifies the Authority of the Assignee's contact information and bank account details to which the Authority shall make payment.

F4.9 The provisions of clause C2 shall continue to apply in all other respects after the assignment and shall not be amended without Approval.

F4.10 Subject to clause F4.11, the Authority may assign, novate or otherwise dispose of its rights and obligations under the Contract or any part thereof to:

(a) any Contracting Authority;

(b) any other body established or authorised by the Crown or under statute in order substantially to perform any of the functions that had previously been performed by the Authority; or

(c) any private sector body which substantially performs the functions of the Authority

provided that any such assignment, novation or other disposal shall not increase the burden of the Supplier's obligations under the Contract.

F4.11 Any change in the legal status of the Authority such that it ceases to be a Contracting Authority shall not, subject to clause F4.12, affect the validity of the Contract and the Contract shall bind and inure to the benefit of any successor body to the Authority.

F4.12 If the rights and obligations under the Contract are assigned, novated or otherwise disposed of pursuant to clause F4.10 to a body which is not a Contracting Authority or if there is a change in the legal status of the Authority such that it ceases to be a Contracting Authority (in the remainder of this clause both such bodies being referred to as the **"Transferee"**):

(a) the rights of termination of the Authority in clauses H1 and H2 shall be available to the Supplier in respect of the Transferee; and

(b) the Transferee shall only be able to assign, novate or otherwise dispose of its rights and obligations under the Contract or any part thereof with the prior consent in writing of the Supplier.

F4.13 The Authority may disclose to any Transferee any Confidential Information of the Supplier which relates to the performance of the Supplier's obligations under the Contract. In such circumstances the Authority shall authorise the Transferee to use such Confidential

Information only for purposes relating to the performance of the Supplier's obligations under the Contract and for no other purpose and shall take all reasonable steps to ensure that the Transferee gives a confidentiality undertaking in relation to such Confidential Information.

F4.14 Each Party shall at its own cost and expense carry out, or use all reasonable endeavours to ensure the carrying out of, whatever further actions (including the execution of further documents) the other Party reasonably requires from time to time for the purpose of giving that other Party the full benefit of the provisions of the Contract.

F5 Waiver

F5.1 The failure of either Party to insist upon strict performance of any provision of the Contract, or the failure of either Party to exercise, or any delay in exercising, any right or remedy shall not constitute a waiver of that right or remedy and shall not cause a diminution of the obligations established by the Contract.

F5.2 No waiver shall be effective unless it is expressly stated to be a waiver and communicated to the other Party in writing in accordance with clause A4 (Notices and Communications).

F5.3 A waiver of any right or remedy arising from a breach of the Contract shall not constitute a waiver of any right or remedy arising from any other or subsequent breach of the Contract.

F6 Variation

F6.1 If, at any time after the Commencement Date, the Authority's requirements change the Authority may request a Variation subject to the terms of this Clause F6.

F6.2 The Authority may request a Variation by notifying the Supplier in writing of the Variation and giving the Supplier sufficient information to assess the extent of the Variation and consider whether any change to the Price is required in order to implement the Variation within a reasonable time limit specified by the Authority. If the Supplier accepts the Variation it shall confirm it in writing.

F6.3 If the Supplier is unable to accept the Variation or where the Parties are unable to agree a change to the Price, the Authority may:

(a) allow the Supplier to fulfil its obligations under the Contract without the Variation to the Specification; or

(b) terminate the Contract immediately except where the Supplier has already delivered all or part of the Goods or where the Supplier can show evidence of substantial work being carried out to fulfil the requirements of the Specification; and in such case the Parties shall attempt to agree upon a resolution to the matter. If a resolution cannot be reached, the matter shall be dealt with under the Dispute Resolution procedure detailed in clause I2 (Dispute Resolution).

F6.4 No Variation will take effect unless and until it is recorded in a validly executed CCN. Execution of a CCN is made via electronic signature as described in clause 1.2 of Section 1 of the Contract.

F6.5 A CCN takes effect on the date on which the Parties communicate acceptance of the CCN via Bravo and, on the date it communicates its acceptance of the CCN in this way, the Supplier is deemed to warrant and represent that the CCN has been executed by a duly authorised representative of the Supplier in addition to the warranties and representations set out in clause G2.

F6.6 The provisions of clauses F6.4 and F6.5 may be varied in an emergency if it is not practicable to obtain the Authorised Representative's approval within the time necessary to make the Variation in order to address the emergency. In an emergency, Variations may be approved by a different representative of the Authority. However, the Authorised Representative shall have the right to review such a Variation and require a CCN to be entered into on a retrospective basis which may itself vary the emergency Variation.

F7 Severability

F7.1 If any provision of the Contract which is not of a fundamental nature is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions of the Contract shall continue in full force and effect as if the Contract had been executed with the invalid, illegal or unenforceable provision eliminated.

F8 Remedies Cumulative

F8.1 Except as expressly provided in the Contract all remedies available to either Party for breach of the Contract are cumulative and may be exercised concurrently or separately, and the exercise of any one remedy shall not be deemed an election of such remedy to the exclusion of other remedies.

F9 Entire Agreement

F9.1 The Contract constitutes the entire agreement between the Parties in respect of the matters dealt with therein. The Contract supersedes all prior negotiations between the Parties and all representations and undertakings made by one Party to the other, whether written or oral, except that this clause shall not exclude liability in respect of any fraudulent misrepresentation.

F10 Counterparts

F10.1 The Contract may be executed in counterparts, each of which when executed and delivered shall constitute an original but all counterparts together shall constitute one and the same instrument.

G. LIABILITIES

G1 Liability, Indemnity and Insurance

G1.1 Neither Party limits its liability for:

(a) death or personal injury caused by its negligence;

(b) fraud or fraudulent misrepresentation;

(c) any breach of any obligations implied by section 12 of the Sale of Goods Act 1979 or section 2 of the Supply of Goods and Services Act 1982;

(d) any breach of clauses D1, E1 or E4;

(e) any breach of Schedule 7; or

(f) any liability to the extent it cannot be limited or excluded by Law.

G1.2 Subject to clauses G1.1, G1.3 and G1.4, the Supplier shall indemnify the Authority and keep the Authority indemnified fully against all claims, proceedings, demands, charges, actions, damages, costs, breach of statutory duty, expenses and any other liabilities which may arise out of the supply, or the late or purported supply, of the Goods or the performance or non-performance by the Supplier of its obligations under the Contract, including in respect of any death or personal injury, loss of or damage to property, financial loss arising from any advice given or omitted to be given by the Supplier, any third party claims, or any other loss which is caused directly by any act or omission of the Supplier.

G1.3 Subject to clause G1.1 the Supplier's aggregate liability in respect of the Contract shall not exceed ten million pounds (£10,000,000.00).

G1.4 The Supplier shall not be responsible for any injury, loss, damage, cost or expense if and to the extent that it is caused by the negligence or wilful misconduct of the Authority or by breach by the Authority of its obligations under the Contract.

G1.5 The Authority may recover from the Supplier the following losses incurred by the Authority to the extent they arise as a result of a Default by the Supplier:

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

(b) any wasted expenditure or charges;

(c) the additional costs of procuring a Replacement Supplier for the remainder of the Contract Period and or replacement deliverables which shall include any incremental costs associated with the Replacement Supplier and/or replacement deliverables above those which would have been payable under the Contract;

(d) any compensation or interest paid to a third party by the Authority; and

(e) any fine or penalty incurred by the Authority pursuant to Law and any costs incurred by the Authority in defending any proceedings which result in such fine or penalty.

G1.6 Subject to clauses G1.1 and G1.5, neither Party shall be liable to the other for any:

(a) loss of profits, turnover, business opportunities or damage to goodwill (in each case whether direct or indirect); or

(b) indirect, special or consequential loss.

G1.7 Unless otherwise specified by the Authority, the Supplier shall, with effect from the Commencement Date for such period as necessary to enable the Supplier to comply with its obligations herein, take out and maintain with a reputable insurance company a policy or policies of insurance providing not less than £10,000,000 of cover in respect of all risks which may be incurred by the Supplier, arising out of the Supplier's performance of its obligations under the Contract, including death or personal injury, loss of or damage to property or any other loss. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Supplier. Such insurance shall be maintained for the duration of the Contract Period and for a minimum of 6 years following the end of the Contract.

G1.8 The Supplier shall hold employer's liability insurance (not less than £10,000,000 of coverage) in respect of Staff and such insurance shall be in accordance with any legal requirement from time to time in force.

G1.9 The Supplier shall give the Authority, on request, copies of all insurance policies referred to in this clause or a broker's verification of insurance to demonstrate that the appropriate cover is in place, together with receipts or other evidence of payment of the latest premiums due under those policies.

G1.10 If the Supplier does not give effect to and maintain the insurances required by the provisions of the Contract, the Authority may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Supplier.

G1.11 The provisions of any insurance or the amount of cover shall not relieve the Supplier of any liabilities under the Contract.

G1.12 The Supplier shall not take any action or fail to take any reasonable action, or (to the extent that it is reasonably within its power) permit anything to occur in relation to the Supplier, which would entitle any insurer to refuse to pay any claim under any insurance policy in which the Supplier is an insured, a co-insured or additional insured person.

G2 Warranties and Representations

G2.1 The Supplier warrants and represents on the Commencement Date and for the Contract Period that:

(a) it has full capacity and authority and all necessary consents to enter into and perform the Contract and that the Contract is executed by a duly authorised representative of the Supplier;

(b) in entering the Contract it has not committed any fraud;

(c) as at the Commencement Date, all information contained in the Tender or other offer made by the Supplier to the Authority remains true, accurate and not misleading, save as may have been specifically disclosed in writing to the Authority prior to execution of the Contract and in addition, that it will advise the Authority of any fact, matter or circumstance of which it may become aware which would render such information to be false or misleading;

(d) no claim is being asserted and no litigation, arbitration or administrative proceeding is presently in progress or, to the best of its knowledge and belief, pending or threatened against it or any of its assets which will or might have an adverse effect on its ability to perform its obligations under the Contract;

(e) it is not subject to any contractual obligation, compliance with which is likely to have a material adverse effect on its ability to perform its obligations under the Contract;

(f) no proceedings or other steps have been taken and not discharged (nor, to the best of its knowledge, are threatened) for the winding up of the Supplier or for its dissolution or for the appointment of a receiver, administrative receiver, liquidator, manager, administrator or similar officer in relation to any of the Supplier's assets or revenue;

(g) it owns, or has obtained or is able to obtain valid licences for, all Intellectual Property Rights that are necessary for the performance of its obligations under the Contract;

(h) any person engaged by the Supplier shall be engaged on terms which do not entitle them to any Intellectual Property Right in any IP Materials;

(i) in the three (3) years (or period of existence where the Supplier has not been in existence for three (3) years) prior to the date of the Contract:

i) it has conducted all financial accounting and reporting activities in compliance in all material respects with the generally accepted accounting principles that apply to it in any country where it files accounts;

ii) it has been in full compliance with all applicable securities and tax laws and regulations in the jurisdiction in which it is established; and

iii) it has not done or omitted to do anything which could have a material adverse effect on its assets, financial condition or position as an ongoing business concern or its ability to fulfil its obligations under the Contract;

(j) it has and will continue to hold all necessary (if any) regulatory approvals from the Regulatory Bodies necessary to perform its obligations under the Contract; and

(k) it has notified the Authority in writing of any Occasions of Tax Non-Compliance and any litigation in which it is involved that is in connection with any Occasion of Tax Non-Compliance.

G2.2 The Supplier warrants and undertakes that:

(a) all Antigen and vials of the Vaccine will comply with the Specification and the Marketing Authorisation;

(b) it will manufacture the Antigen and the Vaccine in accordance with Good Laboratory Practice, Good Manufacturing Practice and the principles of the then-current Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) and the European Pharmacopoeia monographs and guidelines;

(c) the Vaccine is suitable for the treatments and purposes as referred to in the Specification and this Contract;

(d) all vials of the Vaccine will have at least the shelf life referred to at Clause B1.6(c); and

(e) its Business Continuity Plan set out in Schedule 8 is sufficient to ensure continuity of supply of the Vaccine to the Authority in accordance with this Contract in the event of any manufacturing site failure including emergency maintenance work.

G2.3 The Supplier warrants and undertakes that the Supplier shall comply with all Laws and regulations applicable to the Vaccine, including relevant provisions of:

(a) Title II of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

(b) all Laws, regulations and guidelines within the UK implementing the legislation referred to in Clause G2.3(a) above;

(c) any guidelines or directions or like documents that may be published during the Contract Period by the VMD, MHRA or EMA and are applicable to the Vaccine at the time of manufacture; and

(d) the Medicines Acts 1968 and 1971 and the Veterinary Medicines Regulations 2012 (SI 2013/2033) as amended and the regulations made thereunder in the respect of the sale, supply, importation, manufacture or assembly of the Vaccine. For the avoidance of doubt the Veterinary Medicines Regulations 2012 (SI 2013/2033) as amended shall take precedence in all matters covered therein.

G3 Force Majeure

G3.1 Subject to the remaining provisions of this clause G3, a Party may claim relief under this clause G3 from liability for failure to meet its obligations under the Contract for as long as and only to the extent that the performance of those obligations is directly affected by a Force Majeure Event. Any failure or delay by the Supplier in performing its obligations under the Contract which results from a failure or delay by an agent, Sub-Contractor or supplier shall be regarded as due to a Force Majeure Event only if that agent, Sub-Contractor or supplier is itself impeded by a Force Majeure Event from complying with an obligation to the Supplier.

G3.2 The Affected Party shall as soon as reasonably practicable issue a Force Majeure Notice, which shall include details of the Force Majeure Event, its effect on the obligations of the Affected Party and any action the Affected Party proposes to take to mitigate its effect.

G3.3 If the Supplier is the Affected Party, it shall not be entitled to claim relief under this clause G3 to the extent that consequences of the relevant Force Majeure Event:

(a) are capable of being mitigated, but the Supplier has failed to do so; and/or

(b) should have been foreseen and prevented or avoided by a prudent provider of goods similar to the Goods, operating to the standards required by the Contract.

G3.4 Subject to clause G3.5, as soon as practicable after the Affected Party issues the Force Majeure Notice, and at regular intervals thereafter, the Parties shall consult in good faith and use reasonable endeavours to agree any steps to be taken and an appropriate timetable in which those steps should be taken, to enable continued provision of the Services affected by the Force Majeure Event.

G3.5 The Parties shall at all times following the occurrence of a Force Majeure Event and during its subsistence use their respective reasonable endeavours to prevent and mitigate the effects of the Force Majeure Event. Where the Supplier is the Affected Party, it shall take all steps in accordance with Good Industry Practice to overcome or minimise the consequences of the Force Majeure Event.

G3.6 If, as a result of a Force Majeure Event:

(a) an Affected Party fails to perform its obligations in accordance with the Contract, then during the continuance of the Force Majeure Event:

i) the other Party shall not be entitled to exercise its rights to terminate the Contract in whole or in part as a result of such failure pursuant to clause H2.1 or H2.3; and

ii) neither Party shall be liable for any Default arising as a result of such failure;

(b) the Supplier fails to perform its obligations in accordance with the Contract it shall be entitled to receive payment of the Price (or a proportional payment of it) only to the extent that the Goods (or some of the Goods) continue to be supplied in accordance with the terms of the Contract during the occurrence of the Force Majeure Event.

G3.7 The Affected Party shall notify the other Party as soon as practicable after the Force Majeure Event ceases or no longer causes the Affected Party to be unable to comply with its obligations under the Contract.

G3.8 Relief from liability for the Affected Party under this clause G3 shall end as soon as the Force Majeure Event no longer causes the Affected Party to be unable to comply with its obligations under the Contract and shall not be dependent on the serving of notice under clause G3.7.

H. DEFAULT, DISRUPTION AND TERMINATION

H1 Termination on Insolvency and Change of Control

H1.1 The Authority may terminate the Contract (or its requirement for any one or more strain(s) of Antigen in accordance with clause H12) with immediate effect by notice and without compensation to the Supplier where the Supplier is a company and in respect of the Supplier:

(a) a proposal is made for a voluntary arrangement within Part I of the Insolvency Act 1986 or of any other composition scheme or arrangement with, or assignment for the benefit of, its creditors;

(b) a shareholders' meeting is convened for the purpose of considering a resolution that it be wound up or a resolution for its winding-up is passed (other than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation);

(c) a petition is presented for its winding up (which is not dismissed within 14 days of its service) or an application is made for the appointment of a provisional liquidator or a creditors' meeting is convened pursuant to section 98 of the Insolvency Act 1986;

(d) a receiver, administrative receiver or similar officer is appointed over the whole or any part of its business or assets;

(e) an application order is made either for the appointment of an administrator or for an administration order, an administrator is appointed, or notice of intention to appoint an administrator is given;

(f) it is or becomes insolvent within the meaning of section 123 of the Insolvency Act 1986;

(g) being a "small company" within the meaning of section 247(3) of the Companies Act 1985, a moratorium comes into force pursuant to Schedule A1 of the Insolvency Act 1986; or

(h) any event similar to those listed in H1.1(a)-(g) occurs under the law of any other jurisdiction.

H1.2 The Supplier shall notify the Authority immediately in writing of any proposal or negotiations which will or may result in a merger, take-over, change of control, change of name or status including where the Supplier undergoes a change of control within the meaning of section 1124 of the Corporation Taxes Act 2010 (**"Change of Control"**). The Authority may terminate the Contract (or its requirement for any one or more strain(s) of Antigen in accordance with clause H12) with immediate effect by notice and without compensation to the Supplier within 6 Months of:

(a) being notified that a Change of Control has occurred; or

(b) where no notification has been made, the date that the Authority becomes aware of the Change of Control,

but shall not be permitted to terminate where Approval was granted prior to the Change of Control.

H2 Termination on Default

H2.1 The Authority may terminate the Contract (or its requirement for any one or more strain(s) of Antigen in accordance with clause H12) with immediate effect by notice if the Supplier commits a Default and:

(a) the Supplier has not remedied the Default to the satisfaction of the Authority within 25 Working Days or such other period as may be specified by the Authority, after issue of a notice specifying the Default and requesting it to be remedied;

(b) the Default is not, in the opinion of the Authority, capable of remedy; or

(c) the Default is a Material Breach.

H2.2 If, through any Default of the Supplier, data transmitted or processed in connection with the Contract is either lost or sufficiently degraded as to be unusable, the Supplier shall be liable for the cost of reconstitution of that data and shall reimburse the Authority in respect of any charge levied for its transmission and any other costs charged in connection with such Default.

H2.3 If the Authority fails to pay the Supplier undisputed sums of money when due, the Supplier shall give notice to the Authority of its failure to pay. If the Authority fails to pay such undisputed sums within 90 Working Days of the date of such notice, the Supplier may terminate the Contract in writing with immediate effect, save that such right of termination shall not apply where the failure to pay is due to the Authority exercising its rights under clause C3.1 (Recovery of Sums Due) or to a Force Majeure Event.

H3 Termination on Notice

H3.1 The Authority may terminate the Contract at any time by giving not less than 30 days' notice to the Supplier.

H4 Other Termination Grounds

H4.1 The Authority may terminate the Contract (or its requirement for any one or more strain(s) of Antigen in accordance with clause H12) on written notice to the Supplier if:

(a) the Contract has been subject to a substantial modification which requires a new procurement procedure pursuant to regulation 72(9) of the Regulations;

(b) the Supplier was, at the time the Contract was awarded, in one of the situations specified in regulation 57(1) of the Regulations, including as a result of the application of regulation 57(2), and should therefore have been excluded from the procurement procedure which resulted in its award of the Contract;

(c) the Contract should not have been awarded to the Supplier in view of a serious infringement of the obligations under the Treaties and the Regulations that has been declared by the Court of Justice of the European Union in a procedure under Article 258 of the TFEU;

(d) the Supplier has not, in performing the Services, complied with its legal obligations in respect of environmental, social or labour law;

(e) if the Licensing Authority or other relevant regulatory body advises the Authority not to use the Vaccine; or

(f) pursuant to Clause B4.9, Clause B9.2, Clause G3.6 or Clause D1.6.

H5 Consequences of Expiry or Termination

H5.1 If the Authority terminates the Contract (or its requirement for any one or more strain(s) of Antigen in accordance with clause H12) under clauses H2 or H4 and makes other arrangements for the supply of the Goods the Authority may recover from the Supplier the cost reasonably incurred of making those other arrangements and any additional expenditure incurred by the Authority throughout the remainder of the Contract Period.

H5.2 If Contract is terminated (or partially terminated in accordance with clause H12) under clauses H2 or H4 the Authority shall make no further payments to the Supplier (for Goods supplied by the Supplier prior to termination and in accordance with the Contract but where the payment has yet to be made by the Authority), until the Authority has established the final cost of making the other arrangements envisaged under this clause.

H5.3 If the Authority terminates the Contract under clause H3 the Authority shall make no further payments to the Supplier except for Vaccines Delivered to the Authority by the Supplier prior to termination and in accordance with the Contract but where the payment has yet to be made by the Authority.

H5.4 Save as otherwise expressly provided in the Contract:

(a) termination or expiry of the Contract shall be without prejudice to any rights, remedies or obligations accrued under the Contract prior to termination or expiration and nothing in the Contract shall prejudice the right of either Party to recover any amount outstanding at such termination or expiry; and

(b) termination or expiry of the Contract (howsoever occurring) shall not affect the continuing rights, remedies or obligations of the Authority or the Supplier under clauses B1.7 (Specification), C2 (Payment and VAT), C3 (Recovery of Sums Due), D1 (Prevention of Fraud and Bribery), E2 (Data Protection), E3 (Official Secrets Acts 1911 to 1989, Section 182 of the Finance Act 1989), E4 (Confidential Information), E5 (Freedom of Information), E8 (Intellectual Property Rights), E9 (Audit), F8 (Remedies Cumulative), G1 (Liability, Indemnity and Insurance), H5 (Consequences of Expiry or Termination), H7 (Recovery upon Termination) and I1 (Governing Law and Jurisdiction).

H5.6 Following termination of this Contract for any reason other than effluxion of time or an inability of the Supplier to supply the Vaccines, the Authority shall be entitled to require the Supplier at the prices prevailing as at the date of termination to Deliver further vials of

the Vaccine on the terms of this Contract to the extent that they relate to the Delivery of Vaccine in such volumes as may be necessary to enable the Authority to meet demand for the Vaccine existing at the date of termination and for a period of 6 months thereafter subject to payment for such vials of the Vaccine upon Delivery in accordance with Clause C.

H5.7 In the event of termination (including partial termination in accordance with clause H12) pursuant to Clauses B9.2, should the Authority inform the Supplier that the Authority no longer requires unused vials of the Vaccine, the Supplier shall:

(a) refund to the Authority the price paid for all unused vials of the Vaccine Delivered to the Authority as at the date of termination and pay such refund to the Authority within 30 days of the date of the Authority's invoice for the same; and

(b) at its own expense remove all unused vials of the Vaccine Delivered to the Authority as at the date of termination within fourteen (14) days of the date of notification by the Authority that the Authority wishes to return unused vials of the Vaccine. Risk and title in such Vaccines shall pass to the Supplier on the date of such notification by the Authority and if the Supplier fails to remove the Vaccines within fourteen (14) days the Authority may return the Vaccines at the Supplier's expense.

H5.8 In the event of termination (or partial termination in accordance with clause H12) of this Contract under Clause B4.9, Clause H1.1, H2.1 or Clause D1.6 and without prejudice to any other right or remedy of the Authority and/or any Administering Entity, and/or Devolved Administration the Authority and/or any Administering Entity and/or Devolved Administration shall be entitled to claim the Loss Costs from the Supplier arising as a result of such termination provided that the Authority and/or Administering Entity and/or Devolved Administration, as appropriate, shall use its/their reasonable endeavours to mitigate the same. The Supplier shall pay such Loss Costs to the Authority within 30 days of the date of the Authority's invoice for the same.

H6 Disruption

H6.1 The Supplier shall take reasonable care to ensure that in the performance of its obligations under the Contract it does not disrupt the operations of the Authority, its employees or any other contractor employed by the Authority.

H6.2 The Supplier shall immediately inform the Authority of any actual or potential industrial action, whether such action be by its own employees or others, which affects or might affect its ability at any time to perform its obligations under the Contract.

H6.3 If there is industrial action by the Staff, the Supplier shall seek Approval to its proposals to continue to perform its obligations under the Contract.

H6.4 If the Supplier's proposals referred to in clause H6.3 are considered insufficient or unacceptable by the Authority acting reasonably, then the Contract may be terminated with immediate effect by the Authority by notice.

H6.5 If the Supplier is unable to deliver the Goods owing to disruption of the Authority's normal business, the Supplier may request a reasonable allowance of time, and, in addition, the Authority will reimburse any additional expense reasonably incurred by the Supplier as a direct result of such disruption.

H7 Recovery upon Termination

H7.1 On termination of the Contract for any reason:

(a) the Supplier shall at its cost immediately return to the Authority all Confidential Information, Personal Data and IP Materials in its possession or in the possession or under the control of any permitted suppliers or Sub-Contractors, which was obtained or produced in the course of providing the Goods;

(b) the Supplier shall at its cost assist and co-operate with the Authority to ensure an orderly transition of the provision of the Goods to the Authority or a Replacement Contractor and/or the completion of any work in progress; and

(c) at the Authority's discretion the provisions of paragraph 4 of the Specification shall apply in respect of any stocks of Antigen stored by the Supplier on behalf of the Authority at the date of termination.

H7.2 If the Supplier does not comply with clause H7.1(a), the Authority may recover possession thereof and the Supplier grants a licence to the Authority or its appointed agents to enter (for the purposes of such recovery) any premises of the Supplier or its permitted suppliers or Sub-Contractors where any such items may be held.

H8 Retendering and Handover

H8.1 Within 21 days of being requested by the Authority, the Supplier shall provide, and thereafter keep updated, in a fully indexed and catalogued format, all the information necessary to enable the Authority to issue tender documents for the future supply of the Goods.

H8.2 The Authority shall take all necessary precautions to ensure that the information referred to in clause H8.1 is given only to potential providers who have qualified to tender for the future supply of the Goods.

H8.3 The Authority shall require that all potential providers treat the information in confidence; that they do not communicate it except to such persons within their organisation and to such extent as may be necessary for the purpose of preparing a response to an invitation to tender issued by the Authority; and that they shall not use it for any other purpose.

H8.4 The Supplier shall indemnify the Authority against any claim made against the Authority at any time by any person in respect of any liability incurred by the Authority arising from any deficiency or inaccuracy in information which the Supplier is required to provide under clause H8.1.

H8.5 The Supplier shall allow access to it's premises in the presence of the Authorised Representative, to any person representing any potential provider whom the Authority has selected to tender for the future supply of the Goods.

H8.6 If access is required to the Supplier’s premises for the purposes of clause H8.5, the Authority shall give the Supplier 7 days’ notice of a proposed visit together with a list showing the names of all persons who will be visiting. Their attendance shall be subject to compliance with the Supplier’s security procedures, subject to such compliance not being in conflict with the objectives of the visit.

H8.7 The Supplier shall co-operate fully with the Authority during any handover at the end of the Contract. This co-operation shall include allowing full access to, and providing copies of, all documents, reports, summaries and any other information necessary in order to achieve an effective transition without disruption to routine operational requirements.

H8.8 Within 10 Working Days of being requested by the Authority, the Supplier shall transfer to the Authority, or any person designated by the Authority, free of charge, all computerised filing, recording, documentation, planning and drawing held on software and utilised in the

provision of the Services. The transfer shall be made in a fully indexed and catalogued disk format, to operate on a proprietary software package identical to that used by the Authority.

H9 Exit Management

H9.1 Upon termination the Supplier shall render reasonable assistance to the Authority to the extent necessary to effect an orderly assumption by a Replacement Supplier in accordance with the procedure set out in clause H10.

H10 Exit Procedures

H10.1 Where the Authority requires a continuation of all or any of the supply of Goods on expiry or termination of this Contract by engaging a third party to supply them, the Supplier shall co-operate fully with the Authority and any such third party and shall take all reasonable steps to ensure the timely and effective transfer of the supply of the Goods without disruption to routine operational requirements.

H10.2 The following commercial approach shall apply to the transfer of the supply of the Goods if the Supplier:

(a) does not have to use resources in addition to those normally used to supply the Goods prior to termination or expiry, there shall be no change to the Price; or

(b) reasonably incurs additional costs, the Parties shall agree a Variation to the Price based on the Supplier's rates either set out in Schedule 2 or forming the basis for the Price.

H10.3 When requested to do so by the Authority, the Supplier shall deliver to the Authority details of all licences for software used in the supply of the Goods including the software licence agreements.

H10.4 Within one Month of receiving the software licence information described above, the Authority shall notify the Supplier of the licences it wishes to be transferred, and the Supplier shall provide for the approval of the Authority a plan for licence transfer.

H11 Knowledge Retention

H11.1 The Supplier shall co-operate fully with the Authority in order to enable an efficient and detailed knowledge transfer from the Supplier to the Authority on the completion or earlier termination of the Contract and in addition, to minimise any disruption to routine operational requirements. To facilitate this transfer, the Supplier shall provide the Authority free of charge with full access to its Staff, and in addition, copies of all documents, reports, summaries and any other information requested by the Authority. The Supplier shall comply with the Authority's request for information no later than 15 Working Days from the date that that request was made.

H12 Partial Termination

H12.1 Notwithstanding the provisions of paragraph 1.13 of the Specification, in any of the circumstances in clauses H1, H2 and H4 by which the Authority may terminate the Contract, the Authority may instead terminate its requirement for any one or more strain(s) of Antigen, and:

(a) any unused doses of such Antigen or Vaccines developed from such Antigen shall, at the Authority's option, be dealt with in accordance with paragraph 4 of the

Specification or disposed of by the Supplier at its own cost and in compliance with all applicable Laws; and

(b) the provisions of clause H5 shall apply as detailed therein in respect of such partial termination of the Contract.

I. DISPUTES AND LAW

I1 Governing Law and Jurisdiction

I1.1 Subject to the provisions of clause I2 the Contract, including shall be governed by and interpreted in accordance with English Law and shall be subject to the jurisdiction of the Courts of England and Wales. The submission to such jurisdiction shall not limit the right of the Authority to take proceedings against the Supplier in any other court of competent jurisdiction, and the taking of proceedings in any other court of competent jurisdiction shall not preclude the taking of proceedings in any other jurisdiction whether concurrently or not.

I2 Dispute Resolution

I2.1 The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Contract within 20 Working Days of either Party notifying the other of the dispute and such efforts shall involve the escalation of the dispute to the finance director of the Supplier and the commercial director of the Authority.

I2.2 Nothing in this dispute resolution procedure shall prevent the Parties from seeking from any court of competent jurisdiction an interim order restraining the other Party from doing any act or compelling the other Party to do any act.

I2.3 If the dispute cannot be resolved by the Parties pursuant to clause I2.1 either Party may refer it to mediation pursuant to the procedure set out in clause I2.5.

I2.4 The obligations of the Parties under the Contract shall not cease, or be suspended or delayed by the reference of a dispute to mediation (or arbitration) and the Supplier and the Staff shall comply fully with the requirements of the Contract at all times.

I2.5 The procedure for mediation and consequential provisions relating to mediation are as follows:

(a) a neutral adviser or mediator (the **"Mediator"**) shall be chosen by agreement between the Parties or, if they are unable to agree upon a Mediator within 10 Working Days after a request by one Party to the other or if the Mediator agreed upon is unable or unwilling to act, either Party shall within 10 Working Days from the date of the proposal to appoint a Mediator or within 10 Working Days of notice to either Party that he is unable or unwilling to act, apply to the Centre for Effective Dispute Resolution to appoint a Mediator;

(b) the Parties shall within 10 Working Days of the appointment of the Mediator meet with him in order to agree a programme for the exchange of all relevant information and the structure to be adopted for negotiations. If appropriate, the Parties may at any stage seek assistance from the Centre for Effective Dispute Resolution to provide guidance on a suitable procedure;

(c) unless otherwise agreed, all negotiations connected with the dispute and any settlement agreement relating to it shall be conducted in confidence and without prejudice to the rights of the Parties in any future proceedings;

(d) if the Parties reach agreement on the resolution of the dispute, the agreement shall be recorded in writing and shall be binding on the Parties once it is signed by their duly authorised representatives;

(e) failing agreement, either of the Parties may invite the Mediator to provide a non-binding but informative written opinion. Such an opinion shall be provided on a without prejudice basis and shall not be used in evidence in any proceedings relating to the Contract without the prior written consent of both Parties; and

(f) if the Parties fail to reach agreement within 60 Working Days of the Mediator being appointed, or such longer period as may be agreed by the Parties, then any dispute or difference between them may be referred to the Courts unless the dispute is referred to arbitration pursuant to the procedures set out in clause I2.6.

I2.6 Subject to clause I2.2, the Parties shall not institute court proceedings until the procedures set out in clauses I2.1 and I2.3 have been completed save that:

(a) The Authority may at any time before court proceedings are commenced, serve a notice on the Supplier requiring the dispute to be referred to and resolved by arbitration in accordance with clause I2.7;

(b) if the Supplier intends to commence court proceedings, it shall serve notice on the Authority of its intentions and the Authority shall have 21 days following receipt of such notice to serve a reply on the Supplier requiring the dispute to be referred to and resolved by arbitration in accordance with clause I2.7; and

(c) the Supplier may request by notice to the Authority that any dispute be referred and resolved by arbitration in accordance with clause I2.7, to which the Authority may consent as it sees fit.

I2.7 If any arbitration proceedings are commenced pursuant to clause I2.6,

(a) the arbitration shall be governed by the provisions of the Arbitration Act 1996 and the Authority shall give a notice of arbitration to the Supplier (the **"Arbitration Notice"**) stating:

i) that the dispute is referred to arbitration; and

ii) providing details of the issues to be resolved;

(b) the London Court of International Arbitration (**"LCIA"**) procedural rules in force at the date that the dispute was referred to arbitration in accordance with I2.7(b) shall be applied and are deemed to be incorporated by reference to the Contract and the decision of the arbitrator shall be binding on the Parties in the absence of any material failure to comply with such rules;

(c) the tribunal shall consist of a sole arbitrator to be agreed by the Parties;

(d) if the Parties fail to agree the appointment of the arbitrator within 10 days of the Arbitration Notice being issued by the Authority under clause I2.7(a) or if the person appointed is unable or unwilling to act, the arbitrator shall be appointed by the LCIA;

(e) the arbitration proceedings shall take place in London and in the English language; and

(f) the arbitration proceedings shall be governed by, and interpreted in accordance with, English Law.

SCHEDULE 1 – SPECIFICATION

This Section sets out the Authority's requirements.

Glossary

"APHA"	Means the Animal and Plant Health Agency, an Executive Agency of DEFRA.
"Batch Release"	Means an authorisation from VMD for the release of a batch of formulated Vaccine for use within the UK market.
"Buy-Back"	Means when the Supplier buys back from the Authority unused Antigen or Vaccine.
"Day Zero"	Means the day on which a Delivery Order is placed for the formulation of Vaccine for delivery to the GB Storage Facility ready for distribution.
"DEFRA"	Means the Authority
"European Pharmacopoeia"	Means the EU pharmacopoeia which provides common quality standards throughout the human and veterinary pharmaceutical industry in Europe to control the quality of medicines, and the substances used to manufacture them.
"European Union Vaccine Bank"	Means the vaccine bank created by the European Union to provide member states with access to vaccines
"EU"	Means the European Union
"Export Licence"	Means an authorisation from the Supplier's home country to export the formulated Vaccine
"FMDV"	Means Foot and Mouth Disease Virus
"Great Britain" or "GB"	Means England, Scotland and Wales
"OIE"	Means the Office International des Epizooties (World Organisation for Animal Health)
"PO"	Means a Purchase Order
"VDAs"	Means Vaccination Delivery Agents, appointed under a separate Contract(s) by the Authority for the delivery of a vaccination programme
"UK"	Means the United Kingdom of Great Britain and Northern Ireland

1.0 BACKGROUND TO THE REQUIREMENT

1.1 The Animal and Plant Health Agency (APHA) is an executive agency that works on behalf of the Authority, Scottish Government and Welsh Government, from sites across Great Britain. One of its principal functions is the safeguarding of animal and plant health for the benefit of people, the environment and the economy.

1.2 The Authority appoints APHA to act as its contract manager for this Contract (**"Contract Manager"**). APHA undertakes scientific research in areas such as bacterial, viral, prion and parasitic diseases and vaccines, and food safety and act as an international reference laboratory for many farm animal diseases.

1.3 The Authority currently has access to the European Union Vaccine Bank. The UK may / will cease to have access to the European Vaccine Bank from 23:00 on 29th March 2019; or during the implementation period following the United Kingdom exiting the EU.

1.4 The Authority wishes to guarantee access to a stock of Antigen for a variety of Foot and Mouth Disease (FMDV) virus strains, and for the production and delivery of Vaccine to the UK, should formulated Vaccine be required in the event of an FMDV outbreak in the UK or a neighbouring country.

1.5 The initial requirements are for a basic level of resilience, sufficient to protect three hundred and forty thousand [340,000] cattle with four (4) separate / individual Vaccine strains. The Antigen held must be suitable to formulate Vaccine to protect sheep and pigs, as well as cattle.

1.6 During the life of the Contract the Authority will review its requirements and this may include increasing the number of doses or Vaccine Antigen strains held.

Scope of the Requirements

1.7 To guarantee access to a stock of Antigen for a variety of FMDV Vaccine Antigen strains, sufficient to protect at least three hundred and forty thousand (340,000) cattle plus an allowance of ten percent (10%) formulated Vaccine wastage.

1.8 To produce FMDV Antigens which are suitable to be manufactured into inactivated (formulated) Vaccine, for use in cattle, sheep and pigs, which offer immunity against the virus strains in the following serotypes:

- O Serotype of FMD virus
- A Serotype of FMD virus
- Other Serotype of FMD virus

1.9 The Supplier retains responsibility for the safety and efficacy of Antigen throughout the life of the Contract.

1.10 Upon request from the Authority, the Supplier shall manufacture formulated Vaccine from the Antigen stocks and deliver formulated Vaccine to a suitable facility under the Supplier's control in mainland Great Britain (**"GB Storage Facility"**), within ten [10] days of request. This formulated Vaccine held in UK storage must be held until the Authority requests the release of batches to its vaccination delivery agents.

1.11 The Supplier shall have a UK or EU member state Marketing Authorisation for each Vaccine. The Vaccine must be manufactured and meet the Batch Release specifications at the time of release. It is the responsibility of the Supplier to apply for Batch Release authorisations from VMD and shall ensure that it applies for such

approval on the day of completion of vaccine manufacture in respect of each batch of Vaccine.

1.12 The Authority may, by providing a minimum of 9 [nine] months' notice to the Supplier:

a) increase the Dedicated Minimum Viable Stock requirement of all or any strains of Antigen up to a total stock level of 2,500,000 doses of Antigen at a time; and/or
b) require the Supplier to manufacture and store up to 2,500,000 doses per any additional strain(s) of antigen as may be specified by the Authority from time to time (and Schedule 1 shall be updated accordingly to include such additional strain(s) of antigen),

provided that the Authority may not exercise its rights under each of paragraphs 1.12 a) or b) more than five (5) times throughout the duration of this Contract without the consent of the Supplier. The Supplier shall carry out such instructions from the Authority within the period of notice given by the Authority. The Parties shall agree any subsequent revisions to the charges in writing via a CCN, each Party acting reasonably (and providing that the cost of any increase in the Dedicated Minimum Viable stock of Antigen shall not exceed the relevant price per Antigen dose as set out in part 1 of Schedule 2 (Pricing)).

1.13 The Authority may, at any time:

a) reduce the Dedicated Minimum Viable Stock requirement of any or all strains of Antigen; and/or
b) cease its requirement for one or more strain(s) of Antigen,

with the consent of the Supplier, and any unused doses of such Antigen or Vaccines developed from such Antigen shall, at the Authority's option, be dealt with in accordance with paragraph 4 or disposed of by the Supplier at its own cost and in compliance with all applicable Laws.

1.14 In the event that the Authority chooses to place a Delivery Order pursuant to Clause B1.4, the Authority may, at its discretion and by providing a minimum of 6 [six] months' notice to the Supplier, require the Supplier to replenish the stock of Antigen held on behalf of the Authority under this Contract to the Dedicated Minimum Viable Stock level at the relevant price per vial set out in part 1 of Schedule 2. The Supplier shall carry out such replenishment within the period of notice given by the Authority.

2.0 Specific Technical Requirements

2.1 The Vaccine/Antigen strains to be held have been agreed between the Supplier and Authority based on the recommendation by the Supplier as being the best Vaccine/Antigen strain to provide protection against the following list of FMD virus strains assessed by the Authority as presenting greatest threat to the UK.

2.2 Antigen should be produced and tested by 29 h March 2019.

2.3 All Antigen stock must be in storage in less than eight [8] months from Contract award.

2.4 Additional stocks requested by the Authority must be available within a maximum of six (6) calendar months from placement of order.

2.5 Stored Antigen must have an approved remaining life of at least four (4) years from the 29th March 2019.

3.0 Requirement for Formulation and Delivery of Vaccine

3.1 On request by the Authority, the Supplier must manufacture monovalent or multivalent Vaccine from the FMDV Antigen stocks held for the Authority under this Contract.

3.2 On request by the Authority, and with the agreement of the Supplier, the Supplier shall manufacture monovalent or multivalent Vaccine from other stocks that meet the safety, innocuity, sterility, efficacy, potency and production standards of this Specification.

3.3 The Authority shall inform the Supplier which species may be vaccinated when requesting the formulation of the Vaccine. The Supplier must be capable of formulating Vaccine for cattle, sheep and pigs.

3.4 The Supplier must offer a range of vial sizes for the storage of formulated Vaccine, suited to use on small farms with under twenty [20] cattle; on medium size farms up to one hundred [100] cattle and on large farms with in excess of one hundred [100+] cattle. The combinations offered must allow efficient deployment of formulated Vaccine by the Authority's VDAs. The formulated Vaccine must be stored in vials. The vial sizes are to be agreed with the Authority at the time of the request for manufacturing of formulated Vaccine.

3.5 The formulated Vaccine must be tested to confirm its safety and efficacy in accordance with its Marketing Authorisation. Safety studies must meet Good Laboratory Practice standards and efficacy studies must be to Good Clinical Practice standards (GCPv). The Supplier must carry out Batch Release in accordance with its Marketing Authorisation and by the date of Antigen production and testing completion.

3.6 Formulated Vaccines must be produced to ≥6PD50 potency. Where the Marketing Authorisation specifies ≥3PD50, the Supplier must guarantee that it can produce the Vaccine at a potency of ≥6PD50, in accordance with its Marketing Authorisation release requirements and approved shelf-life. The Vaccines will have a minimum of 12 months shelf life from the date of manufacture.

3.7 Formulated Vaccine must be produced in such a way that it does not contain live FMD virus and other adventitious viruses. Formulated Vaccine must be free from FMDV non-structural proteins (NSP)

3.8 The formulated Vaccine must be delivered to a the GB Storage Facility, where it must be kept in suitable conditions to maintain its safety and efficacy up to the shelf-life of the formulated Vaccine.

3.9 The Vaccine remains the responsibility of the Supplier until it is released to the Authority's Vaccination Delivery Agents (VDAs) on request of the Authority.

3.10 Batches of Vaccine must fulfil the Batch Release requirements as per Marketing Authorisation.

3.11 Batch released FMDV Vaccine must be available at the GB Storage Facility, ready for distribution, within 10 [ten] days of the Authority's request. The day on which the order is placed shall be classed as Day Zero.

3.12 Distribution to the field is not required under this Contract but the Supplier shall co-operate with the VDAs to facilitate the release of the Vaccine on request from the Authority. The GB Storage Facility must be open 7 [seven] days a week so as to allow the VDAs to collect Vaccine in quantities requested for delivery to their distribution centre(s).

3.13 Records must be retained to allow audit of the release of Vaccine. On release to the VDAs, the Supplier is relieved of its responsibility for the Vaccine that has been released and any agreed Buy-Back terms of this Contract will cease to apply to any Vaccine that is released to the Authority.

3.14 The Supplier shall keep all records for a period of up to six (6) years after the Contract expiry date.

3.15 In cases of emergency, where the quantity of Vaccines in stock at the GB Storage Facility are not sufficient to cover the Authority's needs at that time, and where a further shipment of Vaccines to the GB Storage Facility is therefore required by the Authority, the Authority reserves the right to negotiate directly with the Supplier the specific terms and conditions of such a shipment using vaccines from the Supplier's own reserves (which may have a shorter remaining shelf life from the day of their delivery to that required by the Specification). In that case the relevant purchase and consignment costs of the vaccines in the above exceptional shipments shall in any case not be higher than the price of Vaccines provided under this Contract.

4.0 Requirement for Buy-Back or Transfer of Unused Antigen and Vaccine

4.1 On request of the Authority the Supplier must Buy-Back unused Antigen or formulated vaccine which has not been collected by the VDAs. The value of Buy-Back shall be as set out in table two of Schedule 2.

4.2 The Supplier shall be responsible for the correct and safe destruction and disposal of any unused Antigen or Vaccine, in accordance with the relevant legislation in the country of disposal, whether at the end of the Contract, on request of the Authority, or at the end of the Vaccine/Antigen shelf life (as the case may be).

4.3 On request of the Authority, the Supplier must make FMDV Antigen and Vaccine being held on behalf of the Authority at any location available to any other organisation or government outside of the UK specified by the Authority, as long as it is legal to do so.

5.0 Manufacturing of Antigen and Vaccine

5.1 The FMDV Antigen and Vaccine must be produced according to the principles of the then-current Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) and the European Pharmacopoeia monographs and guidelines. The Supplier's production process must meet the EU Good Manufacturing Practice standards.

5.2 The Supplier will undertake tests during storage, routine GMP inspections, temperature control checks, Antigen stability tests in accordance with the CVMP Position Paper on Requirements for FMD vaccines (EMEA/CVMP/775/02-FINAL). Additionally yearly 146S quantifications and one mid-term (2.5year) serological potency tests are undertaken to ensure the stability of the Antigen stored in liquid nitrogen. Appropriate sampling will be made at the time of the bank establishment and or addition of Antigens to the bank to allow in-house testing. Results of these tests must be made available to the Authority within ten [10] weeks of their completion along with the information on storage detailed in the paragraph below.

6.0 Storage of Antigen and Vaccine

6.1 The Supplier must store the FMDV Antigen and Vaccine (if produced) according to the principles of the current Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) and provide detailed information to the Authority (and keep the Authority up-to-date throughout the Contract Period on:

- the place and conditions under which the Antigen and/or Vaccine is stored;
- the expiry of the Antigen and/or Vaccine under such conditions;
- the monitoring and testing protocols used to guarantee quality of the Antigen and/or Vaccine; and
- the guarantees provided by the Supplier as regards safety of storage of the Antigen and/or Vaccine;

6.2 The Supplier shall provide this information in a formal report to be sent to the Contract Manager within ten [10] weeks of the Antigen being placed into storage.

6.3 The Supplier must guarantee that Antigen and Vaccine (if any) is stored in accordance with the above standards with consideration of other pathogens worked on at the site and suitably certified in terms of how they are stored.

[redacted]

[redacted]

6.5 The Supplier must ensure labelling complies with the OIE Manual including labelling the vials with information on the volume of the bottles, the expiry of the vaccine, batch number and the number of doses per bottle. All labels and accompanying product information of the Vaccines delivered must be available in English language at least. The labels must ensure accurate identification and the Supplier shall ensure that labels cannot be lost or mixed. Labelling must be in accordance with the product's Marketing Authorisation and follow European Pharmacopoeia guidelines.

6.6 The Supplier guarantees that the stored Antigen and any formulated Vaccines will maintain their potency and sterility throughout their storage period and shall perform regular testing of the Antigen and/or Vaccines in order to confirm the same. The Supplier will send the results of any tests done to ascertain the potency and sterility of stored Antigen to the Authority within two (2) weeks of their completion.

6.7 Any changing condition in storage may alter the characteristics of the stored Antigen and/or Vaccines (if any). The Supplier shall inform the Authority immediately about the time and conditions of such an incidence as well as about the tests that will be performed upon any stored Antigen and/or Vaccines and the time required for their completion. Results of such tests must be submitted to the Authority, in the form of a written report, within two [2] weeks following their completion.

7.0 In Batch Control Procedures (in addition to those already carried out by the Supplier)

7.1 From each Antigen batch delivered for storage or formulated Vaccine delivered to the Supplier's GB Storage Facility, the Supplier must retain five (5) samples stored with the batch. Each sample must be sufficient to perform one [1] animal potency study according to OIE and European Pharmacopeia guidelines. These samples shall be accompanied by documentation, detailing information on the procedure used for their production, including production date and date of expiry, as well as a list of all biological materials used and their origin, results of efficacy, safety, innocuity, sterility tests and any other tests carried out in relation to this batch.

7.2 Within sixty (60) Working Days of a request from the Authority, the Supplier shall send Vaccine formulated from the sample Antigen, under controlled conditions, to a UK laboratory specified by the Authority. The Supplier shall bear all relevant costs in relation to the shipping of these samples.

7.3 Testing of samples described in this section falls out of scope of this Contract.

8.0 Requirements for the Replacement of the Antigen Stock

8.1 As set out in paragraph 1.14 of the Specification (Schedule 1)

9.0 Requirements for Audit of Antigen and Vaccine Stock

9.1 The Supplier shall within two [2] weeks of a request by the Authority, accommodate a visit by the Authority to inspect the FMDV Antigen / Vaccine stock held and / or (at the Authority's discretion) provide relevant production records.

10.0 Documentation for the Supplier

10.1 As of the Commencement Date, the most recent update of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE) is available on the organisation's website (English version):

http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

11.0 Reports and Documents to be Submitted

11.1 The work carried out by the Supplier under this Contract will be the subject of the following reports, which must be sent to the Authority's Contract Manager (APHA) by the Supplier.

Technical report: (to be sent electronically)

Upon production of each batch of FMDV Antigen or Vaccine purchased under the Contract a report must be submitted including information on the procedure used for the production of the formulated vaccine (inactivated), and the outcome of tests. This shall be known as the **"Production Report".**

The Production Report must be sent to the Authority no later than **ten (10) weeks** after the production of the relevant batch of Antigen or Vaccine. This report shall include information on:

- the results of the efficacy, safety, innocuity and sterility tests carried out;
- the system put in place to ensure correct and secure storage, including:
    - the storage equipment used;
    - the security system in place (temperature control, anti-theft measures)
- insurance arrangements (fire, accidents)

11.2 **During the storage period of each batch of Antigen / and or Vaccine** a report must be submitted (electronically) with the results of any tests performed to ensure the continued sterility and potency of the stored Antigen or formulated Vaccine. Each report must be submitted within 10 (ten) weeks after the relevant test was performed.

11.3 **Upon delivery of Vaccines to the GB Storage Facility,** the Supplier must send to the Authority Contract Manager (APHA), by e-mail a report including:

- Date of shipment
- Date of reception
- Quantities delivered including batch details
- Place of delivery
- Proof of receipt or collection of the formulated Vaccines by the recipient
- Evidence of conditions under which the Vaccines were delivered including results of cold chain during shipment

- Batch Release certificate (this will include all finished product tests, specifications and results)

11.4 If any of the Antigen in stock is approaching its expiry date the Supplier shall send the Authority a report, no earlier than eighteen [18] months and no later than eight [8] months before the actual expiry date (or dates), including the quantities of the Antigen in stock that is close to expiry including batch details and expiry date (or dates) thereof.

Upon partial or total replacement of the Antigen stock, due to Antigen use or expiry, the Supplier must send to the Authority a report by e-mail including:

- Date of replacement
- Quantities of Antigen in stock including batch details and final product test outcomes
- Relevant product test outcomes

11.5 **After the end of each calendar year and at the end of the Contract Period** (in each case, no later than thirty [30] days after the end of the calendar year and after the end of the Contract Period) the Supplier shall submit a cumulative report, sent by e-mail, detailing in chronological order all quantities of Vaccine produced and Delivered, the quantities of the Antigen and Vaccine stored, and the quantity of Antigen bought back and removed from the stock, with at least the following information related to the calendar year in question:

Production of Antigen / Vaccines

Numbers of doses of Antigen/Vaccines purchased under this Contract complete with batch details. If any Vaccine is held at the GB Storage Facility, the Supplier shall also provide the Authority with the number and sizes of vials.

Storage of Antigen / Vaccine

- Full description of the Antigen/Vaccine stock at the beginning of the calendar year

  (number of doses, batch details, dates of entry in the stock)
- Full list of all changes in the Antigen/ Vaccine stock throughout the calendar year (for each change numbers of doses of Antigen/Vaccine that were inserted or removed from the stock each time complete with batch details, dates of entry or exit, reason for this movement and number of doses of Antigen/ Vaccines remaining in store following each withdrawal from the stock or replenishment thereof)
- Full description of the Antigen/ Vaccine stock at the end of the calendar year (including number of doses, batch details , dates of entry in the stock)

At the end of the Contract Period the Supplier's report must also contain information on the total number of Antigen/Vaccine doses bought-back, transferred or destroyed.

12.0 Invoicing Schedule

12.1 Following the Supplier's receipt of the relevant Antigen Delivery Milestone Achievement Certificate from the Authority the Supplier shall issue its invoice detailing quantities and batch details to the Authority's Contract Manager (APHA) by e-mail.

After the end of each six (6) month period (no later than thirty (30) days after the end of each six (6) month period) the Supplier shall issue an invoice for the Storage Fees (if any) accompanied by the above mentioned technical report to the Authority's Contract Manager (APHA).

Upon delivery of Vaccines to the GB Storage Facility, the Supplier shall issue its invoice accompanied by the above mentioned technical report.

On Buy Back the Supplier shall make payment to the Authority for any Antigen or Vaccine bought-back by the Supplier in-line with the pricing schedule (Schedule 2).

12.2 After the **end of the Contract**:

- the Supplier shall send the above mentioned technical report to the Authority's Contract Manager (report after the end of the Contract).

- the Supplier shall submit its invoice/ payment for such items as set-out in the pricing schedule (Schedule 2) and agreed Contract terms, after deducting any Antigen bought-back by the Supplier in-line with the pricing schedule (Schedule 2)

13.0 Performance Management Framework (including Key Performance Indicators (KPIs))

13.1 As part of the Authority's continuous drive to improve the performance of all Contracts, this Performance Management Framework (PMF) will be used to monitor, measure and control all aspects of the Supplier's performance of contract responsibilities.

13.2 The purpose of the PMF is to set out the obligations on the Supplier, to outline how the Supplier's performance will be evaluated and to detail the sanctions for performance failure. The Supplier is responsible for the performance of any sub-contractors.

13.3 Key Performance Indicators (KPIs) are essential to align Supplier performance with the requirements of the Authority and to do so in a fair and practical way. KPIs must be realistic, achievable, and set to indicate where the Supplier's performance is failing if they are not achieved. Without the additional use of service credits, failure to meet KPIs will strain the relationship as delivery falls short of agreed performance standards. As a result, the only recourse would be to terminate the Contract and seek an alternative Supplier.

13.4 The use of a strong service credit regime accompanied by a proactive approach to correcting failures and addressing their cause improves the relationship and enables a partnership rather than a confrontational style of working. Its focus is on managing and improving performance. It is not about taking cost out of the Contract.

13.5 KPIs are set out at Table A below. They will be monitored on a monthly, quarterly or annual basis as appropriate to the Contract and will form part of the Contract performance review.

13.6 The Authority will be entitled to refine, vary or modify the KPIs, performance standards and service credits from time to time during the Contract Period through a Variation to be agreed with the Supplier using a Contract Change Note (CCN).

13.7 Where a KPI has a percentage measure, the Supplier's performance will be rounded to the nearest whole number.

13.8 The Authority will produce a monthly and quarterly performance management report, to be sent to the Supplier, detailing the Supplier's performance against KPIs.

13.9 The Supplier will maintain their own management reports, including issues log, which will include detail on periodic checks to ensure quality.

13.10 Any performance issues highlighted in the monthly reports will be addressed by the Supplier, who will be required to provide an improvement plan to address all issues highlighted within a week of receipt of the report. Monthly performance management reports and KPI performance will be a key feature of Quarterly Contract Review meetings.

13.11 Where performance failure attributable to the Supplier is identified in the performance management report and relates to the KPIs then the service credit regime may apply, at the sole discretion of the Authority.

14.0 Service Credits

14.1 The use of service credits is governed by the following principles:

14.2 Service credits sit within the wider service management approach being pursued by the Supplier and the Authority. Use of service credits does not preclude any other remedy for failure of performance available to the Authority under the terms and conditions of the Contract.

14.3 The service credit regime will be instigated on each occasion when there is a performance failure (i.e. where a KPI is identified as having a 'red status') within the performance monitoring period. Failure to meet a KPI may also give rise to a remediation plan.

- KPIs with a service credit rating of 0 will have no associated service credit
- KPIs with a service credit rating of 1 will have a service credit of 3% of the invoice amount for the monitoring period (being the 6 monthly periods commencing at or around the time for payment of the Storage Fees), applied for each KPI failure
- KPIs with a service credit rating of 2 will have a service credit of 5% of the invoice amount for the monitoring period, applied for each KPI failure
- The maximum annual service credit to be applied will be no more than 10% of the total annual Contract value.

14.4 The Supplier will provide the Authority with the information listed in the Specification and such other supporting information as the Authority may reasonably request in order to determine the proper application of any service credits due.

14.5 Service credits will be paid to the Authority as a credit note to the next invoice.

14.6 The full, agreed service credit regime will operate from the Commencement Date until the end of the Contract Period. At the end of the first complete performance monitoring period, the Authority and the Supplier will enter into good faith discussions to review the KPIs and assess their effectiveness. The KPIs may be adjusted to ensure that they are appropriate and achievable.

TABLE A. Key Performance Indicators

KPI	Description	Measure	KPI Target	Source(s)	Service Credit Rating
KPI1	Production and storage of Antigen	As per 2.4, 2.5 and 2.6 of the Specification	100%	Supplier report	2
KPI2	Formulation and Delivery of Vaccine	Within 10 days of request by the Authority	100%	Delivery documents	2
KPI3	Reports	Reports to be sent to the Authority within required timescales set out in section 11 of the Specification	100%	Reports received by CM within required timescale	1

15.0 Governance and Contract Management

15.1 APHA will manage the Contract on behalf of the Authority. APHA will appoint a:

- Supplier Liaison Officer (SLO)
- Deputy SLO (DSLO)
- Contract Manager (CM)

15.2 APHA will decide as appropriate for the Contract whether the SLO or DSLO is the principal point of contact.

15.3 The Supplier will appoint a corresponding Service Manager (SM) and Deputy Service Manager (DSM).

15.4 Six-monthly meetings will be held with the Supplier, principally to review progress and operational delivery of the Contract, but also including key performance indicators (KPIs), invoicing, risks and issues. A Defra Group Commercial (DGC) representative, with responsibility for procurement on behalf of the Authority, may be present at quarterly and annual review meetings.

15.5 The Supplier will submit an exception report to raise any issue requiring authorisation by APHA more immediately than the standard monthly reporting.

15.6 A strategic review meeting will be held annually. The meeting will review performance over the past year and look ahead to the next year, including strategic and financial issues. The risk, issues and actions register will be reviewed.

15.7 Issues which cannot be resolved by the SLO and SM (and/or their respective deputies) through routine contact or in the meetings will be referred to the CM who may either mediate a solution or raise the matter at the next six-monthly and/or annual review meeting as appropriate, involving the Authority as necessary.

15.8 Other ad hoc meetings may be held, at the discretion of APHA or the Authority or at the request of the Supplier, throughout the life of the Contract to discuss specific issues.

15.9 The Supplier will be responsible for travel and subsistence costs incurred as a result of attendance at any meeting. Meetings may also be held by teleconference with the agreement of all parties.

15.10 Six-monthly and annual meetings will be held at the most mutually convenient location, usually face-to-face, but with teleconference facilities available.

15.11 Six-monthly and annual meetings will be minuted, with secretariat support and actions provided by APHA, with agreed dates for completion. The Supplier will maintain a joint register of risks, issues and actions.

15.12 The CM should ensure that all meeting minutes, risk registers and any other contract documentation is recorded against the Authority's contract records.

15.13 Table B gives the purpose of each of these meetings with the Supplier, and the required attendees.

Table B. Contract Management Meeting Schedule

Meeting	Attendance	Content
Specific Issues, ad hoc *Face-to-face / Telecon*	APHA: • SLO (Chair) and/or DSLO • Secretariat support Supplier: • SM and/or DSM Any other APHA, Authority or Supplier staff needed to progress the issue. NB - The CM or Head of Contract Management may alternatively Chair the meeting if facilitation is required.	• Urgent issues • Specific technical or contractual issues requiring detailed discussion
Six-monthly Contract Review Meeting	APHA: • SLO (Chair) and DSLO • CM • Head of Contract Management *(optional, if required)* • Secretariat support • DGC representative *(optional, if required)* Supplier: • SM and/or DSM	• Current and Outstanding Operational issues • Performance in previous six months, including detailed review of KPIs • Risks and issues log • Review of Action Log • Specific service issues • Authority Update • Any issues from Supplier
Annual Review Meeting	APHA: • SLO (Chair) and DSLO • CM • Head of Contract Management *(optional, if required)*	• Annual Service Review against KPIs, including Service Credits • Risks and issues log • Review of Action Log • Specific service issues (including any escalated issues)

Face-to-face	• Secretariat support • DGC representative *(optional, if required)* • Head of Service *(optional, if required)* Supplier: • SM and/or DSM • Any other representative that the Supplier feels relevant from within their organisation	• Service wide issues • Financial update • Strategic Overview (including any policy updates)

SCHEDULE 2 - PRICING

Part 1: Pricing

REDACTED

SCHEDULE 3 - CHANGE CONTROL

Contract Change Note ("CCN")

CCN **Contract Reference Number & Title** **Variation Title** **Number of Pages**	

WHEREAS the Supplier and the Authority entered into a Contract for the supply of [project name] dated [dd/mm/yyyy] (the "Original Contract") and now wish to amend the Original Contract

IT IS AGREED as follows

1. The Original Contract shall be amended as set out in this CCN:

Change Requestor / Originator		
Summary of Change		
Reason for Change		
Revised Contract Price	Original Contract Value	£
	Previous Contract Changes	£
	Contract Change Note [x]	£
	New Contract Value	£
Revised Payment Schedule		
Revised Specification (See Annex [x] for Details)		
Revised Contract Period		
Change in Contract Manager(s)		
Other Changes		

2. Save as amended all other terms of the Original Contract shall remain effective.

3. This CCN takes effect from the date on which the Parties communicate acceptance of its terms via Bravo.

SCHEDULE 4 - COMMERCIALLY SENSITIVE INFORMATION

1.1 Without prejudice to the Authority's general obligation of confidentiality, the Parties acknowledge that the Authority may have to disclose Information in or relating to the Contract following a Request for Information pursuant to clause E5 (Freedom of Information).

1.2 In this Schedule the Parties have sought to identify the Supplier's Confidential Information that is genuinely commercially sensitive and the disclosure of which would be contrary to the public interest.

1.3 Where possible the Parties have sought to identify when any relevant Information will cease to fall into the category of Information to which this Schedule applies.

1.4 Without prejudice to the Authority's obligation to disclose Information in accordance with the FOIA and the EIR, the Authority will, acting reasonably but in its sole discretion, seek to apply the commercial interests exemption set out in s.43 of the FOIA to the Information listed below.

CONTRACTOR'S COMMERCIALLY SENSITIVE INFORMATION	DATE	DURATION OF CONFIDENTIALITY
[redacted]		

SCHEDULE 5 - NON DISCLOSURE AGREEMENT

THIS NON DISCLOSURE AGREEMENT is made the [insert day] day of [insert date] (the "Commencement Date"

BETWEEN:

[Insert full name of contractor] of [insert full address but if registered company please insert the following - (registered in England and Wales under number [insert company number]) whose registered office is situated at [ ] (the "Supplier");

and

[Insert name and address of the Staff member, professional advisor or consultant of the Supplier] (the "Disclosee").

(each a "Party" and together the "Parties").

WHEREAS:

(a) The Supplier has contracted with the Secretary of State for Environment, Food and Rural Affairs (the "Authority") to provide goods to the Authority in an agreement dated [insert date] (the "Contract").

(b) The Contract places an obligation of confidentiality on the Supplier. The Disclosee is an [insert employee, professional advisor or consultant] of the Supplier engaged in the provision of certain goods to the Authority in support of or in connection with the goods to be provided by the Supplier under the Contract.

(c) The Disclosee may therefore, have communicated to it, certain Confidential Information belonging to the Authority which is proprietary and must be held in confidence. Accordingly, the Contract requires the Supplier to ensure that the Disclosee enters into a non-disclosure agreement with the Supplier on the terms set out herein.

(d) Any Confidential Information disclosed by the Authority or the Supplier to the Disclosee, whether contained in original or copy documents, will at all times remain the property of the Authority together with all notes, memoranda and drawings that have been made as a result of access to such Confidential Information.

NOW IT IS AGREED as follows:

Definition and Interpretation

1. In this Agreement:

a) "Confidential Information" means: any information which has been designated as confidential by the Authority in writing or that ought to be considered as confidential (however it is conveyed or on whatever media it is stored) whether commercial, financial, technical or otherwise including (without limitation) information belonging to or in respect of the Authority which relates to research, development, trade secrets, formulae, processes, designs, specifications, the Authority data, internal management, information technology and infrastructure and requirements, price lists and lists of, and information about, customers and employees, all materials and information belonging to third parties in respect of which the Disclosee owes obligations of confidence; information the disclosure of which would, or would be likely to, prejudice the commercial interests of any person, intellectual property rights or know-how of the Authority and all personal data and sensitive personal data within the meaning of the Data Protection Act

1988; whether or not that information is marked or designated as confidential or proprietary; whether arising prior to, on or after the Commencement Date;

b) "Law" means any applicable Act of Parliament, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, exercise of the royal prerogative, enforceable community right within the meaning of Section 2 of the European Communities Act 1972, regulatory policy, guidance or industry code, judgment of a relevant court of law, or directives or requirements of any regulatory body of which the Supplier is bound to comply.

2. In construing this Agreement the general words introduced or followed by the word include(s) or including or in particular shall not be given a restrictive meaning because they are followed or preceded (as the case may be) by particular examples intended to fall within the meaning of the general words.

3. Unless the context requires otherwise, the singular shall include the plural and vice versa, and the masculine shall include the feminine and vice versa.

4. Reference to any legislative and statutory requirement or similar instrument shall be deemed to include reference to any subsequent amendment to them.

5. References to any person shall, as the context may require, be construed as a reference to any individual, firm, company, corporation, government department, agency, or any association or partnership (whether or not having a separate legal personality).

CONFIDENTIALITY

6. The Disclosee undertakes to: keep confidential all Confidential Information and safeguard it accordingly; and that any Confidential Information supplied will not be used by it for any purpose other than in connection with the Supplier's delivery of the goods under the Contract without the prior written permission of the Authority.

7. The Disclosee will take all necessary precautions to ensure that the Confidential Information is held in confidence and will provide proper and secure storage for all information and any papers, drawings or other materials which relate to or are compiled from such information.

8. The Disclosee shall, with respect to any Confidential Information it receives directly from or on behalf of the Authority or from the Supplier, comply, with all instructions and/or guidelines produced and supplied by or on behalf of the Authority from time to time for the handling and storage of Confidential Information, generally or for specific items.

9. The Disclosee will not disclose any Confidential Information or any part thereof to any third party.

10. Where the Disclosee is an employee, breach of the obligations set out herein in this Agreement shall be a cause of disciplinary proceedings, and the Supplier shall institute and enforce such disciplinary proceedings as against the Disclosee in relation to such breach.

11. Where the disclose is a professional advisor or consultant, breach of the obligation set out herein shall entitle the Supplier to terminate the contract of engagement with the Disclosee immediately, and the Supplier shall enforce such right of termination as against the Disclosee in relation to such breach.

12. All Confidential Information in tangible form received hereunder together with all copies thereof shall be destroyed or returned immediately to the Supplier or where so required by

the Authority and notified to the Disclosee, to the Authority, upon request or upon completion of the task for the purposes of which such Confidential Information was released.

13. The Confidential Information will not be used by the Disclosee for any purpose or in any way other than under this Agreement.

14. The following circumstances shall not constitute a breach of the obligations of confidentiality contained in this Agreement:

    14.1 Disclosure of Confidential Information by the Disclosee when required to do so by Law or pursuant to the rules or any order having the force of Law of any court, of competent jurisdiction;

    14.2 Disclosure of Confidential Information by the Disclosee where and to the extent that the Confidential Information has, except as a result of breach of confidentiality, become publicly available or generally known to the public at the time of such disclosure;

    14.3 Disclosure of Confidential Information by the Disclosee where and to the extent that the Confidential Information is already lawfully in the possession of a recipient or lawfully known to it prior to such disclosure;

    14.4 Possession of Confidential Information by the Disclosee where it has been acquired from a third party who is not in breach of any obligation of confidence in providing that Confidential Information;

    provided that no information relating to the affairs of any identifiable person shall be disclosed or released from the obligations herein without the prior written consent of the Authority.

15. The Disclosee shall: notify the Supplier and the Authority promptly of the date and circumstances of the loss or unauthorised disclosure, if any, of the Confidential Information or any part of the Confidential Information and in addition, the action being taken to rectify that loss or unauthorised disclosure.

16. The obligations contained in this Agreement shall continue until notified in writing by the Authority or the Confidential Information becomes public knowledge (other than by breach of the terms of this Agreement).

17. No licence of any intellectual property rights (including but not limited to patent rights, copyrights, trademarks and rights in proprietary information and/or know-how and whether registrable or unregistrable) is granted hereby, beyond that necessary to enable use of the Confidential Information for the purpose for which the Confidential Information was released.

18. Nothing in this Agreement shall be construed as compelling any of the Parties to disclose any Confidential Information or to enter into any further contractual relationship with any other party.

19. No representation or warranties are given regarding the accuracy, completeness or freedom from defects of the Confidential Information or with respect to infringement of any rights including intellectual property rights of others.

20. Without affecting any other rights or remedies that the other Parties may have, the Disclosee acknowledges and agrees that damages alone would not be an adequate remedy for any breach of any of the provisions of this Agreement.

GENERAL

21. No failure or delay by any Party to this Agreement in exercising any of its rights hereunder shall operate as a waiver of such rights, nor shall any single or partial exercise preclude any further exercise of such rights. Any waiver by a Party of any breach or non-compliance with any term of this Agreement shall not constitute a waiver of any subsequent breach of non-compliance with the same or any other term of this Agreement.

22. No Party may assign this Agreement or any of its rights and obligations hereunder without the prior written consent of the Authority.

23. Any notice under this Agreement shall be in writing and shall be delivered by post, fax or e-mail to the address of the Party in question set out at the beginning of this Agreement or such other address (or e-mail address or fax number) as the Parties may notify one another from time to time.

24. No term of this Agreement shall be enforceable, by virtue of the Contracts (Rights of Third Parties) Act 1999, by any person who is not a party to this Agreement other than the Authority. The Parties shall only with the prior written consent of the Authority be entitled to vary any of the provisions of this Agreement without notifying or seeking the consent of any third party and the rights conferred by section 2 of the Contracts (Rights of Third Parties) Act 1999 are excluded.

25. This Agreement shall be governed by and shall be interpreted in accordance with the laws of England.

26. The courts of England have exclusive jurisdiction to settle any disputes which may arise out of or in connection with this Agreement and accordingly that any proceedings, suit or action arising out of or in connection therewith shall be brought in such courts.

This Agreement has been entered into on the date first written above.

SIGNED by the authorised signatory for and on behalf of the Supplier:

_____

SIGNED by the Disclosee:

_____

SCHEDULE 6 - IMPLEMENTATION PLAN

Lot 1 O Serotype of FMD virus

REDACTED

Lot 2 A Serotype of FMD virus

REDACTED

Lot 3 Other Serotype of FMD virus

REDACTED

SCHEDULE 7 - SECURITY REQUIREMENTS, POLICY AND PLAN

INTERPRETATION AND DEFINITION

For the purposes of this Schedule 7, unless the context otherwise requires the following provisions shall have the meanings given to them below:

"Breach of Security" means the occurrence of unauthorised access to or use of the Supplier's premises, the Goods, the Supplier System, or any ICT or data (including Authority Data) used by the Authority or the Supplier in connection with the Contract.

"Supplier Equipment" means the hardware, computer and telecoms devices and equipment supplied by the Supplier or its Sub-Contractor (but not hired, leased or loaned from the Authority) for the provision of the Goods;

"Supplier Software" means software which is proprietary to the Supplier, including software which is or will be used by the Supplier for the purposes of providing the Goods.

"ICT" means Information Communications Technology and includes a diverse set of technological tools and resources used to communicate, and to create, disseminate, store and manage information, including computers, the Internet, broadcasting technologies (radio and television), and telephony.

"Protectively Marked" shall have the meaning as set out in the Security Policy Framework.

"Security Plan" means the Supplier's security plan prepared pursuant to paragraph 3 an outline of which is set out in an Appendix to this Schedule 7.

"Software" means Specially Written Software, Supplier Software and Third Party Software.

"Specially Written Software" means any software created by the Supplier (or by a third party on behalf of the Supplier) specifically for the purposes of this Contract.

"Third Party Software" means software which is proprietary to any third party which is or will be used by the Supplier for the purposes of providing the Goods including the software.

1. INTRODUCTION

This Schedule 7 covers:

1.1 principles of security for the Supplier System, derived from the Security Policy Framework, including without limitation principles of physical and information security;

1.2 wider aspects of security relating to the Goods;

1.3 the creation of the Security Plan;

1.4 audit and testing of the Security Plan; and

1.5 breaches of security.

2. PRINCIPLES OF SECURITY

2.1 The Supplier acknowledges that the Authority places great emphasis on confidentiality, integrity and availability of information and consequently on the security of the Supplier's premises and the security for the Supplier System. The Supplier also acknowledges the confidentiality of Authority Data.

2.2 The Supplier shall be responsible for the security of the Supplier System and shall at all times provide a level of security which:

2.2.1 is in accordance with Good Industry Practice and Law;

2.2.2 complies with Security Policy Framework; and

2.2.3 meets any specific security threats to the Supplier System.

2.3 Without limiting paragraph 2.2, the Supplier shall at all times ensure that the level of security employed in the supply of the Goods is appropriate to maintain the following at acceptable risk levels (to be defined by the Authority):

2.3.1 loss of integrity of Authority Data;

2.3.2 loss of confidentiality of Authority Data;

2.3.3 unauthorised access to, use of, or interference with Authority Data by any person or organisation;

2.3.4 unauthorised access to network elements, buildings, the Supplier's premises, and tools used by the Supplier in the supply of the Goods;

2.3.5 use of the Supplier System or Goods by any third party in order to gain unauthorised access to any computer resource or Authority Data; and

2.3.6 loss of availability of Authority Data due to any failure or compromise of the Goods.

3. SECURITY PLAN

3.1 The Supplier shall develop, implement and maintain a Security Plan to apply during the Contract Period (and after the end of the term as applicable) which will be approved by the Authority, tested, periodically updated and audited in accordance with this Schedule 7.

3.2 A draft Security Plan provided by the Supplier as part of its bid is set out herein.

3.3 Prior to the Commencement Date the Supplier will deliver to the Authority for approval the final Security Plan which will be based on the draft Security Plan set out herein.

3.4 If the Security Plan is approved by the Authority it will be adopted immediately. If the Security Plan is not approved by the Authority the Supplier shall amend it within 10 Working Days of a notice of non-approval from the Authority and re-submit to the Authority for approval. The Parties will use all reasonable endeavors to ensure that the approval process takes as little time as possible and in any event no longer than 15 Working Days (or such other period as the Parties may agree in writing) from the date of its first submission to the Authority. If the Authority does not approve the Security Plan following its resubmission, the matter will be resolved in accordance with clause I2 (Dispute Resolution). No approval to be given by the Authority pursuant to this paragraph 3.4 may be unreasonably withheld or delayed. However any failure to approve the Security Plan on the grounds that it does not comply with the requirements set out in paragraphs 3.1 to 3.4 shall be deemed to be reasonable.

3.5 The Security Plan will set out the security measures to be implemented and maintained by the Supplier in relation to all aspects of the Goods and all processes associated with the delivery of the Goods and shall at all times comply with and specify security measures and procedures which are sufficient to ensure that the Goods comply with:

3.5.1 the provisions of this Schedule 7;

3.5.2 the provisions of Schedule 1 relating to security;

3.5.3 the Information Assurance Standards;

3.5.4 the data protection compliance guidance produced by the Authority;

3.5.5 the minimum set of security measures and standards required where the system will be handling Protectively Marked or sensitive information, as determined by the Security Policy Framework;

3.5.6 any other extant national information security requirements and guidance, as provided by the Authority's IT security officers; and

3.5.7 appropriate ICT standards for technical countermeasures which are included in the Supplier System.

3.6 The references to Quality Standards, guidance and policies set out in this Schedule shall be deemed to be references to such items as developed and updated and to any successor to or replacement for such Quality Standards, guidance and policies, from time to time.

3.7 If there is any inconsistency in the provisions of the above standards, guidance and policies, the Supplier should notify the Authorised Representative of such inconsistency immediately upon becoming aware of the same, and the Authorised Representative shall, as soon as practicable, advise the Supplier which provision the Supplier shall be required to comply with.

3.8 The Security Plan will be structured in accordance with ISO/IEC27002 and ISO/IEC27001 or other equivalent policy or procedure, cross-referencing if necessary to other schedules of the Contract which cover specific areas included within that standard.

3.9 The Security Plan shall not reference any other documents which are not either in the possession of the Authority or otherwise specified in this Schedule 7.

4. AMENDMENT AND REVISION

4.1 The Security Plan will be fully reviewed and updated by the Supplier annually or from time to time to reflect:

4.1.1 emerging changes in Good Industry Practice;

4.1.2 any change or proposed change to the Supplier System, the Goods and/or associated processes;

4.1.3 any new perceived or changed threats to the Supplier System;

4.1.4 changes to security policies introduced Government-wide or by the Authority; and/or

4.1.5 a reasonable request by the Authority.

4.2 The Supplier will provide the Authority with the results of such reviews as soon as reasonably practicable after their completion and amend the Security Plan at no additional cost to the Authority.

4.3 Any change or amendment which the Supplier proposes to make to the Security Plan (as a result of an Authority request or change to Schedule 1 or otherwise) shall be subject to a CCN and shall not be implemented until Approved.

5. AUDIT AND TESTING

5.1 The Supplier shall conduct tests of the processes and countermeasures contained in the Security Plan ("Security Tests") on an annual basis or as otherwise agreed by the Parties. The date, timing, content and conduct of such Security Tests shall be agreed in advance with the Authority.

5.2 The Authority shall be entitled to send a representative to witness the conduct of the Security Tests. The Supplier shall provide the Authority with the results of such tests (in an Approved form) as soon as practicable after completion of each Security Test.

5.3 Without prejudice to any other right of audit or access granted to the Authority pursuant to the Contract, the Authority shall be entitled at any time and without giving notice to the Supplier to carry out such tests (including penetration tests) as it may deem necessary in relation to the Security Plan and the Supplier's compliance with and implementation of the Security Plan. The Authority may notify the Supplier of the results of such tests after completion of each such test. Security Tests shall be designed and implemented so as to minimise the impact on the delivery of the Goods.

5.4 Where any Security Test carried out pursuant to paragraphs 5.2 or 5.3 reveals any actual or potential security failure or weaknesses, the Supplier shall promptly notify the Authority of any changes to the Security Plan (and the implementation thereof) which the Supplier proposes to make in order to correct such failure or weakness. Subject to Approval in accordance with paragraph 4.3, the Supplier shall implement such changes to the Security Plan in accordance with the timetable agreed with the Authority or, otherwise, as soon as reasonably possible. For the avoidance of doubt, where the change to the Security Plan to address a non-compliance with the Security Policy Framework or security requirements, the change to the Security Plan shall be at no additional cost to the Authority. For the purposes of this paragraph, a weakness means a vulnerability in security and a potential security failure means a possible breach of the Security Plan or security requirements.

6. BREACH OF SECURITY

6.1 Either Party shall notify the other immediately upon becoming aware of any Breach of Security including, but not limited to an actual, potential or attempted breach, or threat to, the Security Plan.

6.2 Upon becoming aware of any of the circumstances referred to in paragraph 6.1, the Supplier shall immediately take all reasonable steps necessary to:

6.2.1 remedy such breach or protect the Supplier System against any such potential or attempted breach or threat; and

6.2.2 prevent an equivalent breach in the future.

6.3 Such steps shall include any action or changes reasonably required by the Authority. If such action is taken in response to a breach that is determined by the Authority acting reasonably not to be covered by the obligations of the Supplier under the Contract, then the Supplier shall be entitled to refer the matter to the CCN procedure set out in Schedule 3.

6.4 The Supplier shall as soon as reasonably practicable provide to the Authority full details (using such reporting mechanism as may be specified by the Authority from time to time) of such actual, potential or attempted breach and of the steps taken in respect thereof.

APPENDIX 1- OUTLINE SECURITY PLAN

APPENDIX 2 - SECURITY POLICY: SECURITY POLICY FRAMEWORK

A copy of the Security Policy Framework may be found at:

https://www.gov.uk/government/publications/security-policy-framework

SCHEDULE 8 - CONTRACTOR'S BUSINESS CONTINUITY PLAN

REDACTED

SCHEDULE 9 - PROCESSING, PERSONAL DATA AND DATA SUBJECTS

1. This Schedule shall be completed by the Authority, who may take account of the view of the Supplier, however the final decision as to the content of this Schedule shall be with the Authority at its absolute discretion.

2. The contact details of the Authority Data Protection Officer are:

[redacted]

3. The contact details of the Supplier Data Protection Officer are:

[redacted]

4. The Supplier shall comply with any further written instructions with respect to processing by the Authority.

5. Any such further instructions shall be incorporated into this Schedule.

Data Processing descriptor	Narrative
Identity of the Controller and Processor	The Parties acknowledge that for the purposes of the Data Protection Legislation, the Authority is the Controller and the Supplier is the Processor in accordance with Clause E2.1.
Subject matter of the processing	The processing is needed in order to ensure that the Supplier can effectively deliver the Contract for provision of an antigen, storage and production of foot and mouth vaccines.
Duration of the processing	The duration of the Contract plus a subsequent period until deletion of the personal data by the Supplier in accordance with the terms of the Contract, which subsequent period shall be no longer than necessary, subject to any legal or regulatory obligations on the Supplier to retain any such personal data.
Nature and purposes of the processing	Strictly as required for the performance of the Contract.
Type of Personal Data	Name and business contact details
Categories of Data Subject	Authority staff (which may include agents and temporary workers)

Plan for return and destruction of the data once the processing is complete UNLESS requirement under union or member state law to preserve that type of data	In accordance with the terms of the Contract.