

ADVANCE PURCHASE AGREEMENT

between

**The Department for
Business, Energy and Industrial Strategy,**
acting on behalf of the Crown

(“UK”)

and

Aventis Pharma Limited
Company number – 01535640
Thames Valley Park Drive,
Reading, Berkshire, England, RG6 1PT

(“Aventis”)

and

GlaxoSmithKline Biologicals SA
Rue de l’Institut 89
B-1330 Rixensart
Belgium

(“GSK”)

regarding

Advance Purchase of COVID-19 Adjuvanted Pandemic Vaccine

ADVANCE PURCHASE AGREEMENT

PREAMBLE

Terms used in this Preamble are further defined in Clause 1 below.

Whereas:

- A. GSK owns and controls certain intellectual property rights, data (including established scientific and safety data), know-how and technologies with respect to the Adjuvant and its use in the development and use of vaccines.
- B. Sanofi Pasteur, an Affiliate of Aventis, owns and controls certain intellectual property rights with respect to the S Antigen as well as its related BEVS system used in connection with the production of such S Antigen.
- C. On July 9, 2020, Sanofi Pasteur and GSK entered into a Collaboration and License Agreement to develop and manufacture the Adjuvanted Pandemic Vaccine, which incorporates the Adjuvant and S Antigen components, both in multidose vials and to be reconstituted at bedside before injection.
- D. Sanofi Pasteur and GSK are actively building their production capacities for the Adjuvanted Pandemic Vaccine.
- E. Sanofi Pasteur and GSK aim at making the Adjuvanted Pandemic Vaccine globally directly or through their respective Affiliates as soon as possible after clinical trial success and regulatory approval.
- F. To achieve this ambition in terms of volume manufacturing and time to supply, Sanofi Pasteur and GSK are mobilising their network of internal industrial sites and contract manufacturing organisations.
- G. The UK wishes to secure supply of the Adjuvanted Pandemic Vaccine for human use during the COVID-19 pandemic as promptly as possible. In this regard, on July 21, 2020, Sanofi Pasteur, GSK and the UK entered into a non-binding term sheet for the reservation of production capacity by the UK and supply to the UK of the Adjuvanted Pandemic Vaccine (the “**Term Sheet**”). On September 15, 2020, the Parties subsequently entered into a capacity reservation agreement setting out the terms upon which the Parties will collaborate with respect to the acceleration of the at-risk production of the Reserved Volume (as defined therein) of the Adjuvanted Pandemic Vaccine for supply to the UK, [REDACTED] (such agreement, as amended from time to time, the “**Capacity Reservation Agreement**”).
- H. This Agreement constitutes the “Advance Purchase Agreement” as referred to in the Term Sheet and Capacity Reservation Agreement and sets out terms upon which the UK will secure, in advance, the availability of the Adjuvanted Pandemic Vaccine.
- I. The Suppliers have provided to the UK the [REDACTED] Data for the UK to decide whether to enter into this Agreement and purchase the First Volume. The UK has reviewed the [REDACTED] Data and considers it satisfactory to proceed with execution of this Agreement.

- J. The Parties acknowledge the dosing regimen recommended for the Adjuvanted Pandemic Vaccine is one (1) Dose per person when administered as a booster injection (being an additional Dose for persons who have already received a primary course of an approved COVID-19 vaccine [REDACTED]), meaning the First Volume may be used to vaccinate up to 7.5 million people. Storage, distribution, deployment, administration and any other use of the Adjuvanted Pandemic Vaccine by the UK must be in accordance with the Marketing Authorization and this Agreement.

Now, therefore, the UK, GSK and Aventis have agreed as follows:

1. DEFINITIONS AND INTERPRETATION

1.1. Definitions

In this Agreement, unless otherwise specified or inconsistent with the context, the following definitions shall apply:

“Acceptance”	has the meaning set out in Clause 4.12.2.
“Actual Cause”	means a cause or factor without which the event could not have occurred.
“Additional Facilities”	means any facilities used for the manufacture of the Adjuvanted Pandemic Vaccine, which are not Pandemic Facilities, provided such facilities comply with the requirements in Clause 3.6.
“Additional Volume”	means such number of Doses of the Wild-type Vaccine and/or the Beta Vaccine as may be agreed pursuant to Clause 4.2.
“Adjuvant”	means the squalene-based adjuvant developed by GSK.
“Adjuvanted Pandemic Vaccine”	means the Wild-type Vaccine and/or the Beta Vaccine, as applicable.
“Administering Entity”	means any body administering the Adjuvanted Pandemic Vaccine including all Health Service Bodies but excluding a Health Service Body constituted under section 2 of the National Health Service (Scotland) Act 1978, a Special Health Board constituted under that section, the NHS Wales or any statutory successors to such entities.
“Affiliate”	means any company which Controls, is Controlled by or is under common Control with Aventis and/or GSK, as applicable, and/or its respective ultimate parent company, as applicable.
“Agreement”	means this advance purchase agreement including all Exhibits, as amended from time to time.

[REDACTED]
[REDACTED]

[REDACTED]

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“Beta Vaccine”	means the adjuvanted recombinant monovalent COVID-19 vaccine, comprising the Adjuvant and S Antigen (Beta) at the Dose, to be developed by Sanofi Pasteur and GSK.
“British Overseas Territories”	means Anguilla, Bermuda, the British Virgin Islands, the Cayman Islands, the Falkland Islands, Gibraltar, Montserrat, the Pitcairn Islands, St Helena, Ascension Island, South Georgia, the South Sandwich Islands, the Turks and Caicos Islands, Sovereign base areas of Akrotiri and Dhekelia, the British Antarctic Territory and the British Indian Ocean Territory.
“Business Continuity Event”	means any event or issue that could impact on the operations of the Suppliers and their ability to supply the Adjuvanted Pandemic Vaccine including a pandemic and any Events of Force Majeure but excluding, for the avoidance of doubt, the withdrawal of the United Kingdom (or any part of it) from the European Union and any related circumstances, events, changes or requirements.
“Business Continuity Plan”	means the Suppliers’ business continuity plans which include their plans for continuity of the supply of the Adjuvanted Pandemic Vaccine during a Business Continuity Event.
“Business Day”	means any day other than a Saturday, Sunday or bank holiday in the Territory.
“Capacity Reservation Agreement”	has the meaning set out in Recital G.
“Central Government Body”	<p>means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:</p> <ul style="list-style-type: none">(a) Government Department;(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);(c) Non-Ministerial Department; or(d) Executive Agency.
“Clinical Trial”	means a clinical investigation of the Adjuvanted Pandemic Vaccine conducted on human subjects.
“Component(s)”	means the Adjuvant and/or the S Antigen as the context allows.
“Confidential Information”	means any and all information of any kind disclosed directly or indirectly by one Party and/or any of its Affiliates or Representatives to the other Party and/or any of its Affiliates or Representatives (whether in written, oral, electronic or in any other form and whether or not such

	information is expressly stated to be confidential or marked as such) pursuant to or in connection with this Agreement (whether before, on or after the Effective Date).
“Contract Manager”	has the meaning set out in Clause 15.1.1.
“Control”	means the holding, directly or indirectly, of: <ul style="list-style-type: none"> A) equal to or more than fifty percent (50%) of the voting share capital of a company; or B) the power to appoint at least one half of the Board of Directors or similar body of a company; or C) the power, by virtue of the constitution of the company or other arrangements or documents regulating that company, to secure that the affairs of a company are conducted in accordance with the holder’s wishes.
	“Controls” and “Controlled” shall have the corresponding meaning.
“Crown Dependencies”	means, the Isle of Man, Jersey, and Guernsey.
“Data Protection Legislation”	means the Data Protection Act 2018 (DPA) and the General Data Protection Regulation (EU) 2016/679), and all other applicable laws relating to the processing of personal data and privacy.
“Delivery”	means, (i) with respect to Great Britain, the electronic transfer from the stock of the Suppliers into the stock of the UK following physical delivery of the Adjuvanted Vaccine to the Place of Delivery; and [REDACTED] [REDACTED] in each case (i) and (ii), with respect to any quantity of the Adjuvanted Pandemic Vaccine. “Deliver” “Delivered” and “Delivering” shall have the corresponding meaning.
“Delivery Schedule”	[REDACTED]
“Delivery Specifications”	means the specifications for the Adjuvanted Pandemic Vaccine set out in EXHIBIT D.
“Dispute”	has the meaning set out in Clause 17.2.

“Donation Recipient”	has the meaning set out in Clause 6.2.b).
“Dose”	means a single dose of the applicable Adjuvanted Pandemic Vaccine for a healthy adult based on a final drug product dosage of 5µg of S Antigen per dose. For the avoidance of doubt, this Agreement does not provide for or otherwise cover the manufacture, supply or purchase of other dosages.
“EEA”	means the European Economic Area as its membership may be constituted from time to time, and any successor thereto, and which, as of the date hereof, is comprised of the members of the European Union together with Iceland, Liechtenstein and Norway.
“Effective Date”	means the date of last signature of this Agreement.
“EMA”	means the European Medicines Agency, or any successor agency thereto.
“Emergency Authorisation”	has the meaning set out in Clause 4.11.5.
“Environmental Regulations”	means the Environmental Information Regulations 2004.
“Equality Legislation”	means any and all legislation, applicable guidance and statutory codes of practice relating to equality, diversity, non-discrimination and human rights as may be in force in England and Wales from time to time including the Equality Act 2010, the Part-time Workers (Prevention of Less Favourable Treatment) Regulations 2000 and the Fixed-term Employees (Prevention of Less Favourable Treatment) Regulations 2002 (SI 2002/2034) and the Human Rights Act 1998.
“Events of Force Majeure”	has the meaning set out in Clause 16.13.1.
“Extended Territory”	means the Territory, the British Overseas Territories and the Crown Dependencies.
“First Volume”	means 7.5 million Doses of the Adjuvanted Pandemic Vaccine, as set out in the Delivery Schedule.
“FOIA”	means the Freedom of Information Act 2000.
“General Anti-Abuse Rule”	means (a) the legislation in Part 5 of the Finance Act 2013; and (b) any future legislation introduced into parliament to counteract tax advantages arising from abusive arrangements to avoid national insurance contributions.
“Good Distribution Practice” or “GDP”	means all applicable Good Distribution Practices, as current and in force at the applicable time, including: the Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01); and Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01) and the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

“Good Manufacturing Practice” or “GMP”

means all applicable Good Manufacturing Practices, as current and in force at the applicable time, including: (i) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice; (ii) the principles detailed in the United States Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601, 610 and 820; (iii) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products; (iv) the principles detailed in the ICH Q7A guidelines; and (v) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

“Health Service Bodies”

means:

- (a) the Department of Health and Social Care and all divisions and agencies thereof and any independent NHS board or similar body that may be established including regional agencies of such board;
- (b) a GP (being a medical practitioner providing general medical services or personal medical services under the National Health Service Act 2006 (c.41) (whether operating in partnership with others or not));
- (c) health service bodies referred to in section 9 of the National Health Service Act 2006 (c.41);
- (d) the Secretary of State for Health and Social Care;
- (e) any care trust as defined in section 77 of the National Health Service Act 2006 (c.41);
- (f) any NHS foundation trust listed in the register of NHS foundation trusts maintained pursuant to section 39 of the National Health Service act 2006 (c.41);
- (g) any body replacing or providing similar or equivalent services to any of the above in any area of the United Kingdom including any bodies established pursuant to the Health and Social Care Act 2012, including NHS England; and
- (h) any statutory successor to any of the above.

“ICH Guidelines”

means applicable guidelines used by the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.

“Joint Steering Committee” or “JSC”

has the meaning set out in Clause 15.2.1.

“KPI”	means the key performance indicators as set out in EXHIBIT E.
“Law”	means any applicable binding legal requirements including: <ul style="list-style-type: none">(a) any applicable statute or proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument as applicable in England and Wales;(b) to the extent binding under UK law, any applicable European Union obligation, directive, regulation, decision, law or right (including any such obligations, directives, regulations, decisions, laws or rights that are incorporated into the law of England and Wales or given effect in England and Wales by any applicable statute, proclamation, delegated or subordinate legislation, bye-law, order, regulation or instrument);(c) any enforceable community right within the meaning of section 2(1) European Communities Act 1972 recognised and available in domestic UK law;(d) any applicable judgment of a relevant court of law which is a binding precedent in England and Wales; and(e) requirements set by any applicable regulatory body as applicable in England and Wales.
“Manufacturing Licence”	means the manufacturing licence(s) in respect of the Adjuvanted Pandemic Vaccine granted by the relevant regulatory authority(ies) for the manufacture of the Adjuvanted Pandemic Vaccine and the Components.
“Marketing Authorisation”	means the regulatory approval(s) (conditional, full or otherwise) granted by the relevant regulatory authority(ies) for the administration and use of the Adjuvanted Pandemic Vaccine in the Territory. For the sake of clarity, the Marketing Authorisation for Great Britain will be granted by the MHRA while the Marketing Authorisation for Northern Ireland will likely be granted by the EMA.
“MHRA”	means the UK Medicines and Healthcare products Regulatory Agency, or any successor agency thereto.

“New Phase II Clinical Trial”

means a Clinical Trial of the Adjuvanted Pandemic Vaccine, carried out in a limited number (e.g. few hundreds) of healthy adults, to select for the further stages of development, the dose level of antigen to be formulated in the Adjuvanted Pandemic Vaccine. It will include complementary information about the monovalent (parental strain D614) Adjuvanted Pandemic Vaccine’s ability to produce its desired effect (immunogenicity) in target population and general safety as primary endpoints. An extension of this study will assess the safety and immunogenicity (as primary endpoints) of vaccine candidates used as booster (third dose) for subjects who received a complete primary vaccination schedule (four (4) to ten (10) months prior recruitment to the extension study) with several vaccine platforms (mRNA vaccine priming, adenovirus vaccine priming and protein sub-unit vaccine priming). The extension study will assess the immunogenicity of several vaccine compositions, antigen dosage and adjuvant dosage to support the Marketing Authorisation for booster (third dose) vaccination. The first cohort will assess the monovalent D614 vaccine as a booster candidate while the second cohort will include assessment of other candidates.

“Nonconforming Vaccine”

means Adjuvanted Pandemic Vaccine that, at the time of Delivery, does not comply with the specification of the Marketing Authorisation, GMP (in effect at the time of manufacture) or, to the extent applicable, GDP (in effect at the time of distribution) and “Nonconformance” shall have the corresponding meaning.

“Occasion of Tax Non-Compliance”

means:

(a) any Tax Return of GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited submitted to the Relevant Tax Authority on or after 1 October 2012 is found on or after 1 April 2013 to be incorrect as a result of:

(i) the Relevant Tax Authority successfully challenging GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited 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 principle explained in the CJEU Case C-255/02 Halifax and others;

(ii) the failure of an avoidance scheme which GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited were involved in, and which was, or should have

	<p>been, notified to a Relevant Tax Authority under the DOTAS or any equivalent or similar regime; and/or</p> <p>(b) any Tax Return of GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited submitted to a Relevant Tax Authority on or after 1 October 2012 gives rise, on or after 1 April 2013, to a criminal conviction in any jurisdiction for tax related offences which is not spent at the Effective Date or to a civil penalty for fraud or evasion.</p>
“Pandemic Facilities”	means the facilities listed in EXHIBIT A.
“Parties”	means the UK, GSK and Aventis, and “Party” shall mean each of them, as the context dictates.
“Phase I/II Clinical Trial”	means a Clinical Trial of the Adjuvanted Pandemic Vaccine, carried out in a limited number (e.g. few hundreds) of healthy adults, to select the dose level and immunization schedule for the Phase III Clinical Trial and to test the properties of the Adjuvanted Pandemic Vaccine, including preliminary information about the Adjuvanted Pandemic Vaccine’s ability to produce its desired effect (immunogenicity) in target population and general safety.
“Phase III Clinical Trial”	means a pivotal Clinical Trial with a defined dose and immunization schedule of the adjuvanted pandemic vaccine candidates [REDACTED] and conducted on a sufficient number of subjects to fully assess their protective efficacy and safety to support the Marketing Authorisation in primary vaccination at a dosage not covered in this Agreement.
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
“Product Warranty”	has the meaning set out in Clause 12.4.a).
“Prohibited Acts”	has the meaning set out in Clause 16.5.1.1.
“Pro Forma Change Control”	means the pro forma change control notice set out in EXHIBIT I.
“Pro-rata Rules”	means the principles applicable to the offering and Delivery of Doses to the UK and European Member States as set out in Clause 2.5.
“Redacted Version”	means the redacted copy of this Agreement as agreed by the Parties in accordance with 16.1.4 .
“Regulatory Approvals”	has the meaning set out in Clause 10.4.
“Rejection Notice”	has the meaning set out in Clause 4.12.2.
“Relevant Tax Authority”	means HM Revenue and Customs, or, if applicable, a tax authority in the jurisdiction in which GSK or Aventis (as applicable) are established.
“Representative”	means a Party’s employees, officers, agents, consultants or sub-contractors.

"Requirement to Recall"	has the meaning set out in Clause 4.13.1.
"S Antigen"	means the S Antigen (Beta) and/or the S Antigen (Wild-type), as applicable.
"S Antigen (Beta)"	means the recombinant COVID-19 monovalent spike protein antigen component, designed to target the B.1.351 variant of SARS-CoV-2, developed by Sanofi Pasteur.
"S Antigen (Wild-type)"	means the recombinant COVID-19 monovalent spike protein antigen component, designed to target the D614 wild-type of SARS-CoV-2, developed by Sanofi Pasteur.
"Sanofi Pasteur"	means Sanofi Pasteur S.A, an Affiliate of Aventis.
"Shelf Life"	means the minimum time for which the Adjuvanted Pandemic Vaccine remains stable in accordance with the specification of the Marketing Authorisation.
"Sub-contract"	means a contract between two or more suppliers, at any stage of remoteness from GSK and/or Aventis in a sub-contracting chain, made wholly or substantially for the purpose of performing (or contributing to the performance of) the whole or any part of this Agreement. " Sub-contracted " and " Sub-contractor " shall have the corresponding meaning.
"Supplier Code of Conduct"	means the code of that name published by the Government Commercial Function originally dated September 2017, as amended as of the Effective Date.
"Suppliers"	means GSK and Aventis.
"Tax Return"	means any return, declaration or filing required to be made, prepared or filed by the law of a Relevant Tax Authority in respect of taxes.
"Territory"	means the territory of the United Kingdom.
"Term"	means the term of this Agreement as set out in Clause 14.1.
"Term Sheet"	has the meaning set out in Recital G.
"Third Party Claim"	means any third-party claim, complaint, suit, proceedings or cause of action brought against Aventis and/or GSK and/or any of their respective Affiliates before any competent courts.
"Total Volume"	means the First Volume and, if applicable, any Additional Volume agreed pursuant to Clause 4.2.
[REDACTED]	[REDACTED]
"UK Government Agencies"	has the meaning set out in Clause 16.2.1.
"Vaccine IP Rights"	has the meaning set out in Clause 7.1.
"Wild-type Vaccine"	means the adjuvanted recombinant monovalent COVID-19 vaccine, comprising the Adjuvant and S Antigen (Wild-type), at the Dose, to be developed by Sanofi Pasteur and GSK.

1.2. Interpretation

In this Agreement, the following rules of interpretation shall apply:

- a) references to the singular include the plural and vice versa;
- b) a reference to any law shall include a reference to any revision or re-enactment of that law;
- c) references to “**days**” are to all calendar days including weekends and bank or public holidays in the Territory and references to “week” are to a period of seven consecutive days;
- d) references to “**GSK**” shall be to GlaxoSmithKline Biologicals S.A., and its Affiliates acting together or to each of GlaxoSmithKline Biologicals S.A. and its Affiliates acting severally, as the context allows;
- e) references to “**Aventis**” shall be to Aventis, and its Affiliates (expressly including Protein Sciences Corp., Sanofi Pasteur Inc. and Sanofi Pasteur SA) acting together or to each of Aventis and its Affiliates acting severally, as the context allows;
- f) references to the “**UK**” shall be to the Department for Business, Energy and Industrial Strategy of the UK Government, or any successor agency thereto, and it is acknowledged that the UK is acting on behalf of the Crown, and on behalf of England, Scotland, Wales, and Northern Ireland;
- g) references to Exhibits are to the exhibits attached to this Agreement, as varied, updated and/or replaced from time to time in accordance with this Agreement; and
- h) references to “**including**” shall be construed without limitation.

2. SUPPLY OF ADJUVANTED PANDEMIC VACCINE TO UK

- 2.1. Subject to the terms of this Agreement, Aventis and GSK shall, respectively, manufacture the S Antigen and the Adjuvant in accordance with Clause 3, on an at-risk basis with production anticipated without having all the New Phase II Clinical Trial and Phase III Clinical Trial data, and supply to the UK, the First Volume of Adjuvanted Pandemic Vaccine in accordance with Clause 4.
- 2.2. Subject to the terms of this Agreement, the Suppliers will make the First Volume available for the UK, commencing as soon as possible, but in any case, subject to Clause 4.11.5 and based on the anticipated dates for the granting of the applicable Marketing Authorisation(s) set out in Clause 4.1, [REDACTED]
[REDACTED] which, the Parties acknowledge, requires the Suppliers to start producing the Adjuvanted Pandemic Vaccine as soon as possible and while the Adjuvanted Pandemic Vaccine is still under development.
- 2.3. The Parties acknowledge that production of the First Volume for the UK will require the Suppliers to support substantial expenditures related to the manufacturing and supply of such First Volume without having all the New Phase II Clinical Trial and Phase III Clinical Trial data. Consequentially, the Parties agree to share the financial risk related to such manufacturing and supply of the Adjuvanted Pandemic Vaccine in accordance with the terms of this Agreement.
- 2.4. The Suppliers shall, subject to the terms of this Agreement, apply for the Marketing Authorisation for the Adjuvanted Pandemic Vaccine (Wild-type Vaccine and

subsequently such supplemental filing as may be required for the Beta Vaccine) [REDACTED]

[REDACTED] and the Suppliers shall promptly provide the MHRA with such information and support as the MHRA may reasonably request in order to assess and grant the Marketing Authorisation. The initial application for the Wild-type Vaccine will be extended by a variation to include the formulation for Beta Vaccine (covering 5µg per dose). If the MHRA has questions relating to the Suppliers' data packages for the Adjuvanted Pandemic Vaccine, as submitted to the EMA, or requests that the Suppliers present the data in a different format to that submitted to the EMA, provided such questions or requests do not require substantial expenditure on the part of the Suppliers, the Suppliers shall promptly cooperate with the MHRA as the MHRA may reasonably request in order to answer such questions or reformat such data. [REDACTED]

- 2.5. If following grant of Marketing Authorisation, the Suppliers do not have sufficient quantities of the applicable Adjuvanted Pandemic Vaccine to Deliver the First Volume as scheduled, the Suppliers shall Deliver the First Volume to the UK pursuant to this Agreement on a pro-rated basis by comparing the number of Doses of the Wild-type Vaccine or Beta Vaccine comprising the First Volume with the overall aggregate confirmed volume commitment of the EU Member States (as notified by the European Commission) at the Effective Date. If the Suppliers have additional Doses of the Wild-type Vaccine or the Beta Vaccine potentially available to the UK pursuant to Clause 4.2 or the EU Member States at a similar time, such additional Doses shall be offered on a pro-rata basis with 16.7% of such additional Doses being offered to the UK and 83.3% of such additional Doses being offered to the EU Member States.

- 2.6. If the UK does not receive its First Volume as per the Delivery Schedule, the Suppliers will ensure Delivery of the Adjuvanted Pandemic Vaccine in accordance with Clause 2.2 and the Pro-rata Rules until the full First Volume is Delivered.

3. MANUFACTURE OF ADJUVANTED PANDEMIC VACCINE

- 3.1. The Suppliers shall comply with their respective quality control monitoring systems details of which will be included in the Marketing Authorisation and the Manufacturing Licence. The Suppliers shall manufacture the Adjuvanted Pandemic Vaccine in accordance with Good Manufacturing Practice.

- 3.2. The Suppliers shall maintain the Manufacturing Licence and all other licences necessary for the manufacture of the Adjuvanted Pandemic Vaccine during the Term of this Agreement and shall not make any significant changes (including any changes which will or might reasonably be expected to have an impact on the quality or use of the Adjuvanted Pandemic Vaccine) to the Manufacturing Licence and all other licences necessary for the manufacture of the Adjuvanted Pandemic Vaccine, to the Marketing Authorisation or the Suppliers' quality control monitoring system in relation to the Adjuvanted Pandemic Vaccine without the relevant regulatory authority, including the EMA and/or the MHRA, as applicable, formally approving such change in advance (where approval in advance is required by applicable Law).

- 3.3. The Suppliers shall at their cost, submit sample units from each batch of the Adjuvanted Pandemic Vaccine to the EEA-based official medicines control laboratory OMC(L) in charge of providing European samples testing for quality assessment and batch release prior to Delivery of the batch concerned to the UK. If additional sampling and/or testing is required by the UK National Control Laboratory the Suppliers shall, at their cost, submit sample units of finished product from each batch of the Adjuvanted Pandemic Vaccine when it is in the Territory. Although the Adjuvanted Pandemic Vaccine may undergo quality assurance assessment, such assessment shall not affect the Suppliers' obligations under this Agreement and shall not of itself constitute acceptance or approval by the UK of the Adjuvanted Pandemic Vaccine.

- 3.4. The Suppliers shall ensure manufacture of the S Antigen and the Adjuvant, for supply of the Adjuvanted Pandemic Vaccine to the UK, takes place at the Pandemic Facilities, which for clarity shall be listed in the Marketing Authorisation to the extent required by Law. Notwithstanding the foregoing, the Suppliers may use the Additional Facilities as contingencies in order to meet the obligations set out in this Agreement for supply to the UK, or in the event that the Suppliers consider that the Delivery Schedule could be accelerated compared to using the Pandemic Facilities only. The Suppliers shall notify the UK of their intention to use any of the Additional Facilities in accordance with Clause 3.6.

- 3.5. [REDACTED]

- 3.6. Should the Suppliers wish to utilise Additional Facilities in the manufacture of the Adjuvanted Pandemic Vaccine, they shall provide the UK in writing with full details (full name and address) of the entity concerned, ensure such facilities are fully GMP compliant and hold an appropriate manufacturers licence and provide evidence of

such to the UK, ensure appropriate amendments to the Marketing Authorisation have been made and approved by the relevant regulatory authorities and provide evidence of such to the UK and provide the UK with notice as soon as reasonably practicable to enable it to comply with GDP and its obligations as the holder of a pharmaceutical wholesale dealer's licence. Notwithstanding the foregoing, the Suppliers may not use any Additional Facilities which are subject to mandatory exclusion grounds pursuant to Regulation 57 (1) or 57 (2) of the Public Contracts Regulations 2015) and any proposed Additional Facilities are subject to the UK's right to veto such appointment for such reason, unless the UK has established that the exclusion should be disregarded for reasons set out in Regulation 57(6), 57(7) or 57(13).

- 3.7. Solely as required by applicable Laws, the Suppliers shall permit any person authorised by the UK (solely to the extent required for the UK to comply with the terms of its pharmaceutical wholesale dealer's licence), the MHRA and other applicable regulatory authorities to inspect work being undertaken in relation to the Adjuvanted Pandemic Vaccines, including manufacturing and/or the storage facilities, at all reasonable times at the Suppliers' premises, and shall use commercially reasonable efforts to facilitate inspections at the premises of any Sub-contractor or agent of the Suppliers involved in activities relating to this Agreement, in order to confirm that the Adjuvanted Pandemic Vaccines are being manufactured and/or stored in accordance with applicable Law, GMP (in effect at the time of manufacture) and GDP (in effect at the time of distribution).

4. SUPPLY OF TOTAL VOLUME

- 4.1. As at the Effective Date, subject to successful development of the Adjuvanted Pandemic Vaccine, the Suppliers anticipate that the Marketing Authorisation for (a) [REDACTED]; and (b) the Beta Vaccine will be granted by the [REDACTED]. On the basis of the foregoing assumptions and subject to Clause 4.3, the Suppliers shall Deliver the First Volume in accordance with the Delivery Schedule for such Doses.
- 4.2. Following the Effective Date, the Suppliers may notify the UK from time to time that additional Doses are available for purchase by the UK pursuant to this Agreement. If the UK wishes to purchase all or some of such additional Doses, the UK shall inform the Suppliers within four (4) weeks of receiving notice from the Suppliers under this Clause 4.2, following which the Parties shall, within one (1) week of the UK informing the Suppliers that it wishes to purchase (unless a longer period is agreed by the Parties), discuss and determine the desired quantities of additional Doses to be purchased (including whether of Wild-type Vaccine and/or Beta Vaccine) and an indicative delivery schedule for such Doses, after which period if an agreement on the desired quantities and the indicative delivery schedule is not reached, the offer in respect of such additional quantities shall lapse. If such quantities and delivery schedule are agreed the Parties shall record such agreement by each initialling a copy of the tentative delivery schedule and the Suppliers shall Deliver and the UK shall take Delivery of and pay for, the Doses identified in such schedule (the "Additional Volume") in accordance with the terms of this Agreement.

- 4.3. [REDACTED]

[REDACTED]

- 4.4. The Suppliers shall provide updates on the Delivery Schedules on a rolling fortnightly basis for the Term through the Contract Manager meetings referred to in Clause 15.1.5. Such updates shall include an estimate of the total number of Doses expected to be available for Delivery and the dates in the Delivery Schedule that such Doses will be available for Delivery.

- 4.5. [REDACTED]

- 4.6. [REDACTED]

4.7. **Orders**

- 4.7.1. The Parties acknowledge that this Agreement constitutes a commitment by the UK to purchase the First Volume and, if applicable, the Additional Volume.

4.7.2. Within five (5) Business Days following the Effective Date, the UK shall order Delivery of the First Volume by issuing one order in the form set out in EXHIBIT F for the First Volume. In the event the Parties agree to the Delivery of any Additional Volume and upon the Parties recording such agreement pursuant to Clause 4.2, the UK shall order Delivery of the Additional Volume by issuing one order in the form set out in EXHIBIT F for the Additional Volume.

4.8. **Delivery**

4.8.1. The Suppliers shall Deliver the Adjuvanted Pandemic Vaccines ordered by the UK:

- a) subject to 4.3, in accordance with the applicable Delivery Schedule, but at all times respecting the Pro-rata Rules;
- b) in accordance with the Delivery Specifications;
- c) in accordance with Clause 4.9;
- d) materially in accordance with the applicable specifications of the Marketing Authorisation; and
- e) in accordance with applicable Law, GMP (in effect at the time of manufacture) and GDP (to the extent applicable, in effect at the time of distribution), including by taking measures to avoid abnormal temperatures, humidity and light and to ensure the absence of cross contamination.

4.9. Unless otherwise agreed by the Parties, each Delivery shall contain:

- a) at least the Minimum Delivery Quantity and nothing in this Agreement shall require the Suppliers to Deliver a quantity of the Adjuvanted Pandemic Vaccine per shipment that is less than the Minimum Delivery Quantity; and
- b) no more than the Maximum Delivery Quantity.

4.10.



4.11. The Suppliers shall Deliver the Adjuvanted Pandemic Vaccines securely packaged with the following details being shown clearly on the shipping carton or other such outer packaging:

- a) a description of Adjuvanted Pandemic Vaccine using relevant brand name and/or other name for the Adjuvanted Pandemic Vaccine, as applicable;

- b) the quantity (number of Doses) of Adjuvanted Pandemic Vaccine in each package;
- c) special directions for storage;
- d) batch number;
- e) Sanofi Pasteur's name as holder of the Marketing Authorisation; and
- f) any other details required to be shown on such shipping carton or other outer packaging by the Marketing Authorisation (taking into account any waiver, forbearance or exemption granted or allowed by the MHRA (or the EMA as applicable in respect of Northern Ireland)).

4.11.2. The labelling and marking of all packages of the Adjuvanted Pandemic Vaccine and all relevant information accompanying them shall be in English, provided that in respect of Northern Ireland, such information may be in English and any other language required by the EMA.

4.11.3. The Suppliers shall ensure that a delivery note shall accompany each Delivery of the Adjuvanted Pandemic Vaccines or be provided electronically and contemporaneously with Delivery. Such delivery note shall contain the information specified in Clause 4.11, the UK's order number, the name and address of the UK, and such other information as otherwise agreed with the UK in writing.

4.11.4.



4.11.5. The Parties acknowledge that first Delivery of the Adjuvanted Pandemic Vaccine in the Territory shall not occur prior to the grant of the Marketing Authorisation, provided that if the UK notifies the Suppliers that it wishes to use the Adjuvanted Pandemic Vaccine based on temporary authorisation under Regulation 174 of the UK Human Medicines Regulations 2012, as amended (being "**Emergency Authorisation**"), then the Supplier shall reasonably consider to make Delivery of the Adjuvanted Pandemic Vaccine as soon as possible following the notification of the Emergency Authorisation, with the Parties acknowledging that Delivery may be in advance of the applicable Delivery Schedule but at all times remaining subject to

the availability of the Adjuvanted Pandemic Vaccine and the Pro-rata Rules. For clarity, provisions of this Agreement relating to Delivery of the Adjuvanted Pandemic Vaccine under the Marketing Authorisation shall, where relevant, also apply to Delivery of the Adjuvanted Pandemic Vaccine under Emergency Authorisation.

4.11.6. Without prejudice to the UK's rights under Clause 4.12 below:

- a) Title in the Adjuvanted Pandemic Vaccines shall transfer to the UK upon Delivery of such Adjuvanted Pandemic Vaccines in accordance with this Agreement.
- b) Risk of loss in the Adjuvanted Pandemic Vaccines shall transfer to the UK upon Delivery of such Adjuvanted Pandemic Vaccines pursuant to this Agreement.

4.12. **Acceptance & Nonconforming Vaccine**

4.12.1. Upon Delivery of the Adjuvanted Pandemic Vaccine, the UK shall, through visual examination (including by consulting the relevant documentation accompanying such shipment) inspect each shipment of Adjuvanted Pandemic Vaccine.

4.12.2. In the event the UK considers that a shipment of Adjuvanted Pandemic Vaccine, or any part thereof contains Nonconforming Vaccine, the UK may notify the Suppliers of its intent to reject such shipment of the Adjuvanted Pandemic Vaccine, or any part thereof, by giving written notice to Aventis [REDACTED] [REDACTED] in accordance with Clauses 4.12.3 and 4.12.5 (such notice, the "**Rejection Notice**"). Where the UK does not serve the Rejection Notice in accordance with such provisions, the shipment may be construed by the Supplier as being in good condition and to conform to the relevant documentation and requirements under this Agreement and shall be deemed accepted by the UK ("**Acceptance**").

4.12.3. The UK shall serve the Rejection Notice within the following periods:

- a) where such Nonconformance was discernible at the time of Delivery by visual examination performed with due care pursuant to Clause 4.12.1, within [REDACTED]; or
- b) where such Nonconformance was not discernible at the time of Delivery by visual examination performed in due care pursuant to Clause 4.12.1, [REDACTED] or should have reasonably obtained knowledge, of the relevant Nonconformance,

provided that in no event may the UK serve such Rejection Notice after administration or use, or (if earlier) expiry of the Shelf Life, of such shipment of Adjuvanted Pandemic Vaccine.

- 4.12.4. The whole of any shipment of Adjuvanted Pandemic Vaccine may be rejected if a reasonable sample of the shipment taken indiscriminately from that shipment is agreed by the Parties or determined in accordance with this Clause 4.12 to be Nonconforming Vaccine.
- 4.12.5. The UK shall describe to the Suppliers, in reasonable detail, the alleged Nonconformance in the Rejection Notice and, if requested by the Suppliers, promptly provide sample(s) of the alleged Nonconforming Vaccine.
- 4.12.6. Where it is agreed between the Parties after the conduct of further investigation (such further investigation to be completed as quickly as practicable in accordance with Aventis standard procedures for similar complaints) that the Adjuvanted Pandemic Vaccine referred to in Clause 4.12.2 is Nonconforming Vaccine, the UK may reject such Nonconforming Vaccine and the Suppliers shall at the Supplier's discretion, either [REDACTED]
- 4.12.7. In the event that the Parties cannot agree whether or not the Adjuvanted Pandemic Vaccine referred to in Clause 4.12.2 is Nonconforming Vaccine, the matter shall be determined by an independent laboratory, to be nominated by the UK and agreed by the Suppliers within ten (10) Business Days of the Parties completing the further investigation described in Clause 4.12.6. All costs associated with such independent laboratory shall be borne by [REDACTED]
- 4.12.8. Unless otherwise requested by the Suppliers the Nonconforming Vaccine shall be destroyed by the UK and the UK shall promptly send evidence of such destruction to the Suppliers (including the batch number and quantities of such destroyed Nonconforming Vaccine), provided that the UK reserves the right to charge the Suppliers for the reasonable and documented costs associated with the destruction of the Nonconforming Vaccine and the Suppliers shall promptly pay any such costs on issue of an invoice therefor.
- 4.12.9. The Suppliers shall be relieved of their liabilities under Clause 4.12.6 if and to the extent only that the Nonconformance was caused by any acts or omissions of the UK or its Representatives. For clarity, the Suppliers shall not have any liability for any non-conformance caused after Delivery.

4.13. Recalls

4.13.1. Where the Suppliers are required by applicable Law, GMP or GDP to order a product recall in the Territory in respect of any Adjuvanted Pandemic Vaccine or the Suppliers, in their own reasonable judgement deem a product recall in the Territory in respect of any Adjuvanted Pandemic Vaccine necessary or appropriate (“**Requirement to Recall**”), Aventis shall be responsible for making any product recall decisions in respect of such recall, and for initiating and executing any such product recall in accordance with applicable Law. Without limiting the generality of the foregoing, Aventis shall where and as agreed with the MHRA (or the EMA as applicable in respect of Northern Ireland):

- a) promptly (taking into consideration the potential impact of the continued use of the Adjuvanted Pandemic Vaccines on patients, service users and the UK as well as compliance by the Suppliers with any regulatory requirements including as agreed with the MHRA (or the EMA as applicable in respect of Northern Ireland)) notify the UK in writing of the recall together with the circumstances giving rise to the recall;
- b) if it is agreed or determined in accordance with Clause 4.12 that the Requirement to Recall was caused by Nonconforming Vaccine, treat the Adjuvanted Pandemic Vaccine that is the subject of such recall as Nonconforming Vaccine in accordance with Clause 4.12.6;
- c) consult with the MHRA (or the EMA as applicable in respect of Northern Ireland) as to the most efficient method of executing the recall of the Adjuvanted Pandemic Vaccines and Aventis and the UK shall co-operate to effect the recall in accordance the UK’s standard recall procedures and the reasonable instructions of Aventis and the following shall apply:

i. GMP-related recall: If the Requirement to Recall is due to noncompliance with GMP, the recall shall be carried out [REDACTED]

ii. GDP-related recall caused by the Suppliers: If the Requirement to Recall relates to noncompliance with GDP occurring before Delivery, the recall shall be carried out by [REDACTED] and [REDACTED]

iii. GDP-related recall caused by the UK: If the Requirement to Recall relates to noncompliance with GDP occurring after Delivery, the recall shall be [REDACTED]

5. PRICE AND PAYMENT

5.1. General

5.1.1. [REDACTED]

5.1.2. Unless otherwise agreed by the Parties in writing:

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

- [REDACTED]

5.1.3. [REDACTED]

[REDACTED]

- 5.1.4. Where the UK raises a query in good faith with respect to an invoice the Parties shall liaise with each other and agree a resolution to such query within [REDACTED] of the query being raised. If the Parties are unable to agree a resolution [REDACTED], the query shall be referred to dispute resolution in accordance with Clause 17. For the avoidance of doubt, the UK shall not be in breach of any of its payment obligations under this Agreement in relation to any queried or disputed invoice sums (which have been queried or disputed in good faith) unless the process referred to in this Clause 5.1.4 has been followed and it has been determined that the queried or disputed invoice amount is properly due to the Suppliers and the UK has then failed to pay such sum within a reasonable period following such determination.

- 5.1.5.

[REDACTED]

- 5.1.6.

[REDACTED]

[REDACTED]

[REDACTED]

5.1.7. [Redacted]

5.1.8. [Redacted]

5.2. [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

5.3. [Redacted]

[Redacted]

[REDACTED]

5.4. Late Payments

5.4.1.

[REDACTED]

5.4.2. If any payment due by the UK under this Agreement is more than sixty (60) days late, the Suppliers may cease Delivery of the Adjuvanted Pandemic Vaccine until payment is made (and, for clarity, any such delay shall not be a “**Substantial Alteration**”).

6. USE OF ADJUVANTED PANDEMIC VACCINE

6.1. Following Delivery, the UK shall have sole responsibility for the proper storage, distribution, use and administration of the Adjuvanted Pandemic Vaccine, and such storage, distribution, use and administration shall occur in conformity with GDP, applicable Law and in accordance with this Agreement. The UK shall use the Adjuvanted Pandemic Vaccine solely to vaccinate individuals in the Extended Territory.

6.2. Without prejudice to the generality of Clause 6.1, the UK shall not:

- a) test, or have tested, the Adjuvanted Pandemic Vaccine; or
- b) sell, lend, donate, supply to or otherwise permit the use of the Adjuvanted Pandemic Vaccine by any third party other than treating physicians, nurses and/or, to the extent duly authorised and covered by appropriate professional indemnity insurance or NHS indemnity, suitably trained non-registered/non-healthcare vaccinator volunteers in charge of administering the Adjuvanted Pandemic Vaccine to patients and relevant personnel in the distribution chain in the Extended Territory. Notwithstanding the foregoing, the UK may donate its stocks of the Adjuvanted Pandemic Vaccine that it no longer requires to any third party (each a “**Donation Recipient**”) for use and administering of the Adjuvanted Pandemic Vaccine to patients in countries other than in Covered Nations, for instance through the COVAX facility or similar programs; [REDACTED]

- [REDACTED]
- 6.3. If prior to Delivery of the applicable Doses, the UK notifies the Suppliers that it wishes to donate all or some of the Total Volume (by paying for but not taking Delivery of such Doses) for use outside the Extended Territory, the Parties will discuss potential mechanisms for implementing and applicable conditions with respect to such donations. [REDACTED]
- [REDACTED]

7. INTELLECTUAL PROPERTY

- 7.1. The UK acknowledges and agrees that, as between the Parties, GSK and Aventis shall be the sole owners of all intellectual property rights generated during the development, manufacture, and supply of the Adjuvanted Pandemic Vaccine (collectively, the “**Vaccine IP Rights**”). GSK and Aventis shall be entitled to exclusively exploit any such Vaccine IP Rights. Except as expressly set out in this Agreement, neither Aventis nor GSK grants to the UK by implication, estoppel or otherwise, any right, title, license or interest in the Vaccine IP Rights. All rights not expressly granted by GSK and Aventis hereunder are reserved by GSK and Aventis.
- 7.2. GSK and Aventis shall, on reasonable request by the UK, provide the UK with technical or other documentation and information relating to the Adjuvanted Pandemic Vaccine in such media as reasonably requested by the UK or that the Suppliers have generally available at the time of request for the purposes of the UK receiving, using and administering the Total Volume of Adjuvanted Pandemic Vaccine in accordance with this Agreement.
- 7.3. GSK and Aventis confirm that they will not, during the Term, enforce their intellectual property rights pertaining to the Total Volume to prevent or delay the UK from importing, holding, transporting, administering or using the Adjuvanted Pandemic Vaccine in the Extended Territory for the purpose set out in and otherwise in accordance with Clause 6, and otherwise in accordance with the terms of this Agreement.

8. [REDACTED]

8.1. The UK shall have sole responsibility of the administration of the Adjuvanted Pandemic Vaccine, such administration to occur in conformity with applicable Law.

8.2. [REDACTED]

8.3. [REDACTED]

8.4. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

8.5. [REDACTED]

8.6. [REDACTED]

8.7. [REDACTED]

8.8. [REDACTED]

8.9. [REDACTED]

8.10. [REDACTED]

9. [REDACTED]

- 9.1. [REDACTED]
- 9.2. [REDACTED]
- 9.3. [REDACTED]
- 9.4. [REDACTED]

10. REGULATORY APPROVALS AND COOPERATION

- 10.1. [REDACTED]
- 10.2. During the Term, the Suppliers shall ensure that they will notify the UK or the UK's Contract Manager promptly, and in any event, within [REDACTED] unless required sooner in accordance with applicable Law, upon their knowledge of the following, to the extent they will or may reasonably be expected to materially impact on the obtaining of the Marketing Authorisation or Delivery of the Adjuvanted Pandemic Vaccine in accordance with the Delivery Schedule:
- a) any delay or other problem with the grant of the Marketing Authorisation or its renewal;
 - b) any proposal to vary or amend the granted Marketing Authorisation;
 - c) any Clinical Trial results or findings (including from the Phase I/II Clinical Trial, the New Phase II Clinical Trial and the Phase III Clinical Trial) that impact (or would reasonably be expected to impact) the Delivery of the Adjuvanted Pandemic Vaccine under this Agreement, including information relating to the safety and/or efficacy of the Adjuvanted Pandemic Vaccine

- 11.2. If the Parties agree that such additional terms are necessary, they shall negotiate such additional terms as are necessary to enable:
- a) the Parties to comply with regulatory requirements for the reporting of safety data in accordance with standards stipulated in the ICH Guidelines, and all applicable regulatory and legal requirements regarding the management of safety data;
 - b) the Parties to exchange relevant safety data within timeframes and in a format that will facilitate compliance by each of them with both expedited and periodic regulatory reporting requirements; and
 - c) the Suppliers to comply with any risk management plans or any other plans for minimizing risks or managing potential safety issues, as may be required by the MHRA (or the EMA as applicable in respect of Northern Ireland) in the Regulatory Approvals for the Adjuvanted Pandemic Vaccine.
- 11.3. For clarity, any Product Technical Complaints received by the UK in relation to the Adjuvanted Pandemic Vaccine shall be notified to Aventis or its Affiliate by the UK within one (1) Business Day (using such contact details as Aventis may notify UK from time to time) with, where possible, the defective sample, name of the Adjuvanted Pandemic Vaccine, product strength/pack size, lot batch number, quantity, description of the defect and contact details of the reporter. For the purpose of this Clause 11.3, “**Product Technical Complaint**” shall mean any written or written electronic communication that alleges deficiencies related to the appearance, labelling, identity, quality, and stability of the Adjuvanted Pandemic Vaccine.

12. WARRANTIES

12.1. General



12.2. Warranty by GSK

GSK represents and warrants that it is legally entitled and has the full power to enter into this Agreement, to carry out its obligations under this Agreement either directly or by engaging its Affiliates or Sub-contractors and to grant the rights and benefits granted by it to the UK under this Agreement and by doing so does not infringe any agreement with any third party.

12.3. Warranty by Aventis

Aventis represents and warrants that it is legally entitled and has the full power to enter into this Agreement, to carry out its obligations under this Agreement either directly or by engaging its Affiliates or Sub-contractors and to grant the rights and benefits granted by it to the UK under this Agreement and by doing so does not infringe any agreement with any third party.

12.4. Warranties by both GSK and Aventis

Each of GSK and Aventis warrant and represent that:

- a) the Adjuvanted Pandemic Vaccine will only be released in compliance with the specification of the Marketing Authorisation and with Good Manufacturing Practices in effect at the time of manufacture (for clarity, taking into account any waiver, forbearance or exemption granted or allowed by MHRA or any other applicable regulatory authority) (the “**Product Warranty**”);
- b) it shall: (i) comply with all relevant Law and guidance to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the UK immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;
- c) it shall at all times conduct its business in a manner that is consistent with any anti-slavery policy of the UK that is publicly available or notified to the Suppliers (provided in each case, such policy is generally applicable to other third parties supplying pharmaceutical products or vaccines to the UK) ; and
- d) it will notify the UK in writing of any Occasions of Tax Non-Compliance.

12.5. Warranty by UK

The UK represents and warrants that it is legally entitled and has the full power to enter into this Agreement, to carry out its obligations under this Agreement and to grant the rights and benefits granted by it to Aventis and GSK respectively under this Agreement and by doing so does not infringe any agreement with any third party.

13. LIMITATION OF LIABILITY**13.1. Interpretation**

Where it is stated that Aventis and/or GSK or any of its or their respective Affiliates “anticipates”, “estimates”, “expects” or “believes”, or where there is a stated “assumption” that an event or occurrence will happen on or by a certain date, such anticipated, estimated, expected, believed or assumed happening or date of such happening is only Aventis’ and/or GSK’s or the respective Affiliate’s current good faith expectation and is not a commitment, guarantee or undertaking. Aventis, GSK and their respective Affiliates shall not be liable where such anticipated or expected

events or happenings do not occur or do not occur by the anticipated, estimated or expected date.

13.2. Limitation of Liability

13.2.1. Each Party shall be severally liable under this Agreement.

13.2.2. Nothing in this Agreement shall exclude or limit a Party's liability to any third party or each other to the extent it would be illegal or invalid in any way for that Party to exclude or attempt to exclude or limit its liability under the laws of England and Wales.

13.2.3.

[REDACTED]

14. TERM AND TERMINATION

14.1. Term

This Agreement shall come into force on the Effective Date and shall remain valid, unless and until terminated in accordance with this Clause 14 (the "**Term**").

14.2. Termination on Occurrence of Certain Events

This Agreement shall automatically terminate on the later of:

■ [REDACTED]

■ [REDACTED]

14.3. Termination by Either Party

This Agreement may be terminated, on the one hand by the UK, or on the other by the Suppliers:

a) if the other Party is in material breach of its obligations under this Agreement and has not remedied such breach [REDACTED]

[REDACTED]

- b) in an Event of Force Majeure in accordance with Clause 16.13.2(iii);
- c) in the event that the Suppliers cease development or manufacture of the Adjuvanted Pandemic Vaccine;
- d) [REDACTED]
- e) [REDACTED]
- f) [REDACTED]

14.4. Termination by the UK

14.4.1. The UK may terminate this Agreement by issuing a notice to the Suppliers:

- a) if either GSK or Aventis cease or threaten to cease carrying on its business; suspends making payments on any of its debts or announces an intention to do so; is, or is deemed for the purposes of any Law to be, unable to pay its debts as they fall due or insolvent; enters into or proposes any composition, assignment or arrangement with its creditors generally; takes any step or suffers any step to be taken in relation to its winding-up, dissolution, administration (whether out of court or otherwise) or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) otherwise than as part of, and exclusively for the purpose of, a bona fide reconstruction or amalgamation; has a liquidator, trustee in bankruptcy, judicial custodian, compulsory manager, receiver, administrative receiver, administrator or similar officer appointed (in each case, whether out of court or otherwise) in respect of it or any of its assets; has any security over any of its assets enforced; or any analogous procedure or step is taken in any jurisdiction;
- b) if either GSK and/or Aventis undergo a change of control within the meaning of sections 450 and 451 of the Corporation Tax Act 2010 (other than for an intra-group change of control) without the prior written consent of the UK and the UK shall be entitled to withhold such consent if, in the reasonable opinion of the UK, the proposed change of control will have a material impact on the performance of this Agreement or the reputation of the UK;
- c) if GSK and/or Aventis purport to assign, sub-contract, novate, create a trust in or otherwise transfer or dispose of this Agreement in breach of its provisions;
- d) pursuant to and in accordance with provisions in this Agreement allowing the UK to terminate this Agreement; or

- e) if the warranty given by GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited in respect of any Occasion of Tax Non-Compliance is materially untrue, GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited commit a material breach of their obligations to notify the UK of any Occasion of Tax Non-Compliance, or GlaxoSmithKline Biologicals SA and/or Aventis Pharma Limited fail to provide details of proposed mitigating factors that in the reasonable opinion of the UK are acceptable.

14.4.2. The UK may terminate this Agreement by issuing a notice to the Suppliers where:

- a) this Agreement has been substantially amended to the extent that the Public Contracts Regulations 2015 require a new procurement procedure;
- b) the UK has become aware that GSK and/or Aventis should have been excluded under Regulation 57(1) or (2) of the Public Contracts Regulations 2015 from the procurement procedure leading to the award of this Agreement provided in each case that GSK and/or Aventis has first exhausted its self-cleaning rights with the UK provided for under Regulations 57(13) and 57(14);
- c) there has been a failure by (i) GSK and/or Aventis or (ii) a sub-contractor of GSK and/or Aventis that is directly involved in performance of the Suppliers' obligations hereunder and was appointed after the Effective Date to comply with legal obligations in the fields of environmental, social or labour Law provided that GSK and/or Aventis has first exhausted its self-cleaning rights with the UK provided for under Regulations 57(13) and 57(14). Where such failure to comply with legal obligations in the fields of environmental, social or labour Law is a failure by a party other than Suppliers, as an alternative to and prior to the Authority terminating this Agreement under this section the UK may request the replacement of such party and the applicable Supplier shall use Commercially Reasonable Efforts to comply with such request.

14.5. **Consequences of expiry or early termination of this Agreement**

14.5.1. Upon expiry or earlier termination of this Agreement, the UK agrees to pay the Suppliers for the Adjuvanted Pandemic Vaccines which have been Delivered prior to expiry or earlier termination of this Agreement provided that this shall be the extent of the compensation due by the UK to the Suppliers upon termination of this Agreement for any reason. For clarity, nothing in this Agreement shall require the Suppliers to deliver any further Adjuvanted Pandemic Vaccines after termination or expiration of this Agreement.

14.5.2. The expiry or earlier termination of this Agreement for whatever reason shall not affect any rights or obligations of either Party which accrued prior to such expiry or earlier termination.

- 14.5.3. The expiry or earlier termination of this Agreement shall not affect any obligations which expressly or by implication are intended to come into or continue in force on or after such expiry or earlier termination.

14.6. **Post termination provisions**

- 14.6.1. Clauses 1. (Definitions and Interpretation), 4.13 (Recalls), 5 (to the extent any payments under this Agreement have accrued prior to termination and are still outstanding), 6 (Use of Adjuvanted Pandemic Vaccine), 7.1 (Intellectual Property), [REDACTED], 11.3 (Product Technical Complaints), 12 (Warranties), 13 (Limitation of Liability), 14.5 (Consequences of expiry or early termination of this Agreement), this Clause 14.6.1, Clauses 16.1 (Confidentiality) to 16.3 (Data Protection), 16.12 (Change Control), 16.14 (Relationship of Parties) to 16.19. (Assignment) and 16.20 (Governing Law and Jurisdiction) shall survive termination or expiration of this Agreement.

15. GOVERNANCE

15.1. **Contract Management**

- 15.1.1. From the Effective Date, each Party shall appoint and retain a contract manager who shall be its primary point of contact for the other Parties in relation to matters arising from this Agreement (each a “**Contract Manager**”). Any Contract Manager appointed shall be of sufficient seniority and experience to be able to make decisions on the day to day operation of the Agreement. The Suppliers confirm and agree that they will work closely and cooperate fully with the UK’s Contract Manager, and the UK agrees that it will work closely and cooperate fully with GSK’s and Aventis’ respective Contract Manager.
- 15.1.2. Each Party shall ensure that its Contract Manager shall attend each meeting of the Joint Steering Committee to review the performance of the Parties under this Agreement and shall discuss matters arising generally under this Agreement.
- 15.1.3. Each Party shall procure that its respective Contract Manager shall:
- a) make themselves reasonably available to the other Contract Managers for meetings in accordance with the provisions of this Clause 15;
 - b) co-operate candidly and transparently with the other Contract Managers to ensure that any actual or potential issues, difficulties or problems encountered in connection with the Adjuvanted Pandemic Vaccine, its development, manufacture and supply, in each case under this Agreement and performance of any obligation hereunder, are raised and discussed between Contract Managers at the earliest opportunity;
 - c) be part of the relevant Party’s team working on and has good first-hand knowledge of the arrangements and matters relating to this Agreement; and

- d) ensure that they appraise themselves and keep themselves appraised of all material matters and issues concerning this Agreement and its performance.

15.1.4. The Contract Managers shall monitor and discuss (a) progress in relation to each of the KPIs, [REDACTED]
[REDACTED]
[REDACTED] (and shall propose mitigations to the Joint Steering Committee on the same). Any change of Contract Manager by a Party shall be notified to the other Parties in writing as soon as reasonably possible.

15.1.5. The Contract Managers will meet once every two (2) weeks and at such other times as they reasonably elect to do so as provided by the Joint Steering Committee, provided that in each case the meetings shall last for no more than one and a half (1.5) hours. The Contract Managers shall meet virtually via a secured digital platform (or physically subject to observing then current social distancing guidelines and travelling restrictions). Additionally, any Contract Manager may call a special meeting at any time; provided that the requesting Party provides at least two (2) Business Days' prior notice to the other Contract Managers and such notice includes a proposed agenda for such meeting, and the Contract Manager of the other Party shall use commercially reasonable efforts to attend such special meeting. If a Contract Manager cannot attend a meeting, they may nominate a person of appropriate seniority and experience within their organisation to attend that meeting in their place. Each Party will be solely responsible for its own Contract Manager's expenses relating to attending and participating in the meetings. As appropriate, other representatives and consultants of the Parties may attend such meetings.

15.1.6. Prior to each meeting of the Contract Managers (and in any case before any Joint Steering Committee meeting), the Suppliers' Contract Managers shall provide an updated version of the contract tracking file to the UK. The updates should only cover any changes made as compared with the previous version of the contract tracking file. Unless otherwise agreed by the Parties in writing, such contract tracking file shall contain:

- a) [REDACTED]
[REDACTED]
- b) [REDACTED]
[REDACTED]
[REDACTED]
- c) such other information as reasonably required by the UK or the Joint Steering Committee.

- 15.1.7. Based on the contract tracking file updated by the Suppliers' Contract Managers, the UK's Contract Manager shall prepare a meeting pack in advance of each meeting of the Contract Managers.

15.2. **Joint Steering Committee**

- 15.2.1. The Parties shall establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") that shall be responsible for overseeing the performance and supply contemplated by this Agreement.

- 15.2.2. The Joint Steering Committee shall have responsibility for:

- a) monitoring of, and to encourage and facilitate, ongoing communication and cooperation between the Parties with respect to the Adjuvanted Pandemic Vaccine as relevant for the performance of this Agreement;

- b) [REDACTED]

- c) monitoring the progress of development of the Adjuvanted Pandemic Vaccine;

- d) [REDACTED]

- e) [REDACTED]

15.2.3. **Membership of the Joint Steering Committee**

- 15.2.3.1 The Joint Steering Committee shall comprise an equal number of representatives from each of the Parties (collectively, the "**Members**") initially set at one (1) Member per Party, or such other number as the Parties may mutually agree. Each Party may replace any or all of its Members at any time upon written notice to the other Parties provided that any replacement Members are employees, officers or personnel of that Party, have the appropriate skill and experience to perform the duties of a Member, and sufficient seniority and authorisation on behalf of the applicable Party to take decisions arising within the scope of the Joint Steering Committee.

- 15.2.3.2 Any Member may designate a suitable substitute who is an employee, officer or personnel of that Party to temporarily attend and perform the functions of that Member. Each Party may, in its reasonable discretion, invite non-Member representatives of such Party to attend meetings of the Joint Steering Committee as a non-voting contributor, provided that such persons are bound by confidentiality obligations no less stringent than those of Clause 16.1.

15.2.4. Meetings of the Joint Steering Committee

- 15.2.4.1 The Joint Steering Committee shall aim to meet every six (6) weeks for the Term and in any event no less than eight(8) times in a year. Notwithstanding the foregoing, the Joint Steering Committee shall meet (a) within three (3) Business Days of referral of a dispute or issue to the Joint Steering Committee in order to resolve the same (or sooner if required) and (b) as otherwise proposed by any of the Party's Members in accordance with Clause 15.2.4.3.

- 15.2.4.2 The first meeting of the Joint Steering Committee shall take place no later than six (6) weeks after the Effective Date.

- 15.2.4.3 The Joint Steering Committee may meet virtually via a secured commercial digital platform, or where necessary it may meet physically subject to observing then current social distancing and travel guidelines. Any Party's Member may also call a special meeting of the Joint Steering Committee (via a secure commercial digital platform) upon at least three (3) Business Days' prior written notice to the other Parties, or such shorter period as may be agreed on a meeting-by-meeting basis, if such Party reasonably believes that a significant matter must be addressed, and such Party shall provide the Joint Steering Committee (as applicable) no later than two (2) Business Days prior to the special meeting with materials reasonably adequate to enable an informed understanding to be made by its Members. Each Party shall be responsible for its own expenses relating to such meetings. One of the Suppliers' Contract Managers or the UK's Contract Manager, on a rotating basis, shall be appointed as responsible for preparing reasonably detailed written minutes of all Joint Steering Committee meetings, provided that the relevant Party's Joint Steering Committee Member will be responsible for keeping written minutes of any matters handled in executive session, which minutes will be circulated for comment and approval by the other Parties.

15.2.5. Decision Making

- 15.2.5.1 Except as otherwise expressly provided in this Agreement, decisions of the Joint Steering Committee shall be made by unanimous vote of a quorum of the Members, with the Suppliers (as a collective) and the UK each having one (1) vote. For clarity, GSK and Aventis together have only one vote and not one vote each. Aventis will vote on behalf of the two Suppliers. The presence of at least one (1) Member representing each Party (i.e. a total of at least three (3) Members) shall constitute a quorum of the Joint Steering Committee. The Members shall endeavour in good faith to reach agreement on any and all matters referred to the Joint Steering Committee.

Without prejudice to the foregoing, [REDACTED]
[REDACTED]

- 15.2.5.2 If at any time, the Joint Steering Committee is (i) [REDACTED]
[REDACTED] (ii) otherwise agree any other matter within
the scope of its responsibility (as set out in Clause 15.2.2, in each case [REDACTED]
[REDACTED] after it has met and attempted to reach such
decision, then either Party may, by written notice to the other, have such matter
referred for resolution by an appropriate senior executive officer of each Party.
[REDACTED] of such notice, the relevant
senior executives and member shall meet and attempt to resolve the dispute by good
faith negotiations.

16. MISCELLANEOUS

16.1. Confidentiality

- 16.1.1. Each Party undertakes and shall procure that any third party to whom disclosure may
be made under this Clause 16.1 undertakes, for the benefit of the other Party, to treat
the Confidential Information as confidential and shall keep it confidential, and shall
not disclose such Confidential Information to third parties.

- 16.1.2. The above obligation shall not apply to Confidential Information to the extent that
such information at the time of disclosure (whether such disclosure was or is made
before, on or after the Effective Date):

- a) is or becomes generally available to the public other than as a result of a
disclosure by that Party or any of its Representatives in violation of this
Clause 16.1;
- b) was lawfully in the possession of that Party or any of its Representatives
prior to such information being received from the other Party or any of its
Representatives free of any restriction as to its use and disclosure (as can be
demonstrated by that Party's or its Representative's written records);
- c) becomes available to that Party or any of its Representatives thereafter,
provided that at the time of its receipt such information is not, to the best of
that Party's and its Representative's knowledge, subject to any
confidentiality or restricted-use obligation for the benefit of the other Party;
or
- d) is independently developed by that Party or any of its Representatives
without reference to the other Party's Confidential Information (as can be
demonstrated by that Party's or its Representative's written records).

- 16.1.3. Subject to the provisions of this Clause 16.1, or unless otherwise agreed to in writing
by the other Party, during the Term of this Agreement and for a period of five (5)
years thereafter, each Party hereby agrees not to:

- a) disclose any Confidential Information of the other Party to any person other than its Representatives who need to know the Confidential Information for the purpose of this Agreement; and
- b) use any Confidential Information of the other Party for any purpose other than in connection with this Agreement.

16.1.4.

[REDACTED]

16.1.5. If a Party (the “**Disclosing Party**”) is required by Law, by applicable stock exchange regulation, by legal or parliamentary process or government policy, or for the purposes of enforcement of its rights under this Agreement, to disclose all or any portion of the Confidential Information of the other Party, the Disclosing Party (or its Representative) may so disclose such Confidential Information, provided that the Disclosing Party shall, to the extent permitted by Law:

- a) provide the other Party with a written notice of such requirement so that the other Party may seek a protective order or other appropriate remedy;
- b) exercise commercially reasonable efforts to narrow the scope of any such requirement and consult with the other Party to that effect; and
- c) if such protective order or other remedy is not obtained, furnish only that portion of the Confidential Information which the Disclosing Party (or its Representative) is compelled to disclose and exercise commercially reasonable efforts to obtain assurance that confidential treatment will be accorded to such Confidential Information.

16.1.6. In the event of termination of this Agreement, each Party shall (and shall ensure that its Representatives shall) promptly, upon the other Party’s written request, return all copies of Confidential Information of such other Party in its possession or in the possession of any of its Representatives and destroy all information or other documents derived from such Confidential Information. If so requested, the other Party shall confirm in writing that its undertakings relating to the return or destruction of any such Confidential Information have been complied with.

16.1.7.

[REDACTED]

16.1.8. Notwithstanding the terms of this Clause 16.1, the Suppliers agree that the UK may disclose the Confidential Information of the Suppliers [REDACTED] on a confidential basis only:

- a) to such agencies or offices of the Government of the United Kingdom, including Central Government Bodies, who need to know such information for use as an internal reference price for other COVID-19 vaccines;
- b) to any relevant party who need to know such information for the purpose of the examination and certification of the UK's accounts;
- c) to any relevant party who need to know such information for any examination pursuant to section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the UK has used its resources;
- d) to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirements;
- e) to a proposed successor body in connection with any proposed or actual, assignment, novation or other disposal of rights, obligations, liabilities or property in connection with this Agreement; and
- f) any Administering Entity only with GSK's and Aventis' written consent (such consent not to be unreasonably withheld, delayed or conditioned).

For the purposes of this Clause 16.1.8, references to disclosure "on a confidential basis" shall mean the UK making clear the confidential nature of such information and that it must not be further disclosed except in accordance with Law or this Clause 16.1.

16.1.9. The Suppliers may only disclose the UK's Confidential Information, and any other information provided to the Suppliers by the UK in relation to this Agreement, to the Suppliers' Representatives who are directly involved in the performance of or advising on the Suppliers' rights or obligations under this Agreement. The Suppliers shall ensure that such Representatives are aware of and shall comply with the obligations in this Clause 16.1 as to confidentiality and that all information, including Confidential Information, is held securely, protected against unauthorised use or loss and, at the UK's written discretion, destroyed securely or returned to the UK when it is no longer required. The Suppliers shall not, and shall ensure that its Representatives do not, use any of the UK's Confidential Information received otherwise than for the purposes of performing the Suppliers' obligations or exercising the Suppliers' rights in this Agreement.

16.1.10. The Parties agree that the UK (or any other agency or office of the Government of the United Kingdom), GSK (or any Affiliate) and Aventis (or any Affiliate) may issue a press release and/or make a public announcement about the signing of this Agreement and the transactions contemplated by it. In respect of any press release and/or public announcement contemplated by this Clause 16.1.10, the Parties will exchange and agree in good faith draft press releases prior to publication and also agree the date and time of any press releases and/or public announcements.

16.2. Freedom of Information and Transparency

16.2.1. The Parties acknowledge the duties of the UK, along with other agencies and offices of the Government of the United Kingdom (collectively the “**UK Government Agencies**”), under the FOIA and Environmental Regulations and shall give each other all reasonable assistance as appropriate or necessary to enable compliance with those duties to the extent related to this Agreement.

16.2.2. The Suppliers shall assist and cooperate with the UK to enable it to comply with its disclosure obligations under the FOIA and Environmental Regulations, to the extent such obligations are related to this Agreement. The Suppliers acknowledge and/or agree:

- a) that this Agreement and any recorded information held by the Suppliers on the UK’s behalf for the purposes of this Agreement are subject to the obligations and commitments of the UK under the FOIA and Environmental Regulations;
- b) that the decision on whether any exemption to the general obligations of public access to information applies to any request for information received under the FOIA and Environmental Regulations is a decision solely for the UK;
- c) that where the Suppliers receive a request for information under the FOIA (irrespective of whether the Suppliers are themselves subject to FOIA), or Environmental Regulations they will not respond to that request (unless directed to do so by the UK) and will promptly (and in any event within seven (7) Business Days) transfer the request to the UK and provide such cooperation and assistance as the UK may reasonably request; and
- d) that a UK Government Agency, acting in accordance with the FOIA and Environmental Regulations, may disclose information concerning the Suppliers and this Agreement; provided that in the event that any UK Government Agency receives a request for information under the FOIA or the Environmental Regulations which may relate to the Suppliers’ Confidential Information, prior to making any disclosure of such information it shall notify and consult with the Suppliers, and shall allow the Suppliers a reasonable opportunity to make representations to such UK Government Agency as to the applicability of any exemptions the Suppliers believe apply to such information under the FOIA or Environmental Regulations (as applicable). The UK Government Agency shall, acting in good faith and recognising the importance of protecting the Suppliers’ Confidential Information (i) give due consideration to those representations received, (ii) give the Suppliers reasonable advance notice of what (if any) information it intends to disclose to satisfy the request having given such due consideration, and (iii) disclose only that portion of the Suppliers’ Confidential Information which is required for such UK Government Agency to meet its obligations and commitments under the FOIA and Environmental Regulations.

- 16.2.3. Notwithstanding any other term of this Agreement, the Suppliers consent to the publication of the Redacted Version of this Agreement in accordance with Clause 16.1.4.

16.3. **Data Protection**

- 16.3.1. For the purpose of this Clause 16.3, “Controller”, “Processor”, “Process”, “Processed”, and “Processing” shall have the meanings given to them in the Data Protection Legislation.

- 16.3.2. The Parties each acknowledge and agree that they may need to Process Personal Data relating to each Party’s representatives (in their respective capacities as Controllers) in order to (as appropriate): (a) administer and provide the goods; (b) request and receive the goods; (c) compile, dispatch and manage the payment of invoices relating to the goods; (d) manage the this Agreement and resolve any disputes relating to it.

- 16.3.3. Each party shall Process such Personal Data relating to each Party’s representatives for the purposes set out in Clause 16.3.2 in accordance with their respective privacy policies. The Parties acknowledge that they may be required to share Personal Data with their Affiliates, group companies and other relevant parties, within or outside of the EEA or the Territory, in order to carry out the activities listed in Clause 16.3.2, and in doing so each Party will ensure that the sharing and use of this Personal Data complies with applicable Data Protection Legislation.

16.4. **Business Continuity Plan**

- 16.4.1. The Suppliers currently have in place and shall further develop, implement and thereafter keep current, a reasonable risk management programme for the manufacture and Delivery of the Adjuvanted Pandemic Vaccine, including a Business Continuity Plan. The Suppliers shall keep the Business Continuity Plan under review and shall update the same from time to time as reasonably appropriate.

16.5. **Prohibited Acts**

- 16.5.1. Each of the Suppliers warrant and represent that, to the best of its knowledge:

- 16.5.1.1 it has not, in connection with the award, negotiation or performance of this Agreement, committed any offence under the Bribery Act 2010 or done any of the following (“**Prohibited Acts**”):

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

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

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

16.5.2. If the Suppliers or their staff (or anyone acting on its or their behalf) has done or does any of the Prohibited Acts or has committed or commits any offence under the Bribery Act 2010 with or without the knowledge of the Suppliers in relation to this Agreement with the UK, the UK shall be entitled to terminate this Agreement.

16.5.3. Any termination under Clause 16.5.2 shall be without prejudice to any right or remedy that has already accrued, or subsequently accrues, to the UK.

16.6. **Supplier Code of Conduct**

16.6.1. The Suppliers shall use commercially reasonable endeavours to comply with the material obligations of the Supplier Code of Conduct in so far as is relevant to the Delivery of the Adjuvanted Pandemic Vaccine under this Agreement. In the event of any inconsistency between the terms of this Agreement, the Suppliers' standard operating procedures in effect as at the Effective Date and the Supplier Code of Conduct, the provisions of this Agreement shall prevail over such Suppliers' standard operating procedures and the Supplier Code of Conduct, and such Suppliers' standard operating procedures shall prevail the Supplier Code of Conduct.

16.7. **Sustainable Development**

16.7.1. The Suppliers shall comply in all material respects with applicable environmental and social and labour Law requirements in force from time to time in relation to the provision of the Adjuvanted Pandemic Vaccine. Without prejudice to the generality of the foregoing, the Suppliers shall:

- a) maintain relevant policy statements documenting the Suppliers' significant labour, social and environmental aspects as relevant to the Adjuvanted Pandemic Vaccine being supplied and as proportionate to the nature and scale of the Suppliers' business operations; and
- b) maintain plans and procedures that support the commitments made as part of the Suppliers significant labour, social and environmental policies, as referred to in Clause 16.7.1.a.

16.7.2. The Suppliers shall meet reasonable requests by the UK for available information evidencing the Suppliers' compliance with the provisions of this Clause 16.6, provided that this shall not require the Suppliers to generate or otherwise produce additional information specifically in respect of or in response to such requests.

16.8. **Equality and human rights**

16.8.1. The Suppliers shall:

- a) implement policies to reasonably ensure that (a) they do not, whether as employer or as supplier of the Adjuvanted Pandemic Vaccine and any associated services, engage in any act or omission that would contravene the Equality Legislation, and (b) they comply with all their obligations as employers or suppliers of the Adjuvanted Pandemic Vaccine and any associated services as set out in the Equality Legislation and take commercially reasonable efforts to ensure their staff do not unlawfully discriminate within the meaning of the Equality Legislation; and
- b) in the management of their affairs and the development of their equality and diversity policies, cooperate with the UK in light of the UK's obligations to comply with its statutory equality duties whether under the Equality Act 2010 or otherwise. The Suppliers shall take such reasonable and proportionate steps to promote equality and diversity, including race equality, equality of opportunity for disabled people, gender equality, and equality relating to religion and belief, sexual orientation and age.

16.8.2. The Suppliers shall meet reasonable requests by the UK for available information evidencing the Suppliers' compliance with the provisions of this Clause 16.8, provided that this shall not require the Suppliers to generate or otherwise produce additional information specifically in respect of or in response to such requests.

16.9. **Supply chain integrity**

16.9.1. The Suppliers shall:

- a) comply with the Modern Slavery Act 2015 to ensure that there is no slavery or human trafficking in their supply chains; and
- b) notify the UK immediately if either of them becomes aware of any actual or suspected incidents of slavery or human trafficking in the supply chains of the Adjuvanted Pandemic Vaccine.

16.10. **Records retention and rights of audit**

16.10.1. The Suppliers shall keep secure and maintain for the Term and for [REDACTED] thereafter or such longer period as may be required by applicable Law, full and accurate records of all matters relating to this Agreement.

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- 16.10.2. The Suppliers shall grant the UK or its authorised representative at reasonable times and upon reasonable notice access to such records, for the purposes of:
- a) the examination and certification of the UK's accounts; or
 - b) any examination pursuant to section 6(1) of the National Audit Act 1983 of the economic efficiency and effectiveness with which the UK has used its resources.
- 16.10.3. The Comptroller and Auditor General may examine such documents as they may reasonably require which are owned by the UK (including records held or otherwise within the control of the Suppliers) and may require the Suppliers to provide oral and/or written explanations as they consider necessary. This Clause 16.10 does not constitute a requirement or agreement for the examination, certification or inspection of the accounts of the Suppliers under sections 6(3)(d) and 6(5) of the National Audit Act 1983.
- 16.10.4. The Suppliers shall provide reasonable cooperation to the UK, its representatives and any regulatory body in relation to any audit, review, investigation or enquiry carried out in relation to the subject matter of this Agreement.
- 16.10.5. The Suppliers shall provide all reasonable information as may be reasonably requested by the UK to evidence the Suppliers' compliance with the requirements of this Agreement.
- 16.11. **Conflicts of interest and the prevention of fraud**
- 16.11.1. The Suppliers shall take appropriate steps to ensure that neither the Suppliers nor any of their staff are placed in a position where, in the reasonable opinion of the Suppliers, there is an actual conflict or a risk of a perceived conflict between the pecuniary or personal interests of the Suppliers and the duties owed to the UK under the provisions of this Agreement. The Suppliers will disclose to the UK full particulars of any such conflict of interest which may arise.
- 16.11.2. If, in the reasonable opinion of the UK, there is an actual conflict between the pecuniary or personal interests of the Suppliers and the duties owed to the UK under the provisions of this Agreement, the UK shall notify the Suppliers and shall provide the Suppliers with an explanation of the conflict and an opportunity to remedy the conflict. Subject to the foregoing, the UK reserves the right to terminate this Agreement immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the UK, there is an actual conflict between the pecuniary or personal interests of the Suppliers and the duties owed to the UK under the provisions of this Agreement which is not capable of remedy or where the Suppliers refuse or fail to remedy such conflict within the required timeframe. The actions of the UK pursuant to this Clause 16.11.2 shall not prejudice or affect any right of action or remedy which shall have accrued or shall subsequently accrue to the UK.

16.11.3. The Suppliers shall take reasonable steps to prevent an offence in respect of fraud by their staff and by the Suppliers in connection with the receipt of money from the UK under this Agreement. The Suppliers shall notify the UK promptly if they have reason to suspect that they or their staff or directors have committed, or are committing, such offence.

16.11.4. If the Suppliers or their staff commit fraud in connection with the award, negotiation or performance of this Agreement the UK may terminate this Agreement and recover from the Suppliers the amount of any direct loss suffered by the UK resulting from the termination.

16.12. **Change Control**

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

16.13. **Force Majeure**

16.13.1. No Party shall be responsible or liable to the other Party for any failure to perform any of its covenants or obligations under this Agreement if such failure results from events or circumstances reasonably beyond the control of such Party including war or other national emergency, riot, fire, explosion, pandemic, flood or other Act of God, general and long lasting strike affecting the activity of either Party, the inability of a Party to perform under this Agreement due to an injunction or blockade imposed by a jurisdiction acting further to a claim for infringement of intellectual property rights by a third-party, any injunction, decree, order, law or regulation of any public authority or any decision by a government (for clarity, to the extent such decree, order, law or regulation of any public authority or any decision by a government are reasonably beyond the control of such Party) such as a constraint order or requisition or embargo, or any inability to obtain electricity, fuel or raw material, or restrictions on the export of the Adjuvanted Pandemic Vaccine or Components (collectively, “**Events of Force Majeure**”). For clarity, Brexit, the impact of Brexit and any decrees, orders, laws or regulations of any public authority or any decision by a government implementing Brexit or passed as a result of Brexit shall not be Events of Force Majeure.

16.13.2. The affected Party shall (i) forthwith inform the other Party in writing of the occurrence of the Event of Force Majeure and (ii) exert commercially reasonable efforts to eliminate, cure or overcome any such Event of Force Majeure and to resume performance hereunder with all possible speed; [REDACTED]

16.14. Relationship of Parties

The Parties are independent contractors under this Agreement and no other relationship, including partnership, franchise, joint venture, agency, employer/employee, fiduciary, or other special relationship is intended. No Party shall act in a manner which expresses or implies a relationship other than that of independent contractor, nor attempt to bind another Party.

16.15. Notices

Notices provided for in this Agreement shall only be valid if duly signed by the relevant Party and transmitted by registered mail or delivered by hand to the address of the recipient as set out below:

If to Aventis: General Counsel
Aventis Pharma Ltd
Thames Valley Park Drive,
Reading, Berkshire, England, RG6 1PT

If to GSK: General Counsel, GSK Vaccines
GlaxoSmithKline Biologicals SA
Rue de l'Institut 89
B-1330 Rixensart
Belgium

If to the UK: Attention: Director General of the Vaccine Task Force

Secretary of State, Department for Business,
Energy and Industrial Strategy
1 Victoria St
Westminster
London
SW1H 0ET, England

With copy to: Permanent Secretary, Department for Business,
Energy & Industrial Strategy

Secretary of State, Department for Business,
Energy and Industrial Strategy
1 Victoria St
Westminster
London
SW1H 0ET, England

16.16. Entire Agreement

16.16.1. This Agreement contains all the arrangements made between the Parties in connection with the development and supply of the Adjuvanted Pandemic Vaccine

and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter, including the Capacity Reservation Agreement (which is hereby terminated).

16.16.2. It is the intention of the Parties that this Agreement be executed in the English language. In the case of any translation of this Agreement, the English version of this Agreement shall prevail.

16.16.3. Any amendment of the Agreement and any future representation relating to the Adjuvanted Pandemic Vaccine is only valid if made in accordance with Clause 16.12.

16.17. **Severability**

16.17.1. Should any part of this Agreement be or become or be found by a court, arbitration panel or judicial or administrative body to be void, ineffective or unenforceable for any reason, the validity of the remaining sections of this Agreement shall not be affected. In such a case, the ineffective section or sub-section shall be deemed as replaced by provisions achieving the purpose of this Agreement as far as possible.

16.17.2. Notwithstanding Clause 16.17.1, if Clause 8 is found by a court, arbitration panel or judicial or administrative body to be void, ineffective or unenforceable, all supply obligations of the Suppliers under this Agreement shall terminate immediately.

16.18. **Counterparts**

16.18.1. This Agreement may be executed in counterparts, each of which shall be an original and which together shall constitute one and the same instrument.

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

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

16.19. **Assignment**

16.19.1. This Agreement and/or any right and obligation under this Agreement may only be assigned to third parties with the prior written consent of the non-assigning Parties, provided that neither Aventis nor GSK shall require such consent to assign any rights or obligations to any of their Affiliates listed in **EXHIBIT H**.

16.20. Sub-contracts

- 16.20.1. The Suppliers may each Sub-contract any or all of their obligations under this Agreement to a third party, provided that the Supplier remain liable for the acts and omissions of such third parties as if there were its own.
- 16.20.2. Where, following the Effective Date, a Supplier enters into a Sub-contract in respect of any of its obligations under this Agreement relating to the manufacture, supply or Delivery of the Adjuvanted Pandemic Vaccines, to the extent applicable to the activities of such sub-contractor, the Supplier shall include obligations in such Sub-contract at least equivalent to the Supplier's obligations set out in this Agreement, unless otherwise agreed with the UK in writing.

17. GOVERNING LAW AND JURISDICTION

- 17.1. This Agreement, including the agreement to arbitrate in this Clause 17, and all matters relating to or in connection with it shall be governed by, and construed in accordance with, the law of England and Wales, provided that any treaty, including the UN Convention on Contracts for the International Sale of Goods, shall hereby be expressly excluded.
- 17.2. Any contractual or non-contractual dispute, controversy or claim arising out or in connection with this Agreement, or the breach, termination or validity thereof ("**Dispute**"), shall first be referred to informal dispute resolution discussions between representatives of the UK and the Suppliers, by the UK sending to the Suppliers, or the Suppliers sending to the UK, a written notice of the Dispute, and, within [REDACTED] of such notice, the representatives shall meet and attempt to resolve the Dispute by good faith negotiations. In the event such Dispute cannot be resolved within such [REDACTED] period, such Dispute shall be finally resolved by arbitration. The arbitration shall be conducted under the arbitration rules of the International Chamber of Commerce ("**ICC**"), in effect at the time of the arbitration, except as they may be modified herein or by mutual agreement of the Parties. The arbitration shall be conducted by three arbitrators. The claimant shall appoint an arbitrator in its request for arbitration. The respondent shall appoint an arbitrator within [REDACTED] of the receipt of the request for arbitration. The two arbitrators shall appoint a third arbitrator within [REDACTED] after the appointment of the second arbitrator. The third arbitrator shall act as the chair of the tribunal. If any of the three arbitrators is not appointed within the time prescribed above, then the ICC shall appoint that arbitrator.
- 17.3. The seat of the arbitration shall be London, and it shall be conducted in English. The arbitration award shall be final and binding, and judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party and its assets.

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- 17.4. The above is expressly without prejudice to, and shall not be construed as a waiver of, the right of any Party to seek injunctive or similar interim relief in any court of competent jurisdiction.
- 17.5. The Parties agree that the arbitration shall be kept confidential and that the existence of and any aspect of the proceeding shall not be disclosed beyond the tribunal, ICC International Court of Arbitration, the Parties and their Affiliates, their counsel, insurers and re-insurers, accountants and auditors, and any person necessary to the conduct of the proceeding. The confidentiality obligations shall not apply if (i) disclosure is required by Law or (ii) to the extent necessary to enforce the rights arising out of the award.
- 17.6. The UK hereby expressly, unconditionally, and irrevocably submits to the jurisdiction of any arbitral tribunal constituted in accordance with this Clause 17, and any court in which any award rendered by an arbitral tribunal constituted pursuant to this Clause 17 may be enforced, and for the purposes thereof irrevocably waives any right of sovereign immunity it may have, whether before the arbitral tribunal or otherwise from suit and/or jurisdiction and/or adjudication, including waiving any right of sovereign immunity as to it and any of its property. Such property includes but is in no way limited to any bank account belonging to the UK whether held in the name of a diplomatic mission or otherwise. This waiver extends but is in no way limited to property, including bank accounts, belonging to the central bank or other monetary authority. For the avoidance of doubt, the irrevocable waiver in this Clause includes a waiver of any right of sovereign immunity in respect of pre-judgment interim relief and post-judgment execution of any arbitral award, wherever such relief or execution is sought.

[SIGNATURES APPEAR ON THE NEXT PAGE]

AGREED FOR AND OH BEHALF OF THE PARTIES

Place, Date: _____

**The Secretary of State for the Department for Business, Energy and Industrial Strategy,
acting on behalf of the Crown**

[Redacted]

Director UK Government Investments

Date : 20-Sep-2021

Aventis Pharma Ltd.

[Redacted]

UK&IE MCO Country Lead

Date : 20-Sep-2021

GLAXOSMITHKLINE BIOLOGICALS S.A

[Redacted]
Director

Signature

[Redacted]

Date: 20-Sep-2021

GLAXOSMITHKLINE BIOLOGICALS S.A

[Redacted]
Director

Signature

[Redacted]

Date: 20-Sep-2021

EXHIBIT A

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT B

[Intentionally left blank]

EXHIBIT C

DELIVERY SCHEDULE FOR FIRST VOLUME

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

EXHIBIT D

DELIVERY SPECIFICATIONS

End to End Logistics Information – engagement a minimum of [REDACTED]

Suppliers's Logistic & transportation experts have established a specific check list adapted to the Adjuvanted Pandemic Vaccine

The check list details the following items:

- *Security & tracking with specific device & process (including route assessment & control tower)*
- *Insurance & customs*
- *Cold Chain management*
- *Dedicated process with carrier including kick off with carrier ex com*

A first check list will be provided to the UK [REDACTED] to the first shipment and the final completed check list will be provided to the UK [REDACTED]

The hereunder items will notably be included in the check list

- Third Party Logistics Company / Companies involved to be confirmed
- [REDACTED]
- Control Tower and Mitigations
- [REDACTED]
 - [REDACTED]
 - [REDACTED]
- [REDACTED]
- Incident Response Plan
- 24hr Logistic Points of Contact

Other Logistic Requirements:

- Details of temperature loggers – fitted to trailers, providing live updates as part of tracking. Alarms set outside of vaccine parameters, monitored and evidenced for compliance with vaccine characteristic specification/evidence of process and diligence of movement of vaccine
- Visual inspection during off-loading in addition to inspection on unpacking
- Schedule and timing of delivery to be agreed with [REDACTED]
- To adhere to delivery protocols [REDACTED]
- Forward Look: paperwork would be required a minimum of [REDACTED] of planned delivery with 'End to End Logistics Information'

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

UK to provide maximum vaccine volume that could be delivered in one delivery:

- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - Timing between deliveries to be discussed/notified

EXHIBIT E

KEY PERFORMANCE INDICATORS

Theme	KPI
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
[REDACTED]	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]
	[REDACTED]

EXHIBIT F

ORDER FORM

[Intentionally left blank]

EXHIBIT G

[REDACTED]

[REDACTED]

[REDACTED]

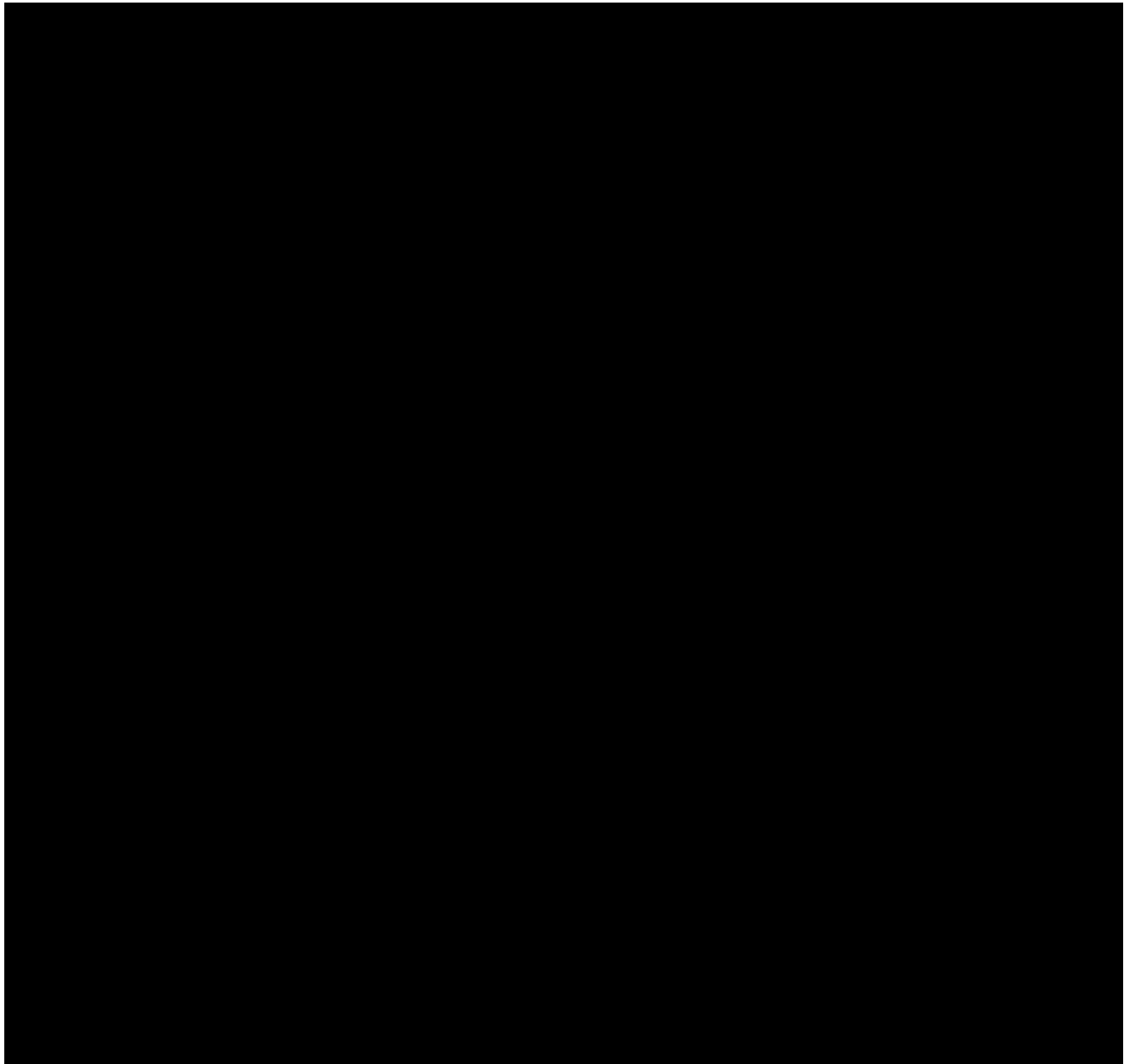


EXHIBIT H

AFFILIATES

[REDACTED]	
[REDACTED]	
[REDACTED]	

EXHIBIT I
Pro forma Change Control Notice

CCN No:	Agreement:	Effective date of Change:
Initiated by: Change requested by [Suppliers OR UK]		
Date of request:		
Period of validity: This Change Control Note is valid for acceptance until [DATE].		
Reason for Change:		
Description and impact of the Change (including to delivery and performance):		
Required amendments to wording of Agreement or Schedules:		
Adjustment to Agreement Price resulting from Change:		
Additional one-off charges and means of determining these (for example, fixed price basis):		
Supporting or additional information:		
<i>Please confirm all Changes relating to procurement, shipment (delivery) and storage have been reviewed and approved by the UK Responsible Person (Y:N)</i>		
SIGNED ON BEHALF OF THE UK	SIGNED ON BEHALF OF THE SUPPLIERS	
Signature:	Signature:	
Name:	Name:	
Position:	Position:	
Date:	Date:	
	SIGNED ON BEHALF OF THE SUPPLIERS	
	Signature:	
	Name:	
	Position:	
	Date:	

