SERVICES AGREEMENT
in relation to the production of fill finished vaccines for COVID-19 and therapeutics for use in the UK health system

THE SECRETARY OF STATE FOR BUSINESS, ENERGY & INDUSTRIAL STRATEGY (1)

AND

C P PHARMACEUTICALS LTD (2)

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THIS AGREEMENT is made on the day of 2020

BETWEEN:

(1) **THE SECRETARY OF STATE FOR BUSINESS, ENERGY & INDUSTRIAL STRATEGY** of 1 Victoria Street, London SW1H 0ET (the "**Authority**"); and

(2) **C P PHARMACEUTICALS LIMITED** (company number 00482106) whose registered office is at Ash Road (North), Wrexham Industrial Estate, Wrexham, Clwyd LL13 9UF (the "**Manufacturer**"),

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

WHEREAS:

(A) The Manufacturer operates the Manufacturing Site, which is a site used to produce (among other things) generic pharmaceuticals, including sterile products for injection.

(B) The Authority engaged with the Manufacturer to secure production capacity for vaccines and therapeutics as part of HMG's emergency response to the COVID-19 pandemic.

(C) The Authority's initial requirement is for the provision of services to support a single population level vaccination programme but as clinical data becomes available further services may be required to support booster vaccine production or annual seasonal vaccination.

(D) Due to the early clinical development of these vaccine candidates and the flexibility which is likely to be required around the scale and timing of any fill finish demand, the Authority wishes to secure access to the Manufacturer's new combination filling line for an extended period of time.

(E) The Authority now wishes to engage the Manufacturer to provide the Services in accordance with its requirements.

(F) The Manufacturer is willing and able to provide the Services for the Authority in accordance with the terms and conditions of this Agreement.

IT IS AGREED as follows:

1 DEFINITIONS AND INTERPRETATION

1.1 The following words and expressions shall have the following meanings:

"**Administrative Entity**" means any court, administrative body, local authority or other governmental or quasi-governmental entity, any supra-national, national, federal, state, municipal, provincial or local governmental, regulatory or administrative authority, agency, commission, court, tribunal, arbitral body, self-regulated entity, private body

exercising any regulatory, taxing, importing or other governmental or quasi-governmental authority, including any relevant Regulator, in each case, with competent jurisdiction in respect of the Services or the Manufacturer's obligations under this Agreement;

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

"**Affiliate(s)**" means:

(a) in the case of the Authority:

(i) any other Central Government Body;

(ii) a body other than a Central Government Body which performs any of the functions that previously had been performed by the Authority; or

(iii) a body other than a Central Government Body which has responsibility for discharging HMG's emergency response to the COVID-19 pandemic;

(b) in the case of the Manufacturer, any other person or company which is directly or indirectly:

(i) Controlled by;

(ii) in Control of; or

(iii) under common Control with that person,

from time to time.

For the purposes of this Agreement, "**Control**" shall consist of the ownership of more than fifty per cent (50%) of the voting stock of any person or company or the power to direct or cause the direction of the general management or actions of the person;

"**Agreed Purpose**" means the reservation of capacity and provision of associated services for the sterile filling of prepared and supplied Bulk Vaccine and/or therapeutics;

"**Agreement**" means this agreement together with all its schedules (the "**Schedules**");

"**Annual Contract Report**" means the report listed in paragraph 3.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Appropriate**" has the meaning given to it in paragraph 1.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Approved Elective Materials**" means those Elective Materials which the Authority shall reimburse the Manufacturer for in accordance with Clause 12.3, as further set out in Appendix 1 of Schedule 7 (Materials);

"**AstraZeneca**" means AstraZeneca UK Limited incorporated in England with company number 3674842 and registered address 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, United Kingdom, CB2 0AA;

"**Attributable**" has the meaning given to it in paragraph 1.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Audit Agents**" means:

(a) the Authority's internal and external auditors;

(b) the Authority's statutory or regulatory auditors;

(c) the Comptroller and Auditor General, their staff and/or any appointed representatives of the National Audit Office;

(d) HM Treasury or the Cabinet Office;

(e) any party formally appointed by the Authority to carry out audit or similar review functions; and

(f) successors or assigns of any of the above;

"**Available**" means that the Reserved Capacity is in an operational state in accordance with cGMP to deliver the Services in accordance with the Statement of Requirements. The Reserved Capacity is not Available to the extent that (and only for so long as) the occurrence of any event prevents the Reserved Capacity from being in an operational state in accordance with cGMP to deliver the Services in accordance with the Statement of Requirements, including but not limited to;

(a) an inspection by the MHRA resulting in the MHRA making to the Manufacturer a critical observation;

(b) an inspection by the MHRA resulting in the MHRA making to the Manufacturer a major observation in relation to the Reserved Capacity complying with applicable Law that prevents the Reserved Capacity from being in an operational state in accordance with cGMP;

(c) actions by any Regulator preventing the Reserved Capacity from being in an operational state in accordance with cGMP;

"**Available Base Fee**" has the meaning given to it in paragraph 1.10 of Schedule 5 (Price, Payment and Invoicing);

"**Availability KPI**" means the KPI relating to availability in the table at Schedule 3Appendix 1 of Schedule 3 (Performance);

"**AZ Vaccine**" means the AZD1222 vaccine for which AstraZeneca owns the Product Licence;

"**Background Intellectual Property**" of a Party means any Intellectual Property controlled, owned or licensed to that Party prior to the date of this Agreement or Intellectual Property generated by that Party independently of this Agreement which is relevant to this Agreement;

"**Base Fee**" has the meaning given to it in paragraph 1.3 of Schedule 5 (Price, Payment and Invoicing);

"**Batch Record**" means a document that records details about the Manufacture of a batch of Product, as further described in the Quality Agreement;

"**Bulk Vaccine**" means the bulk vaccine which is to be provided to the Manufacturer in accordance with Clause 12 for use in the Manufacture of Products;

"**Business Continuity and Disaster Recovery Plan**" has the meaning given to it in Clause 7;

"**Business Day(s)**" means a day (other than a Saturday or Sunday) on which banks are open for general business in the City of London;

"**Central Government Body**" means a body listed in one of the following sub-categories of the Central Government classification of the Public Sector Classification Guide, as published and amended from time to time by the Office for National Statistics:

(a) Government Department;

(b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal);

(c) Non-Ministerial Department; or

(d) Executive Agency;

"**Change Control Notice**" or "**CCN**" has the meaning given to it in Clause 25.2;

"**Change Control Procedure**" means the procedure for changing this Agreement set out in Clause 25;

"**Change in Law**" means any change in Law which impacts on the performance of the Services which comes into force after the date of this Agreement;

"**Claim**" has the meaning given to it in Clause 35.2(a);

"**Comparable Supply**" means the supply of services to another customer of the Manufacturer that are the same or similar to any of the Services;

"**Confidential Information**" means:

(a) means all confidential or proprietary information provided to either Party either directly or indirectly in confidence by or on behalf of the other in connection with this Agreement, whether in written, verbal or other form and whether before or after the date of this Agreement (including without limitation the contents of the Heads of Terms and the commercial and financial arrangements relating to and connected with the Heads of Terms); but

(b) does not include the specific portions of information that the Authority is obliged to publish by virtue of Clause 28 (Transparency) solely to the extent such information is so published;

"**Contract Quarter**" means the following periods (inclusive):

(a) 1 August to 31 October;

(b) 1 November to 31 January;

(c) 1 February to 30 April; and

(d) 1 May to 31 July;

"**Day of Unavailability**" means a full period of 16 hours during which the Reserved Capacity is not Available;

"**Data Protection Legislation**" means (i) the General Data Protection Regulation (GDPR)(Regulation (EU) 2016/679), the Law Enforcement Directive (LED) (Directive (EU) 2016/680) and any applicable national implementing Laws as amended from time to time; (ii) the Data Protection Act 2018 to the extent that it relates to processing of personal data and privacy; (iii) all applicable Law about the processing of personal data and privacy;

"**Delivery**" means a delivery of Products made in accordance with Clause 16 (and "**Deliver**" and "**Delivered**" shall be construed accordingly);

"**Delivery Location**" means the Manufacturing Site, or such other location as may be agreed between the Parties;

"**Demand Forecast Report**" has the meaning given in Clause 5.4;

"**Dispute Resolution Procedure**" means the dispute resolution procedure set out in Clause 55 (Dispute Resolution Procedure);

"**Draft Rectification Plan**" has the meaning given to that term at paragraph 8.2(b) of Schedule 3 (Performance);

"**Effective Date**" means:

(a) the date on which the Manufacturer receives written confirmation by or on behalf of the MHRA of the outcome of the MHRA's inspection of the Reserved Capacity, provided that the MHRA's confirmation does not make to the Manufacturer any:

(i) critical observation; or

(ii) major observation in relation to the Reserved Capacity complying with applicable Law that prevents the Reserved Capacity from being used to deliver the Services in accordance with the Statement of Requirements; or

(b) if the MHRA's confirmation makes any of the observations specified in the foregoing sub-clause (a), the date of such observation(s) having been remediated by the Manufacturer (and confirmed by the MHRA as no longer subsisting),

in the case of either (a) or (b), as notified by the Manufacturer to the Authority in writing promptly after such occurrence;

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

"**Elective Materials**" means the following materials which shall be provided in accordance with Clause 12;

(a) drug substance for therapeutics; and/or;

(b) vials, stoppers and seals for vaccines;

"**End Date**" means eighteen (18) calendar months after 1 August 2020;

"**Final Reconciliation Report**" means the report listed in paragraph 3.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Financial Reports**" means the reports listed in paragraph 3.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Financial Representative**" means a reasonably skilled and experienced member of the Manufacturer's staff who has specific responsibility for preparing, maintaining, facilitating access to, discussing and explaining the Open Book Data and Financial Reports;

"**Financial Transparency Objectives**" has the meaning provided by paragraph 1.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Firm Order**" has the meaning given to it in paragraph 1.1 of Schedule 9 (Manufacture and Supply to Authority);

"**Fit for Purpose**" means that the relevant materials;

(a) comply with GMP;

(b) are in Good Condition; and

(c) are of the type, volume and description approved by the Authority pursuant to paragraph 3 of Part C of Schedule 7 (Materials);

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

"**Force Majeure Event**" subject to Clause 31.9, any event or circumstances outside the reasonable control of either Party (or, in the case of the last sentence of Clause 31.1, the relevant agent, sub-contractor or supplier) and which are not attributable to any wilful act, neglect or failure to take reasonable preventative action by that Party (or, in the case of the last sentence of Clause 31.1, the relevant agent, sub-contractor or supplier), including acts of God, riots, war or armed conflict, acts of terrorism, acts of government, local government or regulatory bodies, fire, flood, storm or earthquake, epidemic, pandemic or disaster but excluding any industrial dispute relating to the Manufacturer or (save as provided in the last sentence of Clause 31.1) any other failure in the Manufacturer's or a sub-contractor's supply chain;

"**Force Majeure Notice**" means a written notice served by the Affected Party on the other Party stating that the Affected Party believes that there is a Force Majeure Event;

"**Forecast Schedule**" has the meaning given to it in paragraph 5.2 of Schedule 9 (Manufacture and Supply to the Authority);

"**General Change in Law**" means a Change in Law where the change is of a general legislative nature (including taxation or duties of any sort affecting the Manufacturer) or which affects or relates to a Comparable Supply;

"**GMO**" means genetically modified organisms;

"**Good Condition**" means that the Product (or Materials, as applicable) supplied is the right product, made in accordance with the registered process, has in no way deteriorated or broken down, is not damaged or contaminated upon Delivery, is in the right container (correctly labelled and properly sealed) and is capable of any agreed standard of performance;

"**Good Industry Practice**" means the exercise of that degree of care, skill, diligence, prudence, efficiency, foresight and timeliness which would be reasonably expected at such time from a leading and expert supplier of services similar to the Services to a customer like the Authority, such supplier seeking to comply with its contractual obligations in full and complying with applicable Laws;

"**Good Manufacturing Practice**" or "**GMP**" means the current practices for Manufacture required for Products classified as medicinal products under applicable Laws:

(a) if the Product is to be supplied to the United Kingdom or a country within the European Union, by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the European Union entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use" as amended from time to time; and

(b) if the Product is to be supplied to any other country not falling within (a) above, as set out in the Quality Agreement (provided that such requirements shall be no more onerous than the requirements set out in (a) above);

"**Heads of Terms**" means the heads of terms agreed between the Parties dated 19 June 2020;

"**HMG**" means Her Majesty's Government;

"**Indemnified Party**" has the meaning given to it in Clause 35.2(a);

"**Indemnifying Party**" has the meaning given to it in Clause 35.2(a);

"**Independent Laboratory**" means a laboratory or other technical expert independent of each Party and mutually agreed in writing between the Parties (or, in the absence of such agreement, nominated by the President of the International Chamber of Commerce or his designee upon the application of either Party) competent to determine the matters referred to in Clauses 12 (Materials), 55 (Dispute Resolution Procedure) and/or 17 (Defective Products);

"**Information**" means all information of whatever nature, however conveyed and in whatever form, including in writing, orally, by demonstration, electronically and in a tangible, visual or machine-readable medium (including CD-ROM, magnetic and digital form);

"**Intellectual Property**" means patents, utility models, trade marks, service marks, rights in designs, copyrights, rights in databases and rights in know-how (whether or not any of these is registered or capable of registration and including applications for registration of any such thing) and all other similar rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world;

"**KPI**" means the key performance indicators set out in the table at Appendix 1 of Schedule 3 (Performance);

"**KPI Failure**" means a failure without a Valid Reason to meet the Target Performance Level in respect of a KPI;

"**Latent Defect**" means any defect or failure of the Product to comply with the terms of this Agreement which was not apparent or could not reasonably have been identified by the Authority following the process defined in Clause 17 (Defective Products);

"**Law**" means any law, statute, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, enforceable right within the meaning of section 2 of the European Communities Act 1972, regulation, order, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body, in each case, that has the force of law and with which a Party is bound to comply;

"**Letter of Intent**" means the letter of intent agreed between the Parties, dated 21 May 2020;

"**Loss**" means all damages, losses, liabilities, costs, expenses (including legal and other professional charges and expenses) and charges whether arising under statute, tort, contract or at common law or otherwise, or in connection with judgements, proceedings, internal costs or demands;

"**Manufacture**" or "**Manufactured**" or "**Manufacturing**" means the stages required for the fill and finish of the Products as set out in the Specification;

"**Manufacturer Personnel**" means all directors, officers, employees, agents, consultants and contractors of the Manufacturer and/or of any sub-contractor engaged in the performance of the Manufacturer's obligations under this Agreement;

"**Manufacturer's Proposal**" means the Manufacturer's proposal at Schedule 2 (Manufacturer's Proposal);

"**Manufacturing Licence**" means all licences necessary for, or required in connection with, the Manufacture of the Products at the Manufacturing Site for supply in the United Kingdom;

"**Manufacturing Site**" means the Manufacturer's manufacturing facility located at Ash Road (North), Wrexham, Wrexham Industrial Estate, Wrexham, Clwyd LL13 9UF;

"**Material KPI Failure**" has the meaning given to that term at paragraph 7.1 of Schedule 3 (Performance);

"**Materials**" means all materials and components required to Manufacture the Products, comprising the:

(a) Bulk Vaccine; and

(b) Elective Materials;

"**Mediator**" has the meaning given to it at Clause 55.4(a);

"**MHRA**" means the Medicines and Healthcare products Regulatory Agency;

"**Modification Works**" means any project activity to modify the Manufacturing Site to handle mRNA or Adeno (BSL1) viral vectors (which for the avoidance of doubt shall not include modifications required to meet BSL2 requirements) to the standard required to comply with any applicable Law, including in relation to GMO, GMP and health and safety, in each case to the extent applicable to the Manufacturer's Manufacture of the Product and performance of the Services;

"**Modification Work Costs**" means costs incurred by the Manufacturer in the performance of the Modification Works;

"**MSA**" means each manufacture and supply agreement entered into between the Manufacturer and a Vaccine Manufacturer pursuant to this Agreement;

"**MSA Breakage Costs**" means any amounts payable by the Manufacturer to the Vaccine Manufacturer as a direct result of the Manufacturer's termination of the relevant MSA pursuant to the Authority's instructions in accordance with Clause 4.11;

"**Open Book Data**" means complete and accurate financial and nonfinancial information which is sufficient to enable the Authority to verify any payments already paid or payable and payments forecast to be paid during the remainder of the Term, including details and all assumptions relating to:

(a) the Manufacturer's costs broken down against each aspect of the Services including actual capital expenditure (including any Modification Work Costs and Remediation Works Costs along with details of any payments received from the Authority or Vaccine Manufacturer in relation to such Modification Works and Remediation Works);

(b) operating expenditure relating to the provision of the Services including an analysis showing:

(i) the unit costs and quantity of Materials along with details of any payments received from the Authority and Vaccine Manufacturer in relation to such Materials;

(ii) manpower resources;

(iii) overheads;

(c) the Manufacturer's profit achieved over the Term and on an annual basis;

(d) confirmation that all methods of cost apportionment and overhead allocation are consistent with and not more onerous than such methods applied generally by the Manufacturer; and

(e) an explanation of the type and value of risk and contingencies associated with the provision of the Services, including the amount of money attributed to each risk and/or contingency.

"**Performance Monitoring Report**" has the meaning given to that term at paragraph 2.1 of Schedule 3 (Performance);

"**Performance Review**" means the process described in Schedule 3 (Performance) used to measure the Manufacturer's Performance against the specific indicators (as detailed in Schedule 3) that will define yearly rebate value;

"**Performance Review Meeting**" has the meaning given to that term at paragraph 2.2 of Schedule 3 (Performance);

"**Personal Data**" shall have the meaning given in the Data Protection Legislation;

"**Planned Maintenance**" means those days of planned maintenance and routine media fill challenges as detailed in the Statement of Requirements or any other time which has been approved in advance in writing by the Authority, including those days of any Modification Works or Remediation Works;

"**Process**" or "**Processing**" has the meaning given in the Data Protection Legislation;

"**Product Conversion Fee**" has the meaning given to it in paragraph 1.11 of Schedule 5 (Price, Payment and Invoicing);

"**Product Licence**" means each and every product licence, marketing authorisation or any other authorisation(s) (as the case may be) required for the commercialisation of the Products;

"**Products**" means any of the products which the Parties agree the Manufacturer is to Manufacture, as further detailed in the relevant Specification(s);

"**Prohibited Act**" means:

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

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

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

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

(c) an offence:

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

(ii) under legislation or common law concerning fraudulent acts (including offences by the Manufacturer under Part 3 of the Criminal Finances Act 2017); or

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

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

"**Rectification Plan**" has the meaning given to that term at paragraph 8.8 of Schedule 3 (Performance);

"**Relevant Monthly Availability Period**" means:

(a) for the period starting on and including 17 August 2020 to and including 31 August 2020; and

(b) thereafter for each calendar month during the remainder of the Term starting on and from 1 September 2020,

the period of [redacted] multiplied by the number of Business Days in such period or month (as applicable), excluding in each case, any Planned Maintenance;

"**Qualified Person**" means the person(s) named in the Quality Agreement (or such replacement person as may be notified by the Manufacturer to the Authority in writing from time to time) who is nominated by the Manufacturer and is suitably qualified to enable the Manufacturer to perform and discharge its quality management obligations required by Good Manufacturing Practice or other applicable Laws, including, without limitation, EC Directive 2001/83/EC (Articles 48 and 49);

"**Quality Agreement(s)**" means each quality agreement entered into between the Manufacturer and the Vaccine Manufacturer in relation to each Product;

"**Quarter Product Value**" has the meaning given to it in paragraph 1.11 of Schedule 5 (Price, Payment and Invoicing);

"**Quarterly Contract Report**" means the report listed in paragraph 3.1 of Schedule 4 (Financial Reports and Audit Rights);

"**Reasonable**" has the meaning given to it in paragraph 1.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Records**" has the meaning given in paragraph 8.1 of Schedule 4 (Financial Reports, Records and Audit Rights);

"**Regulator**" means any relevant authority which regulates any aspect of the Manufacture and/or commercialisation of the Products;

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

"**Relief Event**" means a Force Majeure Event for which the predominant or sole cause is the COVID-19 pandemic, which for the avoidance of doubt shall not include any events in relation to which the Manufacturer is not entitled to claim relief pursuant to Clause 31.9;

"**Remediation Work Costs**" means costs incurred by the Manufacturer in the performance of the Remediation Works;

"**Remediation Works**" means any works required to return the Manufacturing Site to routine commercial use following the implementation of Modification Works;

"**Reserved Capacity**" means the "Bosch CombiLine" combination filling line installed at the Manufacturing Site;

"**Residual Period**" has the meaning given to it in paragraph 1.6 of Schedule 5 (Price, Payment and Invoicing);

"**Service Credit**" means credits for the benefit of the Authority due to the occurrence of one or more KPI Failures in relation to the Availability KPI only, calculated and administered in accordance with paragraph 9 of Schedule 3 (Performance);

"**Services**" means the services to be delivered by the Manufacturer under this Agreement as set out in the Statement of Requirements;

"**Specific Change in Law**" means a Change in Law that relates specifically to the business of the Authority and which would not affect a Comparable Supply;

"**Specification(s)**" means the specification(s) for each Product (solely to the extent of Manufacturer's responsibility for such specification(s)) as set out in the MSA(s) entered into with the relevant Vaccine Manufacturer;

"**Statement of Requirements**" means the Authority's statement of requirements for the Services as set out in Schedule 1;

"**Target Performance Level**" means the minimum level of performance for a KPI which is required by the Authority, as set out against the relevant KPI in the table at Appendix 1 to Schedule 3 (Performance);

"**Term**" has the meaning given to it in Clause 38.1;

"**Third Party**" means any person other than:

(a) the Parties to this Agreement; and

(b) any Vaccine Manufacturer(s) which the Parties have agreed can use the Reserved Capacity.

"**Third Party Claim**" means any allegation, action, claim or proceedings brought or asserted by a Third Party;

"**Total Base Fee**" means the total value of the Base Fee paid or payable by the Authority to the Manufacturer in respect of the Term;

"**Total Product Conversion Fee**" means the sum of all Product Conversion Fees;

"**Total Product Value**" means the total value of all Product invoiced to the Authority by the Manufacturer in respect of the Term;

"**Trade Marks**" means such trade marks as the Authority (or its Affiliates) may from time to time request the Manufacturer to affix to the Products during Manufacture (and "**Trade Mark**" shall mean any one of them); and

"**Utilisation Report**" has the meaning given in Clause 15.3;

"**Vaccine Manufacturer**" means a vaccine manufacturer identified by the Authority in accordance with Clause 3.4;

"**Valid Reason**" means that a failure or non-compliance is due to:

(a) an act, omission or instruction of the Authority; and/or

(b) a Force Majeure Event;

"**VAT**" means value added tax and any similar sales tax; and

"**Virtual Library**" means the data repository hosted by the Authority containing the information about this Agreement and the Services provided under it in accordance with Schedule 4 (Financial Reports, Records and Audit Rights).

1.2 In this Agreement, unless otherwise specified:

(a) any Schedules form part of this Agreement and shall have the same force and effect as if set out in the body of this Agreement, and references to this Agreement include them;

(b) references to Recitals, Clauses and Schedules are to recitals and clauses of, and schedules to, this Agreement and references in a Schedule or part of a Schedule to paragraphs are to paragraphs of that Schedule or that part of that Schedule;

(c) the headings and contents table in this Agreement are for convenience only and do not affect its interpretation;

(d) references to the singular include the plural and vice versa;

(e) words denoting persons include individuals, companies, partnerships, unincorporated associations and other bodies (in each case, wherever resident and whether or not having separate legal personality) and references to a company shall include any company, corporation or other body corporate wherever or however incorporated or established;

(f) a reference to:

(i) a statute, statutory provision, regulation, directive or other enactment shall be construed as including a reference to any subordinate legislation or instrument made from time to time under that statute, provision, regulation, directive or enactment whether before, on or after the date of this Agreement; and

(ii) a statute, statutory provision, regulation, directive, enactment or subordinate legislation shall be construed as including a reference to that statute, provision, regulation, directive, enactment or subordinate legislation as in force at the date of this Agreement and as from time to time amended, modified, consolidated, superseded, re-enacted or replaced (whether with or without modification) after the date of this Agreement;

(g) general words shall not be given a restrictive meaning by reason of the fact that they are preceded by or followed by particular examples intended to be embraced by the general words and accordingly:

(i) the rule known as *ejusdem generis* shall not apply; and

(ii) the words "includes", "including" and "in particular" (or similar terms) are not to be construed as implying any limitation and shall be read and construed as if immediately followed by the words "without limitation";

(h) any reference to this Agreement or any other document is to this Agreement or that document as in force for the time being and as amended from time to time in accordance with this Agreement and/or that document (as the case may be);

(i) if a payment under this Agreement is due on a day which is not a Business Day, the due date for that payment shall be the next Business Day; and

(j) terms other than those defined in this Agreement shall be given their plain English meaning and those terms, acronyms and phrases known in the pharmaceutical industry shall be interpreted in accordance with their generally accepted meanings.

2 WARRANTIES

Authority Warranties

2.1 The Authority represents and warrants that:

(a) it has full capacity and authority to enter into and to perform this Agreement;

(b) this Agreement is executed by its duly authorised representative;

(c) there are no actions, suits or proceedings or regulatory investigations before any court or administrative body or arbitration tribunal pending or, to its knowledge, threatened against it that might affect its ability to perform its obligations under this Agreement; and

(d) its obligations under this Agreement constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms subject to applicable bankruptcy, reorganisation, insolvency, moratorium or similar Laws affecting creditors' rights generally and subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or law).

Manufacturer Warranties

2.2 The Manufacturer represents and warrants that:

(a) it is validly incorporated, organised and subsisting in accordance with the Laws of its place of incorporation;

(b) it has full capacity and authority to enter into and to perform this Agreement;

(c) this Agreement is executed by its duly authorised representative;

(d) it has all necessary consents and regulatory approvals to enter into this Agreement;

(e) there are no actions, suits or proceedings or regulatory investigations before any court or administrative body or arbitration tribunal pending or, to its knowledge, threatened against it or any of its Affiliates that will affect its ability to perform its obligations under this Agreement;

(f) its execution, delivery and performance of its obligations under this Agreement (save for compliance with instructions issued by the Authority pursuant to Clause 30.4 (Measures in a Crisis)) will not constitute a breach of any Law or obligation applicable to it and will not cause or result in a default under any agreement by which it is bound;

(g) its obligations under this Agreement constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms subject to applicable bankruptcy, reorganisation, insolvency, moratorium or similar Laws affecting creditors' rights generally and subject, as to enforceability, to equitable principles of general application (regardless of whether enforcement is sought in a proceeding in equity or law);

(h) the Manufacturer is not in default in the payment of any due and payable taxes or in the filing, registration or recording of any document or under any legal or statutory obligation or requirement which default might have a material adverse effect on its business, assets or financial condition or its ability to observe or perform its obligations under this Agreement;

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

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

(k) as at the date of this Agreement, during the previous two (2) years it has received no communication from any Regulator in relation to the Manufacturing Site (including in relation to the compliance of that Manufacturing Site with all applicable requirements of GMP) that is likely to have an adverse effect on the Manufacturer's ability to perform its obligations under this Agreement;

(l) as at the date of this Agreement, so far as the Manufacturer is aware, there are no circumstances in existence which give any Regulator grounds to issue a communication in relation to the Manufacturing Site that is likely to have an adverse effect on the Manufacturer's ability to perform its obligations under this Agreement; and.

(m) as at the date of this Agreement, none of the mandatory or discretionary grounds for exclusion in Regulation 57 of the Public Contracts Regulations 2015 apply to the Manufacturer.

2.3 The representations and warranties set out in Clause 2.1 and 2.2 shall be deemed to be repeated by the Parties on the Effective Date (if later than the date of signature of this Agreement) by reference to the facts then existing.

3 AGREED PURPOSE

3.1 The Authority and the Manufacturer shall work together in good faith to achieve the Agreed Purpose. In particular:

(a) each Party agrees to notify the other as soon as reasonably practicable of any circumstances that may adversely affect its ability to perform this Agreement;

(b) the Manufacturer acknowledges that the provision of the Reserved Capacity and the Services is a critical aspect of the Authority's response to COVID-19 and that any delay in notifying the Authority of any such circumstance could compromise the Authority's COVID-19 response efforts; and

(c) the Manufacturer acknowledges that the performance of its obligations under an MSA in accordance with the terms of the MSA is also a critical aspect of the Authority's response to COVID-19.

3.2 With effect from the Effective Date and for the duration of the Term, the Manufacturer shall provide the Services for the Authority and/or its Affiliates.

3.3 Other than where the Authority has provided consent in accordance with Clause 4, the Manufacturer (and any of its Affiliates) shall not enter into arrangements with Third Parties requiring use of the:

(a) Reserved Capacity during the Term; or

(b) Manufacturing Site that may adversely affect the Manufacturer's ability to deliver the Services.

3.4 If the Authority identifies a Vaccine Manufacturer that requires use of the Reserved Capacity to pursue the Agreed Purpose, then the Manufacturer shall work with the Authority and relevant Vaccine Manufacturer in good faith to:

(a) allow the Vaccine Manufacturer to use the Reserved Capacity to pursue the Agreed Purpose; and

(b) enter into such arrangements as may be necessary to enable the Vaccine Manufacturer to use the Reserved Capacity to pursue the Agreed Purpose,

in accordance with the process set out in Clause 4.

3.5 For the avoidance of doubt, nothing in this Agreement shall prevent the Authority and/or its Affiliates from providing, or from appointing any Third Party to provide, services in respect of any of the Products which are the same as or similar to the services to be provided by the Manufacturer to the Authority and/or its Affiliates under this Agreement.

4 AGREEMENTS WITH VACCINE MANUFACTURERS

4.1 Where the Authority notifies the Manufacturer that a Vaccine Manufacturer requires use of the Reserved Capacity to pursue the Agreed Purpose, the Parties and the Vaccine Manufacturer shall meet as soon as reasonably practicable to discuss the requirements for Manufacturing the relevant Product using the Reserved Capacity, including in relation to:

(a) the technical requirements to Manufacture the Product;

(b) the likely cost and timescale of any Modification Works;

(c) the likely unit fee for the Product (which, where the Product is the AZ Vaccine, is envisaged to be [redacted] subject to the assumptions and qualifications in the Manufacturer's Proposal);

(d) the timeframe within which the Product could be produced, bearing in mind any current manufacturing activity using the Reserved Capacity; and

(e) the remaining Term of this Agreement.

4.2 Where, acting in good faith, the Parties agree that the Reserved Capacity can be used to Manufacture the relevant Product using the Reserved Capacity, the Manufacturer shall make all reasonable endeavours to negotiate and enter into as soon as reasonably practicable:

(a) a MSA in accordance with the requirements of this Clause 4; and

(b) such other agreements as may be necessary to achieve the Agreed Purpose, including a Quality Agreement,

provided that the Authority acknowledges that, as a result of negotiations between the Manufacturer and a prospective Vaccine Manufacturer, the Manufacturer may require certain changes to be made to this Agreement from time to time, requests for which the Authority shall consider in good faith and in accordance with Clause 25.

4.3 Any MSA entered into between the Manufacturer and a Vaccine Manufacturer shall:

(a) be on commercially reasonable terms which a reasonable, diligent party in a similar situation (with respect to size, resources and assets) in the pharmaceutical industry would negotiate and enter into in its own interests; and

(b) unless the Authority in its sole discretion provides written consent otherwise, contain provisions which adequately address the following issues:

(i) the time period during which the Reserved Capacity is available for use by the Vaccine Manufacturer and any restrictions on the volumes of Product to be manufactured during such time period;

(ii) that the Product shall be Manufactured in accordance with Good Manufacturing Practice to meet any requirements for it to be supplied in the UK;

(iii) an agreed unit fee for each Product which shall be on fair and reasonable market terms;

(iv) an acknowledgment that the Authority's payment to the Manufacturer of the Base Fee under this Agreement shall be used as a credit to reduce the payments due from the Vaccine Manufacturer to the Manufacturer under the MSA in accordance with the process set out in Schedule 5 (Pricing, Payment and Invoicing) of this Agreement;

(v) that the Vaccine Manufacturer shall pay the Manufacturer any Product Conversion Fee over and above the Available Base Fee;

(vi) the extent of the Vaccine Manufacturer's obligations to procure and/or pay for any Modification Works, Remediation Works, Materials or other items required to Manufacture the Product;

(vii) that the Manufacturer shall not be entitled to recover any costs in relation to the Agreed Purpose from the Authority under this Agreement to the extent it has a right to recover such costs from the Vaccine Manufacturer under the MSA and similarly that the Manufacturer shall not be entitled to charge the Vaccine Manufacturer under the MSA for any costs in relation to the Agreed Purpose which the Authority has agreed to pay under this Agreement;

(viii) an obligation to:

(A) provide a copy of the MSA to the Authority;

(B) notify the Authority prior to making any written amendment to the MSA;

(C) obtain the prior consent of the Authority to any written amendment to the mandatory terms referred to in this Clause 4.3(b) (provided that if such change has been agreed by the Manufacturer and the Vaccine Manufacturer and is required in order for the Manufacturer to carry out the MSA in accordance with the requirements of applicable Law, the Quality Agreement, the Specification, Product Licence, Manufacturing Licence or other quality or technical requirements then the Authority shall not refuse such consent);

(ix) a right for the Manufacturer to terminate the MSA where the Authority exercises its rights under Clause 4.11 and commercially reasonable terms relating to the calculation and minimisation of the MSA Breakage

Costs, which shall include such terms as the Manufacturer would negotiate and enter into in its own interests for the MSA Breakage Costs to be properly evidenced, incurred and mitigated by the Vaccine Manufacturer;

(x) an obligation for the Manufacturer and the Vaccine Manufacturer to provide financial information to the Authority in relation to their respective costs and payments made and/or received under the MSA on equivalent terms to Clause 20 (Financial Reports, Records and Audit Rights); and

(xi) an acknowledgement of the Authority's rights to take action under Clause 30 (Measures in a Crisis) and provisions which flow down the requirements of Clause 30 (Measures in a Crisis) in order to allow the Manufacturer to discharge its obligations to the Authority under Clause 30 (Measures in a Crisis).

4.4 The Manufacturer shall keep the Authority informed of the progress of negotiations with the Vaccine Manufacturer, which shall include as a minimum providing the Authority with an update on material issues and, when requested, the latest draft of the MSA exchanged between the parties. The Authority shall provide comments promptly following any update and the Manufacturer shall take such comments into account during its negotiations with the Vaccine Manufacturer.

4.5 The Vaccine Manufacturer shall provide the Authority with a copy of the draft MSA as soon as reasonably practicable following agreement of the terms with the Vaccine Manufacturer. The Authority shall review the draft MSA and, provided the Manufacturer has complied with its obligations under Clause 4.4, shall within a reasonable period, either:

(a) provide its consent for the Manufacturer to enter into the MSA; or

(b) acting reasonably, reject the MSA.

4.6 For the avoidance of doubt, the Parties acknowledge and agree that the Authority shall be acting reasonably in refusing its consent under Clause 4.5(b) if the MSA does not contain the terms required pursuant to Clause 4.3 in a form which is acceptable to the Authority (acting reasonably).

4.7 Where the Authority rejects the MSA under Clause 4.5(b) or refuses its consent under Clause 4.3(b)(viii)(C), it shall provide the Manufacturer with notice of the reasons for the rejection and the suggested changes to the MSA which would be required in order to obtain the Authority's consent. Following receipt of such notice, the Manufacturer shall make all reasonable endeavours to agree changes with the Vaccine Manufacturer as

soon as reasonably practicable in order to provide an updated MSA to the Authority which complies with the requirements of Clause 4.3.

4.8 Where the Authority provides consent under Clause 4.5(a), the Manufacturer shall enter into the MSA in the approved form as soon as reasonably practicable. The Manufacturer shall provide the Authority with a copy of the duly executed MSA within five (5) Business Days of entering into the MSA.

4.9 For the avoidance of doubt, the Parties acknowledge and agree that the Authority shall bear no responsibility or any liability in relation to the requirements of the Product Licence, Manufacturing Licence or any other regulatory, technical or quality requirement in relation to the Product, which shall at all times remain the responsibility of the Manufacturer and the Vaccine Manufacturer in accordance with Clause 21 (Product Licence and Manufacturing Licence).

4.10 Where the Manufacturer enters into an MSA, Quality Agreement or any other agreements for use of the Reserved Capacity with a Vaccine Manufacturer and there is any conflict between the terms of this Agreement and the terms of the agreement with the Vaccine Manufacturer, subject to the form of the MSA having been approved by the Authority in accordance with this Clause 4:

(a) where the conflict relates to the Manufacture of the Product, including any aspect of the Specification, quality or technical requirements, the terms of the agreements with the Vaccine Manufacturer shall take precedence over this Agreement; and

(b) where the conflict relates to any other element of the Services, the terms of this Agreement shall take precedence.

4.11 The Authority shall, provided that it gives at least ten (10) Business Days' notice to the Manufacturer, have the right to require the Manufacturer to terminate an MSA where:

(a) the Authority reasonably believes that the MSA no longer pursues the Agreed Purpose; or

(b) the Authority requires the Reserved Capacity to be available for another Vaccine Manufacturer,

and upon receipt of such notice the Manufacturer shall terminate the MSA in accordance with such notice.

4.12 Where the Manufacturer terminates an MSA in accordance with instructions issued by the Authority pursuant to Clause 4.11 then the Authority shall pay the Manufacturer the MSA Breakage Costs, subject to the Manufacturer pursuing its rights under the MSA as

if it was acting in its own interests in order to minimise the MSA Breakage Costs in accordance with the terms of the MSA.

5 ORDERING AND FORECASTING

Responsibility for ordering and forecasting

5.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the Vaccine Manufacturer shall be responsible for ordering Product from the Manufacturer, and the ordering and forecasting process and the resolution of disputes relating to the same shall be governed by the relevant MSA; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 5.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 5.1(a) above.

5.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 5.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 25 (Change Control); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out at Schedule 9 (Manufacturing and Supply to Authority).

Authority visibility of production pipeline

5.3 The Authority requires visibility of the pipeline for production of Product, and so the Manufacturer shall notify the Authority (and provide the Authority with a copy of the relevant information) within five (5) Business Days following:

(a) the Manufacturer's receipt of any;

(i) forecast schedule for Product demand; or

(ii) firm order for Product;

from the Vaccine Manufacturer; and

(b) the Manufacturer's issuing any relevant information (including any relevant updates) to the Vaccine Manufacturer concerning an anticipated delivery date for Product.

5.4 Notwithstanding Clause 5.3, the Manufacturer shall provide the Authority with a report (the "**Demand Forecast Report**") in advance of each Contract Quarter setting out:

(a) anticipated demand for Product over the coming three (3) month period; and

(b) its actual demand for Product over the next four (4) week period.

6 MANUFACTURER'S OBLIGATIONS

6.1 The Manufacturer shall:

(a) provide the Services to the Authority in accordance with the Statement of Requirements;

(b) perform its obligations under this Agreement, including in relation to the supply of the Services, in accordance with:

(i) Good Industry Practice; and

(ii) all applicable Laws;

(c) work together with the Authority in good faith to enter into such agreements with Vaccine Manufacturers as are necessary to Manufacture the Products;

(d) where the Parties agree that the Authority should assume some of the rights and obligations normally held by a Vaccine Manufacturer under a manufacture and supply agreement, work together with the Authority in good faith to agree such changes as are required to this Agreement to facilitate this change in role on the part of the Authority in accordance with the Change Control Procedure, including any changes necessary to give effect to the rights and obligations set out in Schedule 9 (Manufacture and Supply to the Authority);

(e) Manufacture the Products at the Manufacturing Site;

(f) Manufacture the Products in accordance with;

(i) the Manufacturer's Manufacturing Licences;

(ii) Good Manufacturing Practice; and

(iii) applicable Laws;

(g) provide and maintain premises of sufficient size and quality and all labour, plant, machinery, equipment and services necessary to enable the Manufacturer to fulfil all its obligations under this Agreement including, in particular, the performance of the Services; and

(h) maintain all premises, plant, machinery and equipment used for or in connection with the performance of its obligations under this Agreement in good working condition and in compliance with GMP and applicable Laws.

6.2 Other than with the approval of the Vaccine Manufacturer, the Manufacturer shall not, at any time during the Term, carry out any activities that adversely affect the quality, safety or efficacy of the Products. In order for the Vaccine Manufacturer and the Authority to identify any potential effects on quality, safety or efficacy of the Products, the Manufacturer shall disclose to any Vaccine Manufacturer and the Authority the nature of any other products manufactured by the Manufacturer for itself or Third Parties at the Manufacturing Site (in particular, any penicillins, cephalosporins, hormones or any other critical product).

6.3 Without prejudice to its other obligations under this Agreement, the Manufacturer shall comply with any applicable Laws addressing environmental and health and safety matters that relate to the performance of this Agreement.

7 BUSINESS CONTINUITY

7.1 Prior to entry into this Agreement the Manufacturer provided the Authority with details of the Manufacturer's policies for ensuring business continuity during the COVID-19 pandemic, receipt of which is hereby acknowledged by the Authority.

7.2 From the date of this Agreement, the Manufacturer shall provide updates in writing to the Authority with details of any changes being made to the policy supplied under Clause 7.1 from time to time as soon as reasonably practicable following any material changes as part of the process to prepare and deliver a business continuity and disaster recovery plan in accordance with Clause 7.3.

7.3 Within twenty (20) Business Days from the date of this Agreement the Manufacturer shall prepare and deliver to the Authority for the Authority's written approval a draft plan (a "**Business Continuity and Disaster Recovery Plan**"), which shall detail the processes and arrangements that the Manufacturer shall follow to ensure:

(a) continuity of the Services following any failure or disruption of any element of the Services; and

(b) the recovery of the Services if one or more events occur (including reasonably foreseeable events linked to the COVID-19 pandemic) which, either separately or cumulatively, mean that:

(i) the whole of the Services; or

(ii) a material part of the Services;

are likely to be unavailable, or are in fact unavailable, for a continuous period of five (5) Business Days.

7.4 Following receipt of the draft Business Continuity and Disaster Recovery Plan from the Manufacturer, the Authority shall:

(a) review and comment on the draft Business Continuity and Disaster Recovery Plan as soon as reasonably practicable; and

(b) notify the Manufacturer in writing that it approves or rejects the draft Business Continuity and Disaster Recovery Plan no later than ten (10) Business Days after the date on which the draft Business Continuity and Disaster Recovery Plan is first delivered to the Authority.

7.5 If the Authority rejects the draft Business Continuity and Disaster Recovery Plan:

(a) the Authority shall inform the Manufacturer in writing of its reasons for its rejection; and

(b) the Manufacturer shall then revise the draft Business Continuity and Disaster Recovery Plan (taking reasonable account of the Authority's comments) and shall re-submit a revised draft Business Continuity and Disaster Recovery Plan to the Authority within twenty (20) Business Days of the date of the Authority's notice of rejection for the Authority's approval. The provisions of Clause 7.2 and this Clause 7.3 shall apply again to any resubmitted draft Business Continuity and Disaster Recovery Plan, provided that either Party may refer any disputed matters for resolution by the Dispute Resolution Procedure at any time.

7.6 The Business Continuity and Disaster Recovery Plan shall set out the arrangements that are to be invoked to ensure that the business processes and operations facilitated by the Services remain supported and to ensure continuity of the business operations supported by the Services including, unless the Authority expressly states otherwise in writing:

(a) the alternative processes (including business processes), options and responsibilities that may be adopted in the event of a failure in or disruption to the Services; and

(b) the steps to be taken by the Manufacturer upon resumption of the Services in order to address any prevailing effect of the failure or disruption including a root cause analysis of the failure or disruption.

7.7 The Business Continuity and Disaster Recovery Plan shall:

(a) address the various possible levels of failures of or disruptions to the Services;

(b) set out the services to be provided and the steps to be taken to remedy the different levels of failures of and disruption to the Services; and

(c) clearly set out the conditions and/or circumstances under which the Business Continuity and Disaster Recovery Plan is invoked.

7.8 The Manufacturer shall review, test and update the Business Continuity and Disaster Recovery Plan (and the risk analysis on which it is based) on a regular basis and as a minimum once every six (6) months.

8 AUTHORITY OBLIGATIONS

8.1 The Authority shall:

(a) pay the Manufacturer in consideration for providing the Services in accordance with Schedule 5 (Price, Payment and Invoicing);

(b) procure the supply of Materials where required in accordance with Clause 12;

(c) subject to Clauses 9.1 and 10.1 respectively, pay the Manufacturer the Modification Work Costs and Remediation Work Costs in accordance with Schedule 6 (Modification Works and Remediation Works); and

(d) provide the Manufacturer, or make all reasonable endeavours to procure that the Vaccine Manufacturer provides the Manufacturer, with all the necessary details, technical & non-technical data and methods that are required by the Manufacturer to perform the Services.

9 MODIFICATION WORKS

9.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the procurement and cost of any Modification Works needed to manufacture the Product shall be governed by the relevant MSA; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to

Clause 9.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 9.1(a) above.

9.2 Where the Parties agree that some or all of the required Modification Works are to be paid for by the Authority under this Agreement, then the Parties shall comply with the provisions set out in Schedule 6 (Modification Works and Remediation Works) in relation to the Modification Works.

10 REMEDIATION WORKS

10.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the procurement and cost of any Remediation Works which are needed as a result of Modification Works carried out pursuant to the relevant MSA shall also be governed by the relevant MSA;

(b) the procurement and cost of any Remediation Works which are needed as a result of Modification Works carried out pursuant to Schedule 6 (Modification Works and Remediation Works) shall be governed by Schedule 6 (Modification Works and Remediation Works); and

(c) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to Clause 10.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 10.1(a) above.

10.2 Where the Parties agree that some or all of the required Remediation Works are to be paid for by the Authority under this Agreement, then the Parties shall comply with the provisions set out in Schedule 6 (Modification Works and Remediation Works) in relation to the Remediation Works.

11 INTELLECTUAL PROPERTY

11.1 This Agreement does not affect the ownership of any Background Intellectual Property. All rights in Background Intellectual Property are and shall remain the exclusive property of the Party owning it (or, where applicable, the third party from whom such Party's right to use the Background Intellectual Property has derived).

11.2 The Parties do not believe that either Party will be required to provide the other Party with any Intellectual Property in order to carry out their obligations in accordance with this Agreement.

11.3 If as a result of any changes to this Agreement pursuant to the Change Control Procedure either Party does require the other Party to provide Intellectual Property for the other Party's use, the Parties shall agree appropriate changes to this clause, which shall include:

(a) licences for use of such Intellectual Property as is required to perform the amended Agreement; and

(b) appropriate indemnities for the benefit of the other Party in relation to Third Party claims for infringement where one Party is using Intellectual Property provided by the other Party.

12 MATERIALS

12.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the procurement and testing of any Materials needed to manufacture the Product shall be governed by the relevant MSA and the corresponding Quality Agreement; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to Clause 12.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 12.1(a) above.

12.2 Where:

(a) Bulk Vaccine; or

(b) Elective Materials;

are procured or provided by the Authority under this Agreement, then the provisions of Schedule 7 (Materials) shall apply to those Materials.

12.3 Prior to entering into this Agreement, the Authority instructed the Manufacturer to procure certain Elective Materials as further specified in Schedule 7Appendix 1 (Approved Elective Materials) of Schedule 7 (Materials). The Authority shall reimburse the Manufacturer for the price (including applicable VAT) of such Approved Elective Materials and the Manufacturer shall be entitled to invoice the Authority for such costs as set out in Appendix 1 of Schedule 7 (Materials) in accordance with paragraph 5 of Schedule 7 (Materials) and for these purposes the Authority shall be deemed to have provided the approval required by paragraph 5.1(b) of Schedule 7 (Materials).

13 STORAGE OF PRODUCTS AND MATERIALS

13.1 The Manufacturer shall:

(a) at its own cost (subject to the assumptions and qualifications in the Manufacturer's Proposal), at all times store and warehouse all Materials procured or provided by the Authority pursuant to Schedule 7 (Materials) of this Agreement in premises that are secure, clean and otherwise acceptable to the Authority;

(b) store the Materials procured under an MSA and any Products manufactured pursuant to an MSA in accordance with the requirements of the relevant MSA and any Specification; and

(c) operate a warehousing system which identifies all Products according to type and status.

14 ARTWORK

14.1 The artwork to be used in relation to the packaging of the Product shall be a matter for the Vaccine Manufacturer and the Manufacturer and any requirements relating to artwork shall be governed by the terms of MSA.

14.2 The Authority shall not be liable to the Manufacturer for any costs or claims in relation to the artwork required for the Products, including but not limited to any costs arising from any third party claims, disputes or costs associated with any changes required to the artwork.

15 MANUFACTURING CAPACITY

15.1 The Manufacturer undertakes that it will be capable of delivering the Services in accordance with the Statement of Requirements at all times from the Effective Date during the Term.

15.2 If a breakdown, fault or other event occurs (other than as a result of a Force Majeure Event) that prevents (or may prevent) the Manufacturer from delivering a material part of the Services, then the Manufacturer shall notify the Authority and any relevant Vaccine Manufacturer immediately if it anticipates (acting reasonably) that such breakdown/fault cannot be remedied within two (2) Business Days and the Manufacturer shall:

(a) where it has entered into an MSA:

(i) comply with its obligations under the MSA in relation to the rectification of such faults or events; and

(ii) advise the Authority within two (2) Business Days of agreeing with the Vaccine Manufacturer pursuant to Clause 15.2(a)(i) above the details of any remedial action to be taken by the Manufacturer;

(b) where no MSA exists at the time of the breakdown/fault:

(i) advise the Authority within two (2) Business Days after such notification of the remedial action to be taken by the Manufacturer.

15.3 After the Effective Date, the Manufacturer shall submit a report to the Authority with details of the utilisation of the Reserved Capacity (including days in active use and details of the extent to which on time in full deliveries were made in accordance with any MSA) (the "**Utilisation Report**") within five (5) Business Days after the end of each calendar month and the Parties shall meet at least once a month to discuss the Utilisation Report.

16 DELIVERY OF PRODUCTS

16.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the rights and obligations in relation to Delivery and acceptance of the Product and the resolution of disputes relating to the same shall be governed by the relevant MSA; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 16.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 16.1(a) above.

16.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 16.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 6.1(d); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out in paragraphs 6.2 to 6.8 of Schedule 9 (Manufacture and Supply to the Authority).

16.3 Payment by the Authority or its Affiliates of the Base Fee shall not be deemed to constitute acceptance of such Products by the Authority or its Affiliates. Acceptance of Products is subject always to Clause 17.

17 DEFECTIVE PRODUCTS

17.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the rights and obligations in relation to the inspection, acceptance, rejection, identification of defects, remedies in relation any defects and testing of Products, and the resolution of disputes relating to these issues, shall be governed by the relevant MSA; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 18.1 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 17.1(a) above.

17.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 17.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 6.1(d); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out in paragraphs 1.1 to 1.8 of Schedule 9 (Manufacture and Supply to the Authority).

18 PRICE, PAYMENT AND TAXATION

18.1 The Parties shall comply with the pricing and payment profile and the invoicing procedure specified in Schedule 5 (Price, Payment and Invoicing).

18.2 The payments to be made under the Agreement are stated exclusive of VAT, which shall be added at the prevailing rate as applicable and paid by the Authority following delivery of a valid VAT invoice.

18.3 The Manufacturer shall indemnify the Authority against any liability (including any interest, penalties or costs incurred) that is levied, demanded or assessed on the Authority at any time in respect of the Manufacturer's failure to account for or to pay any VAT to the relevant taxation authority on payments made to the Manufacturer under this Agreement. Any amounts due under this Clause 18.3 shall be paid in cleared funds by the Manufacturer to the Authority not less than five (5) Business Days before the date upon which the tax or other liability is payable by the Authority.

19 PERFORMANCE AND INCENTIVISATION

19.1 The Parties shall comply with the performance regime set out in Schedule 3 (Performance).

20 FINANCIAL REPORTS, RECORDS AND AUDIT RIGHTS

20.1 The Parties shall comply with the provisions of Schedule 4 (Financial Reports, Records and Audit Rights) in relation to the:

(a) maintenance of Open Book Data;

(b) provision of the Financial Reports;

(c) exercise of the audit Rights by the Authority or any Audit Agents; and

(d) maintenance and retention of Records.

21 THE PRODUCT LICENCE AND MANUFACTURING LICENCE

21.1 The Vaccine Manufacturer (or its Affiliates or nominees) shall hold the Product Licence and therefore responsible for the registration of the Products with all relevant authorities.

21.2 The Manufacturer undertakes to observe and comply with all requirements of the Product Licence and any amendments or additions to such Product Licence in accordance with the terms of the relevant agreements entered into with the Vaccine Manufacturer.

21.3 The Manufacturer shall at its own cost:

(a) obtain and maintain throughout the Term all Manufacturing Licences; and

(b) supply to the Authority on request a copy of each Manufacturing Licence.

22 QUALITY ASSURANCE

22.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the rights and obligations in relation to quality assurance and related issues shall be governed by the relevant MSA and Quality Agreement; and

(b) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 22.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 22.1(a) above.

22.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 22.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 6.1(d); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out in paragraphs 2.1 to 2.6 of Schedule 9 (Manufacture and Supply to the Authority).

23 COMPLAINTS AND RECALL PROCEDURES

23.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the Vaccine Manufacturer shall be responsible in accordance with applicable Laws for the reporting to Regulators of all complaints and product recalls relating to Products;

(b) the rights and obligations in relation to complaints and product recalls shall be governed by the relevant MSA and Quality Agreement; and

(c) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 23.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 23.1(a) and 23.1(b) above.

23.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 23.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 6.1(d); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out in paragraphs 3.1 to 3.5 of Schedule 9 (Manufacture and Supply to the Authority).

24 INSPECTIONS BY ADMINISTRATIVE ENTITY

24.1 Where the Product is being Manufactured and Delivered to the Vaccine Manufacturer pursuant to an MSA entered into between the Manufacturer and the Vaccine Manufacturer in accordance with Clause 4 (Agreements with Vaccine Manufacturers):

(a) the rights and obligations of the Vaccine Manufacturer and the Manufacturer in relation to inspections by an Administrative Entity shall be governed by the relevant MSA;

(b) the Manufacturer shall notify the Authority promptly that such an inspection is taking place and keep the Authority informed of any events in relation to the inspection which, in each case, are likely to have a material impact on the Manufacturer's ability to perform its obligations under this Agreement; and

(c) notwithstanding the fact that the Base Fee paid by the Authority under this Agreement may have been used as credit for the relevant Products, subject to any amendments agreed pursuant to Clause 24.2 below, the Authority shall have no responsibility or liability whatsoever in relation to the issues set out in Clause 24.1(a) above.

24.2 Where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out in Clause 24.1(a) above, the Parties:

(a) shall make all reasonable endeavours to agree any changes necessary to this Agreement in accordance with Clause 6.1(d); and

(b) acknowledge and agree that the terms relating to such issues shall be in substantially the same form as those set out in paragraphs 4.1 to 4.4 of Schedule 9 (Manufacture and Supply to the Authority).

25 CHANGE CONTROL

25.1 No amendment or variation to the terms of the Agreement shall be valid unless previously agreed in writing between the Authority and the Manufacturer.

25.2 Where the Authority or the Manufacturer requires any changes to be made to this Agreement, including with respect to the Services, the Statement of Requirements and/or Manufacture of the Products, the Authority or the Manufacturer shall notify the other Party by completing Section A of the Change Control Notice ("**CCN**") set out at Schedule 8 and provide details of the required change.

25.3 Where the Authority requires a change, the Manufacturer shall, within ten (10) Business Days after receipt of the Authority's CCN provide the Authority with an estimate of the timeframe and cost required to implement the change. The Manufacturer shall review the CCN provided by the Authority and either:

(a) accept the CCN;

(b) reject the CCN;

(c) request an amendment to the CCN (providing reasonable details of the items it requests or rejects or queries); or

(d) request any such further information it reasonably requires to review the CCN.

25.4 Where the Manufacturer requires a change, the Manufacturer shall provide the Authority with an estimate of the timeframe and cost required to implement the change. The Authority shall review the CCN provided by the Manufacturer and either:

(a) accept the CCN;

(b) reject the CCN;

(c) request an amendment to the CCN (providing reasonable details of the items it requests or rejects or queries); or

(d) request any such further information it reasonably requires to review the CCN.

25.5 Each party shall be responsible for its own costs incurred in the preparation and assessment of CCNs.

25.6 Once the changes are agreed and accepted by both parties, Section B of the CCN must be completed. A CCN signed by both Parties shall constitute an amendment to the Agreement.

25.7 The Manufacturer shall maintain a record of all CCN requests and approved changes.

26 CHANGE IN LAW

26.1 The Manufacturer shall neither be relieved of its obligations to supply the Services in accordance with the terms and conditions of this Agreement nor be entitled to an increase in the payments due under this Agreement as the result of:

(a) a General Change in Law; or

(b) a Specific Change in Law where the effect of that Specific Change in Law on the Services is reasonably foreseeable at the date of this Agreement.

26.2 If a Specific Change in Law occurs or will occur during the Term (other than as referred to in Clause 26.1(b)), the Manufacturer shall:

(a) notify the Authority as soon as reasonably practicable of the likely effects of that change, including:

(i) whether any Change is required to the Services, the payments due under this Agreement or the terms of this Agreement; and

(ii) whether any relief from compliance with the Manufacturer's obligations is required; and

(b) provide the Authority with evidence:

(i) that the Manufacturer has minimised any increase in costs or maximised any reduction in costs;

(ii) as to how the Specific Change in Law has affected the cost of providing the Services; and

(iii) demonstrating that any expenditure that has been avoided has been taken into account in amending the payments due under this Agreement.

26.3 Any variation in the payments due under this Agreement or relief from the Manufacturer's obligations resulting from a Specific Change in Law (other than as referred to in Clause 26.1(b)) shall be implemented in accordance with the Change Control Procedure.

27 CONFIDENTIALITY

27.1 Subject to Clause 27.3, Clause 27.4, Clause 27.6, Clause 27.7 and Clause 29 (Freedom of Information), neither Party shall without the consent of the other Party during the Term or at any subsequent time in the period five (5) years after the date of this Agreement either:

(a) disclose Confidential Information to any other person save:

(i) insofar as is necessary to further the objectives set out in this Agreement; or

(ii) where disclosure is required by applicable law (including, for the avoidance of doubt, any stock exchange rules or regulations applicable to the Manufacturer or any of its Affiliates); or

(b) use Confidential Information other than for the Agreed Purpose.

27.2 Any Party disclosing Confidential Information in accordance with Clause 27.1 shall procure that (other than in respect of stock exchange announcements or other public announcements pursuant to Clause 27.1(a)(ii)) the person to whom such information is disclosed is made aware of the obligations of confidentiality under this Agreement and complies with those obligations as if they were a party to this Agreement.

27.3 The Authority may disclose the Confidential Information of the Manufacturer:

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

(b) to Parliament and Parliamentary Committees or if required by any Parliamentary reporting requirement or by the National Audit Office;

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

(d) on a confidential basis to a professional adviser, consultant, supplier or other person engaged by any of the entities described in Clause 27.3(a) for any purpose relating to or connected with this Agreement, provided that the Authority shall not disclose any Confidential Information of the Manufacturer:

(i) to any competitor or customer of the Manufacturer; or

(ii) to any Vaccine Manufacturer, other than for the purpose of (and solely to the extent necessary for):

(A) performing its obligations under this Agreement; and

(B) calculating any payments due to the relevant Vaccine Manufacturer for supply of Products to HMG which have been Manufactured by the Manufacturer,

save that, notwithstanding the foregoing, the Authority shall not disclose to any Vaccine Manufacturer or prospective Vaccine Manufacturer the terms or contents of Clauses [redacted] without the prior written consent of the Manufacturer (not to be unreasonably withheld or delayed);

(e) on a confidential basis for the purpose of the exercise of its rights under this Agreement;

and for the purposes of the foregoing (and for purpose of Clause 27.4 below), references to disclosure on a confidential basis shall mean disclosure subject to a confidentiality agreement or arrangement on terms no less stringent than those placed on the Authority (or in the case of Clause 27.4 below, the Manufacturer) under this Clause 27 (Confidentiality).

27.4 The Manufacturer may disclose the Confidential Information of the Authority:

(a) on a confidential basis to a professional adviser, consultant, supplier or other person engaged by the Manufacturer or its Affiliate for any purpose relating to or connected with this Agreement; and

(b) on a confidential basis for the purpose of the exercise of its rights under this Agreement.

27.5 The confidentiality obligations set out in this Clause 27 (Confidentiality) shall not extend to any information which:

(a) is, or becomes, generally available to the public other than as a result of the information being disclosed by or on behalf of the receiving Party in breach of this Agreement;

(b) was available to the receiving Party on a non-confidential basis before disclosure by the disclosing Party;

(c) was, is, or becomes available to the receiving Party on a non-confidential basis from a person who, to the receiving Party's knowledge, is not under any confidentiality obligation in respect of that information; or

(d) was lawfully in the possession of the receiving Party before the information was disclosed by the disclosing Party.

27.6 Notwithstanding Clause 28 (Transparency), subject to Clause 27.7, neither Party shall make, or permit any person to make, any pre-prepared formal written public announcement concerning this Agreement without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed), provided that the foregoing shall not restrict:

(a) the Party confirming that it is in discussions with the other Party;

(b) subject to the Party carrying out any activity under this Clause 27.6(b) providing notice to the other Party as soon as reasonably practicable prior to (or where prior notice is not possible as soon as reasonably practicable after) carrying out such activity:

(i) any announcement, communication or confirmation of any information that is already in the public domain; and

(ii) any interviews or publicity in relation to such information already in the public domain; or

(c) any announcement or circular (including by an Affiliate of the Manufacturer) required of the Manufacturer or any of its Affiliates by applicable Law, by any stock exchange or any regulatory or supervisory body or authority of competent jurisdiction (and the Manufacturer shall provide the Authority with a copy of any such announcement or circular as soon as reasonably practicable).

27.7 As soon as reasonably practicable, and in any event within ten (10) Business Days after the date of this Agreement, the Parties shall agree a press release in relation to the Agreement and the Manufacturer's provision of the Services. The Manufacturer shall not

publish such agreed press release until the Parties have, each acting reasonably, agreed the date for publication.

28 TRANSPARENCY

28.1 In order to comply with the HMG's policy on transparency in the areas of procurement and contracts, subject to Clause 28.2, the Authority may publish:

(a) a notice of the award of the Agreement;

(b) the contract value;

(c) details of the performance regime;

(d) the content of this Agreement, including any changes to this Agreement agreed from time to time, except for the following information (which the Authority shall ensure is irreversibly redacted and remains confidential in accordance with Clause 27):

(i) any information which is exempt from disclosure in accordance with the provisions of the FOIA, which shall be determined by the Authority subject to and in accordance with Clauses 29.3 and 29.4; and

(ii) commercially sensitive information (which shall be agreed or determined in accordance with Clauses 28.3 and 28.4),

on a designated web site.

28.2 The Authority shall notify the Manufacturer of the information it intends to publish at least five (5) Business Days in advance of so publishing.

28.3 The Supplier shall notify the Authority as soon as reasonably practicable after the date of the Agreement of any information included in this Agreement which it considers to be of a commercially sensitive nature, including but not limited to relating to:

(a) [redacted]

(b) [redacted]

(c) [redacted]

(d) [redacted]

(e) [redacted]

28.4 The Authority shall work together in good faith with the Manufacturer to agree, both parties acting reasonably and each Party making reasonable endeavours to reach such agreement within 30 calendar days of the Manufacturer's notification under Clause 28.3, what information notified by the Manufacturer pursuant to Clause 28.3 shall be redacted from the information to be published pursuant to Clause 28.1. Where the Parties are unable to agree such redactions within a reasonable period then the Authority shall have the final decision on what information is to be redacted.

29 FREEDOM OF INFORMATION

29.1 The Manufacturer acknowledges that the Authority is subject to the requirements of the FOIA and the EIR.

29.2 The Manufacturer shall transfer to the Authority all Requests for Information that it receives as soon as practicable and in any event within two (2) Business Days of receipt and shall:

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

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

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

29.3 The Authority shall determine in its absolute discretion and notwithstanding any other provision in the Services Agreement or any other agreement whether Confidential Information and any other Information is exempt from disclosure in accordance with the provisions of the FOIA and/or the EIR and the Authority shall use reasonable endeavours to notify the Manufacturer of any request that relates to the Manufacturer.

29.4 The Manufacturer acknowledges that the Authority may, acting in accordance with the Ministry of Justice's Code of Practice on the Discharge of the Functions of Public Authorities under Part 1 of the Freedom of Information Act ("**the Code**"), be obliged under the FOIA or the EIR to disclose certain Confidential Information that is the subject of a Request for Information:

(a) in certain circumstances, without consulting the Manufacturer; or

(b) following consultation with the Manufacturer and having taken its views into account,

provided always that, where this Clause 29.4 applies, the Authority shall (a) in accordance with any recommendations of the Code, take reasonable steps, where appropriate, to give the Manufacturer advance notice or, failing that, to draw the disclosure to the Manufacturer's attention after any such disclosure and (b) not disclose any Confidential Information of the Manufacturer that is exempt from disclosure or not required to be disclosed under the FOIA or the EIR.

30 MEASURES IN A CRISIS

30.1 If, at any time, the Authority believes, in its sole opinion, that there exist circumstances where, due to the impact of the COVID-19 pandemic (whether as a result of a second wave of infection or for any other reasons), in view of:

(a) the national interest or the occurrence of a state of emergency; and

(b) any material reduction in the Manufacturer's ability to perform the Services or Manufacture the Product due to the COVID-19 pandemic,

it is necessary, appropriate, or desirable for the Authority on a temporary basis to take all or any of the measures described in Clauses 30.2 to 30.5, the Authority may issue a notice in writing to the Manufacturer of such belief.

30.2 The Authority may require the Manufacturer, within such reasonable period as may be specified by the Authority given the urgency of the circumstances, to provide such information in the possession knowledge or control of the Manufacturer as the Authority may in its sole discretion reasonably require in relation to the Services, including without limitation information relating to all or any of the following matters:

(a) the Services currently being carried out by the Manufacturer;

(b) the Manufacturing activity currently being carried out by the Manufacturer;

(c) the Manufacturer's current deployment of its employees and any restrictions on its ability to deploy its employees; and

(d) details of the process, roles and competencies of personnel required to pursue the Agreed Purpose using the Reserved Capacity.

30.3 Upon providing the Authority with the information requested pursuant to Clause 30.2, or upon expiry of the period specified by the Authority for the supply of such information, the Manufacturer shall, upon being so requested by the Authority, discuss in good faith with the Authority any matters which the Authority, in its sole opinion, may consider relevant or appropriate to any proposals the Authority may have for the reallocation of priorities for, the reorganisation of the Services provided, or to be provided, by the Manufacturer and any support to be procured or provided by the Authority. These will be in order to

deal with the circumstances which gave rise to the issuing of a notice pursuant to Clause 30.1, including, without limitation, the following matters:

(a) the temporary revision of the Services for the Authority;

(b) the early completion or revision of any services by the Manufacturer for a Vaccine Manufacturer;

(c) the immediate implementation of new services which are within the competence of the Manufacturer to perform or procure; and/or

(d) the provision of assistance, support and/or personnel by the Authority to the Manufacture in order to continue to Manufacture the Product and/or carry out any of the actions above,

and the Parties shall endeavour, as far as reasonable possible, to reach agreement as a matter of urgency on such matters.

30.4 Notwithstanding any provision to the contrary in the Agreement, and notwithstanding that any of the measures described in Clauses 30.2 and 30.3 may not have been taken, required to be taken, or have been completed, the Authority may, at any time following a notice issued pursuant to Clause 30.1 and in its sole discretion (provided that the circumstances that led to the issue of the notice are continuing), require the Manufacturer to comply to the extent it is possible with any written instructions related to achieving the Agreed Purpose issued by the Authority including, without limitation, instructions issued in relation to all or any of the following matters:

(a) to accelerate to early completion any Manufacturing activity and to procure that any such action is carried out on terms with such parties which result in the least possible loss or damage to the Manufacturer;

(b) to accelerate to early completion or to suspend any of the Services provided or to be provided by the Manufacturer;

(c) to carry out any changes whatsoever to the Services required by the Authority without reference to the Change Control Procedure;

(d) to deploy its employees and all other assets or rights used in connection with the provision of the Services or to use, or make available for use by the Authority or as directed by the Authority, all such other assets or rights in accordance with the Authority's directions; and

(e) to permit personnel procured or provided by the Authority to provide support to the Manufacturer in carrying out the actions above,

provided that in each case:

(i) such matters are on a temporary basis;

(ii) such matters are within the competence of the Manufacturer or which the relevant personnel can reasonably be expected to perform;

(iii) the Manufacturer notifies the Authority as soon as reasonably practicable in advance of complying with such instructions of the extent to which, so far as the Manufacturer is aware, compliance with the instructions is or is likely to lead to:

(A) a breach by the Manufacturer of any obligations under

1) this Agreement;

2) an MSA; or

3) any contract between the Manufacturer and a Third Party; and

(B) Losses which the Manufacturer believes it will suffer as a result of complying with such instructions,

such that the Manufacturer shall not knowingly incur Losses without providing such notice; and

(iv) the Parties acknowledge and agree that Manufacturer shall not be in breach of its obligation to comply with the Authority's written instructions issued under this Clause 30.4 to the extent it can provide reasonable evidence that carrying out such instructions is or is likely to result in the Manufacturer suffering a Loss which is not recoverable under the indemnities in Clause 30.8.

30.5 The provisions of Clauses 30.2 to 30.4 shall cease to apply when the Authority issues a written notice to that effect to the Manufacturer and thereafter the Manufacturer shall continue to be bound by the provisions of the Agreement as in place prior to the circumstances referred to in Clause 30.1 arising. The Authority shall promptly issue such written notice to the Manufacturer once the circumstances that led to the application of the provisions of Clauses 30.2 to 30.4 are no longer continuing.

30.6 Any action or measures which the Authority may, or is required to, take pursuant to the provision of this Clause 30 may validly be taken by the Authority acting through such person as the Authority may from time to time authorise for that purpose.

30.7 To the extent that any works carried out and/or services provided by the Manufacturer at the request of the Authority pursuant to this Clause 30 are not covered by express agreement between the Parties, the Authority shall pay to the Manufacturer a fair and reasonable price for any work and/or services carried out by the Manufacturer in complying with the Authority's instructions under Clause 30.4, taking into account the extent to which such instructions alter the Manufacturer's obligation to provide the Services, and where it is agreed between the Parties that any such payments will be made via an adjustment to the Base Fee, such adjustment shall be calculated in accordance with the Change Control Procedure.

30.8 If the Authority has exercised its rights under this Clause 30, then

(a) for so long as any instruction issued by the Authority pursuant to Clause 30.4 prevents the Manufacturer from providing all or any part of the Services or complying with any other obligation under this Agreement, the Manufacturer shall be relieved from its obligations to provide such part of the Services or such other obligations under this Agreement;

(b) in respect of the period in which the Authority is taking action under this Clause 30 and provided that the Manufacturer complies with its obligations under this Clause 30 (save for any minor or inconsequential breaches which shall not deprive the Manufacturer of the benefit of the indemnities in this Clause), then:

(i) in respect of the period in which the Manufacturer is complying with the process and/or instructions issued by the Authority under Clause 30.4, any payment due from the Authority to the Manufacturer shall equal the amount the Manufacturer would receive if it were satisfying all its obligations and providing the Services affected by the actions under this Clause 30 in full over that period (such that, for the avoidance of any doubt, nothing as a result of this Clause 30 shall affect the Manufacturer's right to receive at least the Base Fee); and

(ii) subject to Clause 35.2;

(A) the Authority shall indemnify the Manufacturer against any direct Losses which the Manufacturer proves it has suffered in complying with any instruction issued by the Authority under Clause 30.4; and

(B) the Authority shall further indemnify the Manufacturer against any reasonable indirect Losses which it proves it has suffered in relation to any contract with any third party by reason of

complying with any instruction issued by the Authority under Clause 30.4,

provided that in each case the Manufacturer may recover through the indemnities in this Clause 30.8(b)(ii) only those Losses incurred by the Manufacturer which:

1) would not have been incurred but for the Manufacturer complying with the instructions issued by the Authority under Clause 30.4;

2) the Manufacturer has used reasonable endeavours to mitigate;

3) are unavoidable, proven, evidenced and not capable of recovery by any other means;

4) are incurred under arrangements and/or agreements that are consistent with terms that have been entered into in the ordinary course of business and on reasonable commercial terms; and

5) do not in aggregate exceed [redacted]

30.9 Notwithstanding the limit on the Authority's liability under the indemnities in Clause 30.8(b)(ii), where the Manufacturer provides reasonable evidence that carrying out instructions under Clause 30.4 is or is likely to result in the Manufacturer suffering a Loss which is not recoverable under the indemnities in Clause 30.8(b)(ii), the Authority may in its sole discretion commit to indemnifying the Manufacturer for such further Losses to the extent required for the Manufacturer to carry out the Authority instructions under Clause 30.4. The terms of the Authority's obligation to indemnify the Manufacturer for such further Losses shall be agreed by the Parties pursuant to the Change Control Procedure.

31 FORCE MAJEURE

31.1 Notwithstanding the Parties' obligations under Clause 30, subject to the remaining provisions of this Clause 31 (and, in relation to the Manufacturer, subject to its compliance with its obligations under its Business Continuity and Disaster Recovery Plan), a Party may claim relief under this Clause 31 from liability for failure to meet its obligations under this Agreement for as long as and only to the extent that the performance of those obligations is hindered, delayed or prevented by a Force Majeure Event. Any failure or delay by the Manufacturer in performing its obligations under this Agreement which results from a failure or delay by an agent, sub-contractor or supplier shall be regarded

as due to a Force Majeure Event only if that agent, sub-contractor or supplier is itself impeded by a Force Majeure Event from complying with an obligation to the Manufacturer.

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

31.3 If the Manufacturer is the Affected Party, it shall not be entitled to claim relief under this Clause 31 to the extent that consequences of the relevant Force Majeure Event are reasonably capable of being mitigated, including through:

(a) compliance with the Business Continuity and Disaster Recovery Plan; and

(b) actions which a prudent Manufacturer delivering services similar to the Services could reasonably be expected to carry out,

but the Manufacturer has failed to do so.

31.4 Subject to Clause 31.5, as soon as practicable after the Affected Party issues the Force Majeure Notice, and at regular intervals thereafter, the Parties shall consult in good faith and use reasonable endeavours to agree any steps to be taken and an appropriate timetable in which those steps should be taken to enable continued performance of the obligations hindered, delayed or prevented by the Force Majeure Event.

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

31.6 Where, as a result of a Force Majeure Event for which the Affected Party is entitled to claim relief pursuant to Clause 31.1:

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

(i) such failure shall not constitute a breach of this Agreement and the other Party shall not be entitled to exercise any rights to terminate this Agreement in whole or in part as a result of such failure other than pursuant to Clause 38.2(b); and

(ii) neither Party shall be liable for any breach of its obligations arising as a result of such failure;

(b) the Manufacturer fails to perform its obligations in accordance with this Agreement:

(i) the performance regime shall not apply to the extent that a performance failure has been caused by the Force Majeure Event; and

(ii) the Manufacturer shall only be entitled to receive and/or retain payment to the extent that it continues to be able to perform its obligations in accordance with the terms of this Agreement during the occurrence of the Force Majeure Event, which shall be calculated in accordance with Clause 31.10.

31.7 The Affected Party shall notify the other Party as soon as practicable after the Force Majeure Event ceases or no longer causes the Affected Party to be hindered, prevented or delayed in complying with its obligations under this Agreement.

31.8 Relief from liability for the Affected Party under this Clause 31 shall end as soon as the Force Majeure Event no longer causes the Affected Party to be hindered, prevented or delayed in complying with its obligations under this Agreement and shall not be dependent on the serving of notice under Clause 31.7.

31.9 The Manufacturer shall not be granted any relief from disruption resulting from COVID-19 related workforce issues to the extent that government guidance remains the same or less stringent than it was on the date of this Agreement and the Manufacturer shall ensure that it has mitigation plans in place at all times in accordance with Clause 7 to facilitate performance of its obligations under this Agreement despite the impacts of COVID-19. In relation to a Force Majeure Event consisting of disruption resulting from COVID-19 related workforce issues (to the extent that government guidance becomes more stringent than it was on the date of this Agreement), the Manufacturer shall be deemed to have taken all reasonable preventative action to the extent it:

(a) takes the actions set out in respect of such an event in the Business Continuity and Disaster Recovery Plan;

(b) complies with any relevant HMG guidance; and

(c) takes those actions which a prudent Manufacturer delivering services similar to the Services could reasonably be expected to carry out.

31.10 Subject to Clause 31.9, the Manufacturer shall be entitled to receive (or retain as appropriate) the following payments pursuant to Clause 31.6(b)(ii) during the occurrence of a Force Majeure Event:

(a) in relation to any Force Majeure Event other than a Relief Event:

(i) the Base Fee shall be payable to the extent the Services are delivered by the Manufacturer in accordance with the Agreement, such that where no Services are being delivered, no Base Fee shall be payable; and

(ii) where the Base Fee has already been paid in full for any period and the Manufacturer fails to deliver the Services due to the Force Majeure Event during the relevant period, the Manufacturer shall reimburse the Authority such portion of the Base Fee on a pro-rata basis for any element of the Services which are not delivered in accordance with this Agreement, such that where no Services were delivered for a period, the Base Fee in relation to the relevant period shall be reimbursed in full;

(b) in relation to a Relief Event:

(i) the payments calculated in accordance with Clause 31.10(a) above, provided that when calculating the payments due under Clause 31.10(a) the Manufacturer shall, [redacted]

1) [redacted]

2) [redacted]

3) [redacted]

32 AUTHORITY DEPENDENCIES

32.1 The Parties acknowledge and agree that where the Authority takes on as obligations under this Agreement some of the roles and responsibilities normally held by a Vaccine Manufacturer under an MSA, this may create dependencies where the Manufacturer is reliant on the Authority performing certain actions before the Manufacturer can perform its obligations in full. Where such a situation arises, the Parties shall agree any appropriate changes required to this Clause 32 in accordance with the Change Control Procedure, which shall include a mechanism for providing relief to the Manufacturer from the consequences of failing to perform its obligations in the event such failure is caused by the Authority failing to provide a dependency.

33 DATA PROTECTION

33.1 Other than limited business contact information in respect of the Parties' employees and sub-contractors, which may be used by the other Parties solely for contract management activities required to perform the Agreement during the Term in accordance with Data Protection Legislation, the Parties shall not Process any Personal Data in relation to the Agreement and shall not appoint any sub-processors unless and until the subject Party has authorised such Processing in accordance with the requirements of the Data Protection Legislation. If a Party provides the other Party with any business contact information of its employees and sub-contractors in connection with the Agreement (including without limitation, the identities of the relevant individuals, their contact information, and their role and their responsibilities), each Party shall comply with their notification obligations under the Data Protection Legislation.

34 LIMITATION OF LIABILITY

34.1 Neither Party limits its liability for:

(a) death or personal injury caused by its negligence, or that of its employees, agents or sub-contractors (as applicable);

(b) fraud or fraudulent misrepresentation by it or its employees;

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

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

34.2 Subject to Clause 34.1 and Clause 30.8, neither Party, nor their respective Affiliates, nor any of its or their respective directors, officers, employees or agents shall be liable to the other Party, nor its Affiliates, nor any of its or their respective directors, officers, employees or agents under or in relation to this Agreement for any:

(a) loss of savings or anticipated savings;

(b) loss of goodwill;

(c) indirect or consequential loss or damage (including, to the extent indirect or consequential, loss of profit, loss of revenue, loss of business or loss of business opportunities); or

(d) punitive or exemplary damages.

34.3 The Manufacturer's aggregate liability in respect of:

(a) the indemnity in Clause 18.3 shall [redacted]

(b) any Losses or claims relating to any loss or damage caused to the Approved Elective Materials shall be [redacted]

(c) subject to Clause 34.1, Clause 34.2, Clause 34.3(a) and Clause 34.4, the Manufacturer's aggregate liability in respect of all other Losses or claims under or in connection with this Agreement [redacted]

(i) [redacted]

(ii) [redacted]

(iii) [redacted]

34.4 Subject to Clause 34.1, the Manufacturer shall not be liable to the Authority for:

(a) any Losses to the extent such Losses arise as a result of the Manufacturer acting on the instruction of the Authority (whether pursuant to Clause 30 (Measures in Crisis) or otherwise), [redacted]

(i) [redacted]

(ii) [redacted]

(b) any Losses that arise as a result of the negligence, wilful misconduct or breach by the Authority of its obligations under this Agreement; or

(c) any Loss incurred by the Authority or any of its Affiliates to the extent that the Loss has been recovered by the Authority or any of its Affiliates, or has been or is made good or is otherwise compensated for without cost to the Authority or any of its Affiliates.

34.5 Subject to Clause 34.1, and excluding the Authority's obligations to pay the Manufacturer the Base Fee, any other amounts payable in accordance with Schedule 5 (Price, Payment and Invoicing), Schedule 6, Schedule 7, Clause 12.3 or Clause 30.7, the Authority's aggregate liability in respect of:

(a) the indemnities in Clause 30.8(b)(ii) shall be subject to the limit set out in Clause 30.8(b)(ii)(B)5); and

(b) subject to Clause 34.2 and Clause 34.5(a), all other Losses or claims under or in connection with this Agreement shall in no event exceed [redacted]

34.6 Each Party acknowledges and agrees that:

(a) the provision of the Services is a critical aspect of the Authority's response to COVID-19;

(b) similar services would not be readily available to the Authority as a replacement to the Services in the event of a failure by the Manufacture to perform the Agreement;

(c) the Authority may have urgent requirements in the national interest to ensure that the Services are delivered in accordance with this Agreement;

(d) without prejudice to any other rights or remedies that the Authority may have, damages alone would not be an adequate remedy for breach by the Manufacturer of the provisions of this Agreement; and

(e) that accordingly, the Authority shall be entitled to the remedies of injunction, specific performance or other equitable relief for breach by the Manufacturer of the provisions of this Agreement.

34.7 For the avoidance of doubt, neither Party shall be liable to the other Party under this Agreement for, and neither Party is making warranties or representations in relation to, the quality, safety, efficacy or fitness for their intended use of the Products or the Bulk Vaccine. The Parties acknowledge and agree that the Vaccine Manufacturer shall hold the Product Licence and shall be responsible for the quality, safety, efficacy and

compliance of the Product and the Bulk Vaccine with the conditions of any Product Licence and that the Vaccine Manufacturer shall be liable for any Third Party claims relating to such issues in accordance with the terms of the MSA.

34.8 The Parties acknowledge and agree that where the Authority takes on as obligations under this Agreement some of the roles and responsibilities normally held by a Vaccine Manufacturer under an MSA, the Parties shall agree any appropriate changes required to this Clause 34 to reflect the respective liabilities of each Party to the other in accordance with the Change Control Procedure.

35 INDEMNITIES

35.1 [redacted]

35.2 The procedure for claiming under any indemnity under this Agreement shall be as follows:

(a) if any person (the "**Indemnified Party**") receives a claim or demand in respect of a matter which is the subject of an indemnity in its favour under this Agreement (a "**Claim**") it shall give the Party obliged to indemnify it (the "**Indemnifying Party**") notice thereof as soon as reasonably practicable specifying the nature of the Claim;

(b) the Indemnifying Party shall have the right to undertake the defence of any such Claim with legal counsel of its choice. The Indemnified Party shall cooperate in such defence and, at its expense, shall make available all records, materials and witnesses reasonably requested by the Indemnifying Party in connection with such Claim; and

(c) if the Indemnifying Party assumes the defence of a Claim:

(i) the Indemnifying Party shall not be liable to the Indemnified Party for any legal or other expenses subsequently incurred by the Indemnified Party in connection with the defence of such Claim;

(ii) the Indemnifying Party shall keep the Indemnified Party informed of, and shall from time to time consult with the Indemnified Party regarding the status of, any proceedings and shall provide to the Indemnified Party

copies of all documents filed in, and written communications relating to, any such proceedings, provided that the Indemnifying Party shall not be obliged to do anything that it has been advised by external counsel would amount to a waiver of legal privilege in any information;

(iii) the Indemnifying Party shall obtain the written consent of the Indemnified Party (such consent not to be unreasonably withheld) prior to ceasing to defend, settling or otherwise disposing of any Claim if, as a result thereof, the Indemnified Party:

(A) would become subject to injunctive or other equitable relief; or

(B) may reasonably object to such disposition of such Claim based on a material adverse effect on the Indemnified Party (including any anticipated adverse effect on the Indemnified Party's goodwill or reputation); and

(iv) the Indemnifying Party shall not be liable for any Claim settled by the Indemnified Party without its consent.

35.3 A Party shall be required to mitigate any Loss in respect of which it is the Indemnified Party.

35.4 [redacted]

36 INSURANCE

36.1 The Manufacturer shall take out, and maintain for the duration of the Term, insurance policies to the value sufficient to meet its liabilities under or in connection with this Agreement including, without limitation:

(a) insurance in respect of any Elective Materials which have been provided or procured at the Authority's cost against loss or damage due to fire, flood, theft and such other risks as appropriate for the relevant replacement values at all times whilst risk in such Elective Materials remains with the Manufacturer; and

(b) any other insurances as may be required by Law.

36.2 The Manufacturer shall procure that the Authority is notified promptly upon any material change to, or cancellation of, any such insurance.

36.3 Upon the Authority's request the Manufacturer will provide the Authority with written evidence that the insurance referred under Clause 36.1 is in place.

36.4 Without prejudice to the Manufacturer's obligations under Clauses 36.1, 36.2 and 36.3, prior to entry into this Agreement the Manufacturer notified the Authority of its insurance policies and the Authority acknowledges that the policies and cover levels as notified were sufficient to meet the Manufacturer's liabilities under or in connection with the Agreement.

37 PREVENTION OF FRAUD AND BRIBERY

37.1 The Manufacturer represents and warrants that neither it, nor to the best of its knowledge any of the Manufacturer's personnel, have at any time prior to the date of the Agreement:

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

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

37.2 The Manufacturer shall not during the term of this Agreement:

(a) commit a Prohibited Act; and/or

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

37.3 The Manufacturer shall during the term of this Agreement:

(a) establish, maintain and enforce, and use commercially reasonable endeavours to require that its sub-contractors under this Agreement establish, maintain and enforce, policies and procedures which are adequate to ensure compliance with the Relevant Requirements and prevent the occurrence of a Prohibited Act;

(b) have in place reasonable prevention measures (as defined in sections 45(3) and 46(4) of the Criminal Finance Act 2017) to ensure that Associated Persons of the Manufacturer do not commit tax evasion facilitation offences as defined under that Act;

(c) keep appropriate records of its compliance with its obligations under Clause 37.3(a) and make such records available to the Authority on request; and

(d) take account of any guidance about preventing facilitation of tax evasion offences which may be published and updated in accordance with Section 47 of the Criminal Finances Act 2017.

37.4 The Manufacturer shall immediately notify the Authority in writing if it becomes aware of any breach of Clause 37.1 and/or 37.2, or has reason to believe that it has or any of the Manufacturer's personnel have:

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

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

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

37.5 If the Manufacturer makes a notification to the Authority pursuant to Clause 37.4, the Manufacturer shall respond promptly to the Authority's enquiries, co-operate with any investigation, and allow the Authority to audit any books, records and/or any other relevant documentation in accordance with Schedule 4 (Financial Reports, Records and Audit Rights).

37.6 If the Manufacturer breaches Clauses 37.1 and/or 37.2 the Authority may by notice:

(a) require the Manufacturer to remove from performance of this Agreement any Manufacturer Personnel whose acts or omissions have caused the breach; or

(b) immediately terminate this Agreement.

37.7 Any notice served by the Authority under Clause 37.6 shall specify the nature of the Prohibited Act, the identity of the Party who the Authority believes has committed the Prohibited Act and the action that the Authority has elected to take (including, where relevant, the date on which this Agreement shall terminate).

38 TERM AND TERMINATION

38.1 This Agreement shall come into force on the date of the Agreement and shall remain in full force and effect until the End Date unless terminated earlier in accordance with its terms (the "**Term**").

38.2 Without prejudice to its other rights and remedies, either Party may, by written notice to the other Party, terminate this Agreement immediately if:

(a) that other Party commits a material breach of this Agreement and, where such breach is capable of remedy, fails to remedy the same within thirty (30) calendar days after receipt of a written notice from the terminating Party giving particulars of the breach and requiring it to be remedied; or

(b) a Force Majeure Event endures for a continuous period of more than ninety (90) calendar days.

38.3 Events which shall constitute a material breach of this Agreement include, but are not limited to, a breach by the Manufacturer of:

(a) Clause 3.3 (Agreed Purpose);

(b) Clause 6.2 (Manufacturer's Obligations);

(c) Clause 37 (Prevention of Fraud and Bribery);

(d) Clause 6.1(f) where such breach gives rise to a right for the Vaccine Manufacturer to terminate the MSA; and

38.4 Without prejudice to its other rights and remedies, the Authority may terminate this Agreement:

(a) immediately by written notice to the Manufacturer if there is a change of Control of the Manufacturer, where "Control" has the meaning given in the definition of "Affiliate";

(b) immediately by written notice to the Manufacturer if any step, application, order, proceeding or appointment is taken or made by or in respect of the Manufacturer for a distress, execution, composition or arrangement with creditors, winding up, dissolution, administration, receivership (administrative or otherwise) or bankruptcy, of if the Manufacturer is unable to pay its debts or if any event occurs which, under the applicable law of any jurisdiction to which it is subject, has an effect similar to that of any of the events referred to in this Clause 38.4(b); or

(c) without cause by giving at least six (6) months' written notice to the Manufacturer, such notice not to be served until after 1 February 2021 (such that such right to terminate without cause cannot take effect until, at the earliest, after 1 August 2021).

39 CONSEQUENCES OF EXPIRY OR TERMINATION

39.1 If this Agreement is terminated by the Authority pursuant to Clause 38.4(c) then the Base Fee payable for the Residual Period shall be payable in advance of the Residual Period and calculated on a pro-rata basis in accordance with paragraph 1.6 of Schedule 5 (Price, Payment and Invoicing).

39.2 If this Agreement is terminated by either Party pursuant to Clause 38.2(b) then the Manufacturer shall reimburse the Authority on a pro-rata basis for any portion of the Base Fee which has been paid by the Authority but relates to a period after the date of termination.

39.3 If this Agreement is terminated by the Authority pursuant to Clause 38.2(a), 38.4(a) or 38.4(b) then the Manufacturer shall reimburse the Authority on a pro-rata basis for any portion of the Base Fee which has been paid by the Authority but relates to a period after the date of termination.

39.4 If this Agreement is terminated by the Manufacturer pursuant to Clause 38.2(a);

(a) prior to 1 August 2021, then the Authority shall pay the Manufacturer the balance of the Base Fee that but for the termination would have been payable by the Authority in the first twelve (12) months from 1 August 2020 in accordance with Schedule 5 (Price, Payment and Invoicing); or

(b) on or after 1 August 2021, then the Authority shall pay the Manufacturer the Base Fee that but for the termination would have been payable by the Authority after the date of termination up to the End Date in accordance with Schedule 5 (Price, Payment and Invoicing).

39.5 Upon termination of this Agreement, the following shall apply:

(a) in relation to any Materials for which the Authority has paid under this Agreement and which are held by the Manufacturer as at the date of termination:

(i) on demand from the Authority, the Manufacturer shall notify the Authority in writing of the quantity and description of any such Materials; and

either:

(A) the Authority may take possession without charge of any such Materials; or

(B) if the Manufacturer wishes to purchase, and the Authority wishes to sell such Materials, a sale may be agreed provided the sale price reflects a fair and reasonable market rate;

(b) the Parties shall comply with the provisions of Schedule 5 (Price, Payment and Invoicing) in relation to the calculation of any Final Reconciliation Payment; and

(c) the Parties shall comply with the provisions of Schedule 6 (Modification Works and Remediation Works) in relation to any Remediation Works and any equipment paid for by the Authority under this Agreement which the Manufacturer wishes to purchase and retain after the Term.

40 SURVIVAL

40.1 The expiry or termination of this Agreement shall not release either Party from any liability or right of action which at the time of expiry or termination has already accrued to such Party or which may thereafter accrue in respect of any act or omission prior to such expiry or termination. Such rights shall include recovery of any monies due under this Agreement.

40.2 The expiry or termination of this Agreement shall not affect the coming into force or continuation in force of any provision hereof which is expressly or by implication intended to come into force or continue in force on or after such expiry or termination.

40.3 Without prejudice to the generality of Clause 40.2, the provisions of the following Clauses shall survive the expiry or termination of this Agreement:

(a) Clause 10.2 (Remediation Works);

(b) Clause 11 (Intellectual Property);

(c) Clause 18 (Price, Payment and Taxation)

(d) Clause 20 (Financial Reports, Records and Audit Rights);

(e) Clause 27 (Confidentiality);

(f) Clause 28 (Transparency);

(g) Clause 29 (Freedom of Information);

(h) Clause 30.8 (Measures in a Crisis);

(i) Clause 33 (Data Protection);

(j) Clause 34 (Limitation of Liability);

(k) Clause 35 (Indemnities);

(l) Clause 39 (Consequences of Expiry or Termination);

(m) Clause 40 (Survival);

(n) Clause 41 (Notices);

(o) Clause 45 (Third Party Rights);

(p) Clause 46 (Entire Agreement);

(q) Clause 47 (Severance);

(r) Clause 54 (Set Off);

(s) Clause 55 (Dispute Resolution Procedure);

(t) Clause 56 (Governing Law and Jurisdiction);

(u) Schedule 4 (Financial Reports, Records and Audit Rights);

(v) Schedule 5 (Price, Payment and Invoicing); and

(w) Paragraph 3 of Schedule 6 (Modification Works and Remediation Works).

41 NOTICES

41.1 A notice given under or in connection with this Agreement shall be:

(a) in writing in the English language and signed by or on behalf of the Party giving the notice;

(b) sent for the attention of the person and to the address given in this Clause 41 (as amended from time to time) and:

(i) delivered by hand;

(ii) delivered by commercial courier;

(iii) sent by email and marked "Notice", dispatched as a PDF attachment to the specified email address without any error message; or

(iv) sent by pre-paid first-class recorded delivery post in the country in which the recipient's address is located (or such other next Business Day postal delivery service in that country).

41.2 The addresses for service of notice are:

(a) in the case of the Authority:

Contact: [redacted]

Address: Department of Business, Energy & Industrial Strategy, 1 Victoria Street, London SW1H 0ET

Email: [redacted]

For the attention of: [redacted]

(b) in the case of the Manufacturer:

Contact: [redacted]

Address: C P Pharmaceuticals Limited, Ash Road (North), Wrexham Industrial Estate, Wrexham, Clwyd LL13 9UF

Email: [redacted]

For the attention of: [redacted]

With copies to:

Contact: [redacted]

Address: Wockhardt Limited, Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India

Email: [redacted]

For the attention of: [redacted]

And:

Contact: [redacted]

Address: [redacted]

Email: [redacted]

For the attention of: [redacted]

41.3 A Party may change the details recorded for it in this Clause 41 by notice to the other Party (in accordance with this Clause 41). Such change shall take effect one (1) Business Day after that notice is deemed received pursuant to Clause 41.4.

41.4 Unless proved otherwise and subject to Clause 41.5, a notice is deemed to have been received:

(a) if delivered by hand, at the time of delivery;

(b) if delivered by commercial courier, at the time of signature of the courier's receipt;

(c) if sent by email, two (2) hours from the time (in the United Kingdom) of transmission provided no error message is received; or

(d) if sent by pre-paid first class recorded delivery post or other next Business Day delivery service, seventy two (72) hours from the date of posting or at the time recorded by the delivery service.

41.5 If deemed receipt under the previous paragraph of this clause is not within business hours in the place of deemed receipt (meaning 9.00 am to 5.30 pm local time in the place of receipt Monday to Friday on a day that is a Business Day), the notice will be deemed received at the start of business hours on the next Business Day in the place of receipt.

41.6 This Clause 41 does not apply to the service of any proceedings or other documents in any legal action or where, applicable, any arbitration or other method of dispute resolution.

42 RELATIONSHIP OF THE PARTIES

Nothing in the Agreement shall create or be construed as creating a partnership, joint venture, a contract of employment or relationship of employer and employee, or a relationship of principal and agent between the Authority and the Manufacturer. Save where expressly stated in this Agreement, neither Party is authorised to incur any expenditure or cost for the other Party or any of its Affiliates without the written consent of that other Party.

43 ASSIGNMENT AND NOVATION

43.1 The Manufacturer shall not assign, novate or otherwise dispose of or create any trust in relation to any or all of its rights, obligations or liabilities under this Agreement without the prior written consent of the Authority. Subject to compliance with applicable Law, nothing in this Clause 43.1 shall prevent the Manufacturer from making payments to, or receiving payments from, its Affiliates in the ordinary course of business.

43.2 The Authority may at its discretion assign, novate or otherwise dispose of any or all of its rights, obligations and liabilities under this Agreement and/or any associated licences to:

(a) any Central Government Body; or

(b) to a public sector body other than a Central Government Body which performs any of the functions that previously had been performed by the Authority in relation to this Agreement,

and the Manufacturer shall, at the Authority's request, enter into a novation agreement in such form as the Authority shall reasonably specify in order to enable the Authority to exercise its rights pursuant to this Clause 43.2.

43.3 A change in the legal status of the Authority such that it ceases to be a Central Government Body shall not affect the validity of this Agreement and this Agreement shall be binding on any successor body to the Authority.

44 SUB-CONTRACTORS

44.1 The Manufacturer shall not, without the prior written consent of the Authority, sub-contract the performance of any of its obligations under this Agreement to any other person.

44.2 If the Authority consents to any sub-contracting pursuant to Clause 44.1, the Manufacturer shall remain liable to the Authority for the performance of all such obligations and for any act or omission under this Agreement of the person to whom such obligations are sub-contracted.

44.3 The Authority may sub-contract the performance of any of its obligations under this Agreement to any Affiliate without the prior written consent of the Manufacturer, provided that the Authority shall remain liable to the Manufacturer for the performance of all its obligations and for any act or omission under this Agreement of such sub-contractor.

45 THIRD PARTY RIGHTS

45.1 This Agreement shall not, either expressly or by implication, confer any benefit on any person who is not a Party to the Agreement and accordingly the Contracts (Rights of Third Parties) Act 1999 shall not apply.

46 ENTIRE AGREEMENT

46.1 Subject to Clause 46.2, the Agreement constitutes the entire agreement and understanding between the Parties and supersedes all prior written and oral representations, agreements or understandings between them relating to the subject matter of the Contract, including the:

(a) Letter of Intent entered into between the Parties dated 21 May 2020; and

(b) Heads of Terms entered into between the Parties dated 19 June 2020 (which Heads of Terms the Parties hereby agree is terminated and shall cease to have effect).

46.2 Neither Party excludes liability for fraudulent misrepresentations upon which the other Party has relied.

47 SEVERANCE

47.1 If any Clause or provision of the Agreement not being of a fundamental nature is held to be unlawful, invalid or unenforceable by a court or any other competent body in any proceedings relating to the Agreement, the validity or enforceability of the remainder of the Agreement shall not be affected. If the court finds invalid a provision so fundamental as to prevent the accomplishment of the purpose of the Agreement, the Parties shall immediately commence negotiations in good faith to remedy the invalidity.

48 NON-DISCRIMINATION

48.1 The Manufacturer shall not unlawfully discriminate within the meaning and scope of the anti-discrimination legislation within the UK in relation to the supply of the Products or otherwise and shall take all reasonable steps to ensure that no Manufacturer personnel unlawfully discriminate.

49 DISABILITY EQUALITY SCHEME

49.1 The Authority is subject to the Disability Discrimination Act 1995 as amended by the Disability Discrimination Act 2005. The Authority has published a Disability Equality Scheme, which is set out on the Authority's website. The Manufacturer shall, and shall procure that its sub-Manufacturers, agents and personnel, comply with both the Disability Discrimination Act 1995 as amended by the Disability Discrimination Act 2005 and the Authority's Disability Equality Scheme.

49.2 Upon the Manufacturer breaching either the applicable Law or the Authority's Disability Equality Scheme the Authority shall be entitled to terminate the Agreement with immediate effect by notice in writing to the Manufacturer and without prejudice to any other rights or remedies of either Party in respect of the breach concerned or any other breach of the Agreement.

50 RACE EQUALITY SCHEME

50.1 The Authority is subject to the Race Relations (Amendment) Act 2000. The Authority has published a Race Equality Scheme, which is set out on the Authority's website. The Manufacturer shall, and shall procure that its sub-contractors, agents and personnel, comply with both the Race Relations (Amendment) Act 2000 and the Authority's Race Equality Scheme. Upon the Manufacturer breaching either the applicable Law or the Authority's Race Equality Scheme, the Authority shall be entitled to terminate the Agreement with immediate effect by notice in writing to the Manufacturer and without prejudice to any other rights or remedies of either party in respect of the breach concerned or any other breach of the Agreement.

51 SUSTAINABLE PROCUREMENT

51.1 The Manufacturer shall comply in all material respects with all applicable environmental laws and regulations in force from time to time in relation to the Products and their supply. Without prejudice to the generality of the foregoing, the Manufacturer shall promptly provide all such information regarding the environmental impact of the Products and the supply of the Products as may reasonably be requested by the Authority.

51.2 The Manufacturer shall meet all reasonable requests by the Authority for information evidencing compliance with the provisions of this Clause 51 by the Manufacturer.

51.3 As far as practicable, all written outputs, including reports, produced in connection with the Agreement shall (unless otherwise specified) be produced on recycled paper containing at least eighty per cent (80%) post-consumer waste and used on both sides where appropriate.

52 WAIVER

52.1 The failure by either Party to exercise any right or remedy shall not constitute a waiver of that right or remedy.

52.2 No waiver shall be effective unless it is communicated to the other Party in writing.

52.3 A waiver of any right or remedy arising from a breach of the Agreement shall not constitute a waiver of any right or remedy arising from any other breach of the Agreement.

53 COUNTERPARTS

53.1 This Agreement may be entered into in the form of two or more counterparts, each executed by one or more of the Parties, but will not be effective until all Parties have executed and delivered at least one counterpart. Each counterpart will be an original of this Agreement and all the counterparts taken together will constitute one instrument.

53.2 Transmission of the executed signature page of a counterpart of this Agreement by means of a facsimile machine or electronic transmission (including PDF or other agreed format) shall be treated in all manner and respects as delivery of an original executed counterpart of this Agreement and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. If either method of delivery is adopted, without prejudice to the validity of the agreement thus made, each Party shall deliver the original hard copy counterpart to the other on request.

54 SET OFF

54.1 Whenever under the Agreement any sum of money shall be recoverable from or payable by the Manufacturer, such sum may be deducted from any amount then due, or which at

any time thereafter may become due, to the Manufacturer under this Agreement or any other agreement or arrangement with the Authority or with any other department, agency or office of Her Majesty's Government.

54.2 Any over-payment by the Authority to the Manufacturer whether in respect of the charges or VAT shall be a sum of money recoverable from the Manufacturer pursuant to 54.1 or otherwise.

55 DISPUTE RESOLUTION PROCEDURE

55.1 The Parties shall attempt in good faith to negotiate a settlement to any dispute between them arising out of or in connection with the Agreement.

55.2 If the Parties cannot resolve the dispute pursuant to Clause 55.1, the dispute may, by agreement between the Parties, be referred to mediation pursuant to Clause 55.4.

55.3 The supply of the Services shall not cease or be delayed by the reference of a dispute to mediation pursuant to Clause 55.2.

55.4 If the Parties agree to refer the dispute to mediation:

(a) in order to determine the person who shall mediate the dispute (the "**Mediator**") the Parties shall by agreement choose a neutral adviser or mediator from one of the dispute resolution providers listed by the Government Procurement Service on its website or in its printed guidance on dispute resolution within thirty (30) days after agreeing to refer the dispute to mediation;

(b) the Parties shall within fourteen (14) calendar days of the appointment of the Mediator meet with him in order to agree a programme for the exchange of all relevant information and the structure to be adopted for negotiations to be held. If considered appropriate, the Parties may at any stage seek assistance from Government Procurement Service to provide guidance on a suitable procedure;

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

(d) if the Parties reach agreement on the resolution of the dispute within sixty (60) calendar days of the Mediator being appointed, or such longer period as may be agreed between the Parties, the agreement shall be reduced to writing and shall be binding on the Parties once it is signed by both the Authority and the Manufacturer;

(e) failing agreement within sixty (60) calendar days of the Mediator being appointed, or such longer period as may be agreed between the Parties, either of the Parties

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

55.5 If the Parties do not agree to refer the dispute to mediation, or if the Parties fail to reach agreement as to who shall mediate the dispute pursuant to Clause 55.4(a) or if they fail to reach agreement in the structured negotiations within sixty (60) calendar days of the Mediator being appointed or such longer period as may be agreed by the Parties, then any dispute or difference between them may be referred to the courts.

56 GOVERNING LAW AND JURISDICTION

56.1 The Agreement shall be governed by and construed in accordance with English Law.

56.2 Subject to Clause 55 (Disputes), the Parties agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (whether contractual or non-contractual) that arises out of or in connection with this Agreement or its subject matter or formation.

IN WITNESS of which each Party has caused this Agreement to be duly executed by its duly authorised representative in a manner binding upon it on the day and year first before written.

SIGNED on behalf of the **DEPARTMENT FOR BUSINESS, ENERGY AND INDUSTRIAL STRATEGY**:

Signed: [redacted]

Print Name: [redacted]

Position: [redacted]

SIGNED on behalf of **CP PHAR[redacted]S LIMITED**:

Signed: [redacted]

Print Name: [redacted]

Position: [redacted]

Schedule 1

Statement of Requirements

1 The Authority requires and the Manufacturer shall provide the reservation of the Manufacturer's combination filling line and associated capabilities in order to provide the Services as set out in this Schedule 1.

2 The Authority also requires the Manufacturer to comply with Clauses 3 (Agreed Purpose) and 4 (Agreements with Vaccine Manufacturers) in relation to the use of the Reserved Capacity for the Agreed Purpose.

3 The Services consist of:

(a) the reservation of the Reserved Capacity for the Authority subject to and in accordance with the terms of this Agreement; and

(b) the Manufacturer's maintenance for the Authority at all times during the Term of:

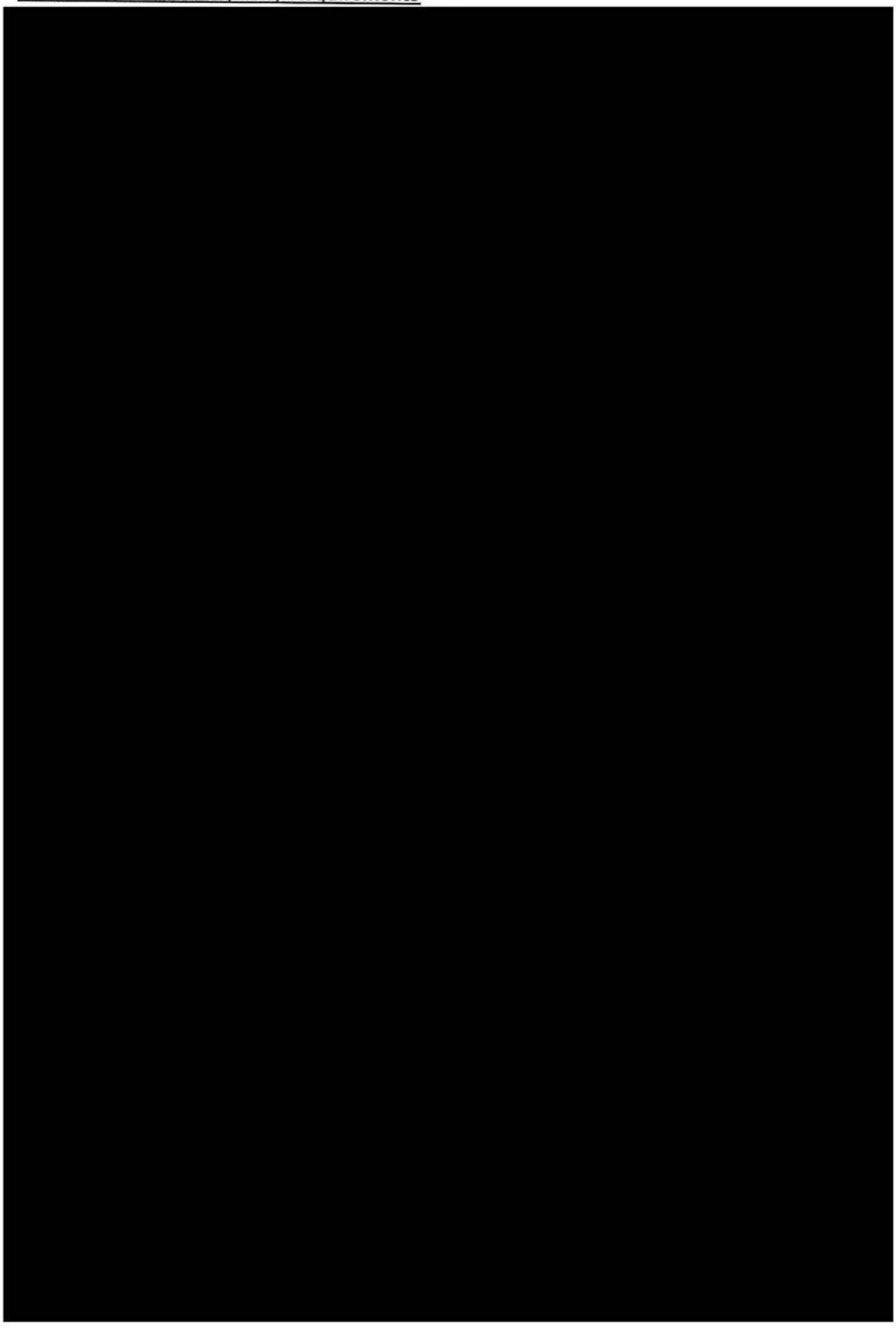
(i) the capability (regardless of the requirements or any agreed outputs under an MSA, which the Parties agree may be different from the requirements of this Schedule 1) of the equipment comprising the Reserved Capacity, and of the other equipment, plant and facilities in the Manufacturing Site, to:

(A) comply with the requirements of the MHRA (but in respect of the Reserved Capacity, only after 17 August 2020) and any other Regulator such that such equipment is capable of being used for the sterile filling of prepared and supplied Bulk Vaccine and/or therapeutics for supply in the United Kingdom;

(B) meet the criteria identified in respect of such equipment or Manufacturing Site in Column A and the relevant requirements in Column B (subject to any assumptions listed in Column C) in Table 1 below, in each case, as further elaborated in the detailed description of the relevant requirement as set out below Table A in relation to each of the criteria in Column A; and

(ii) sufficient staff levels to meet the criteria in respect of such staff levels identified in Column A and the relevant requirements in Column B (subject to any assumptions listed in Column C) in Table 1 below, in each case, as further elaborated in the detailed description of the relevant requirement as set out below Table A in relation to each of the criteria in Column A.

Table 1 – Reserved Capacity Requirements



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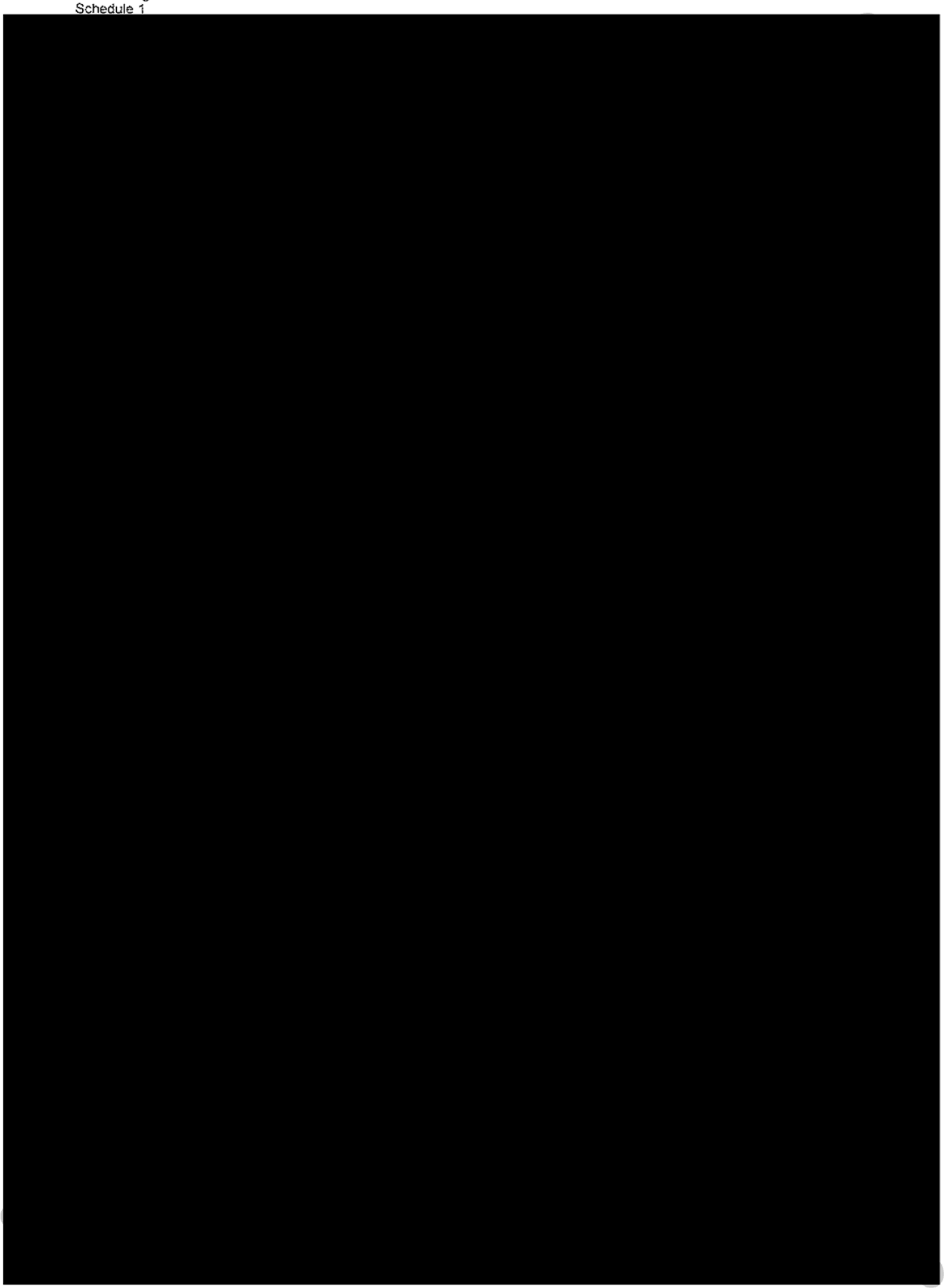

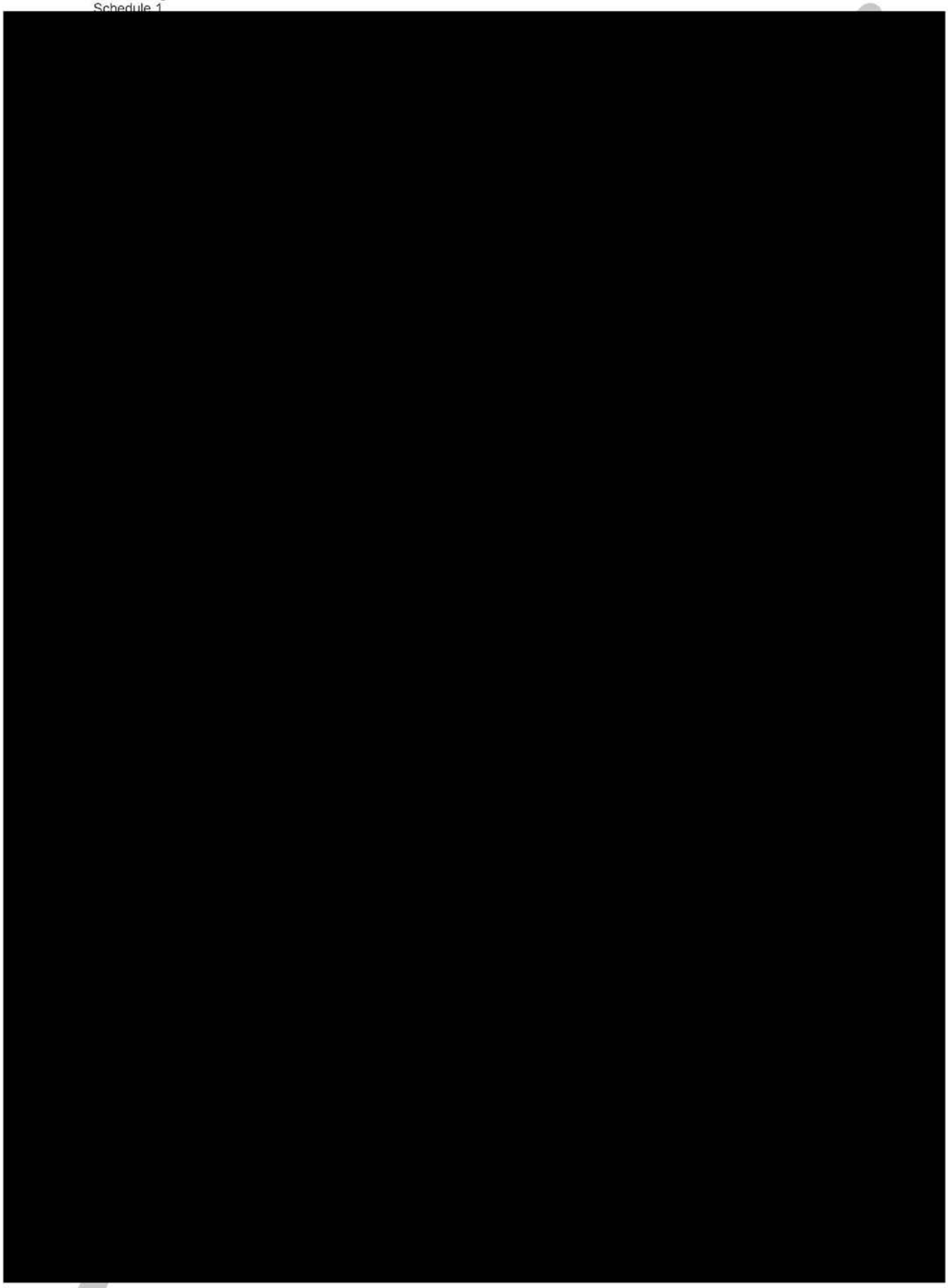

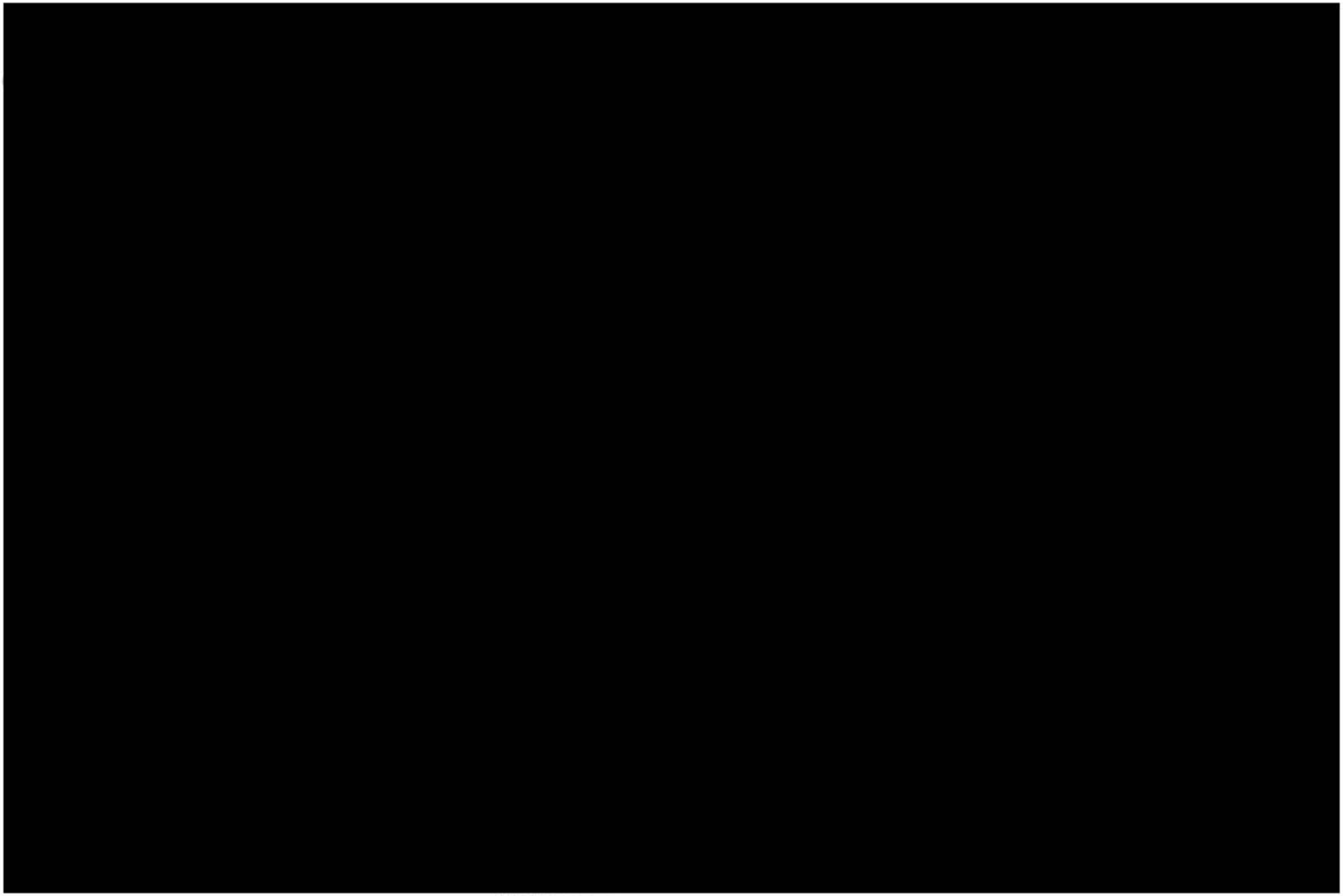

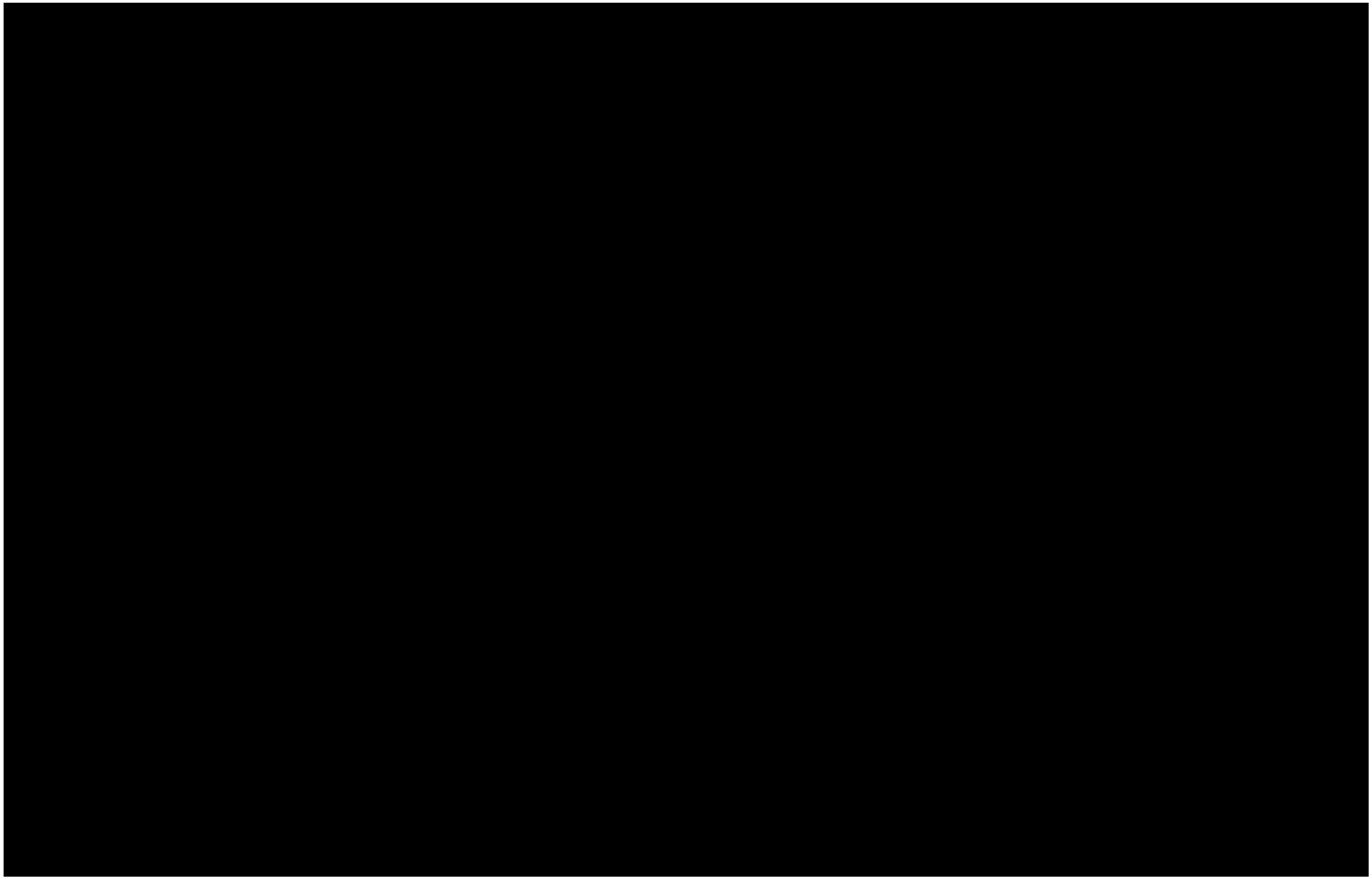

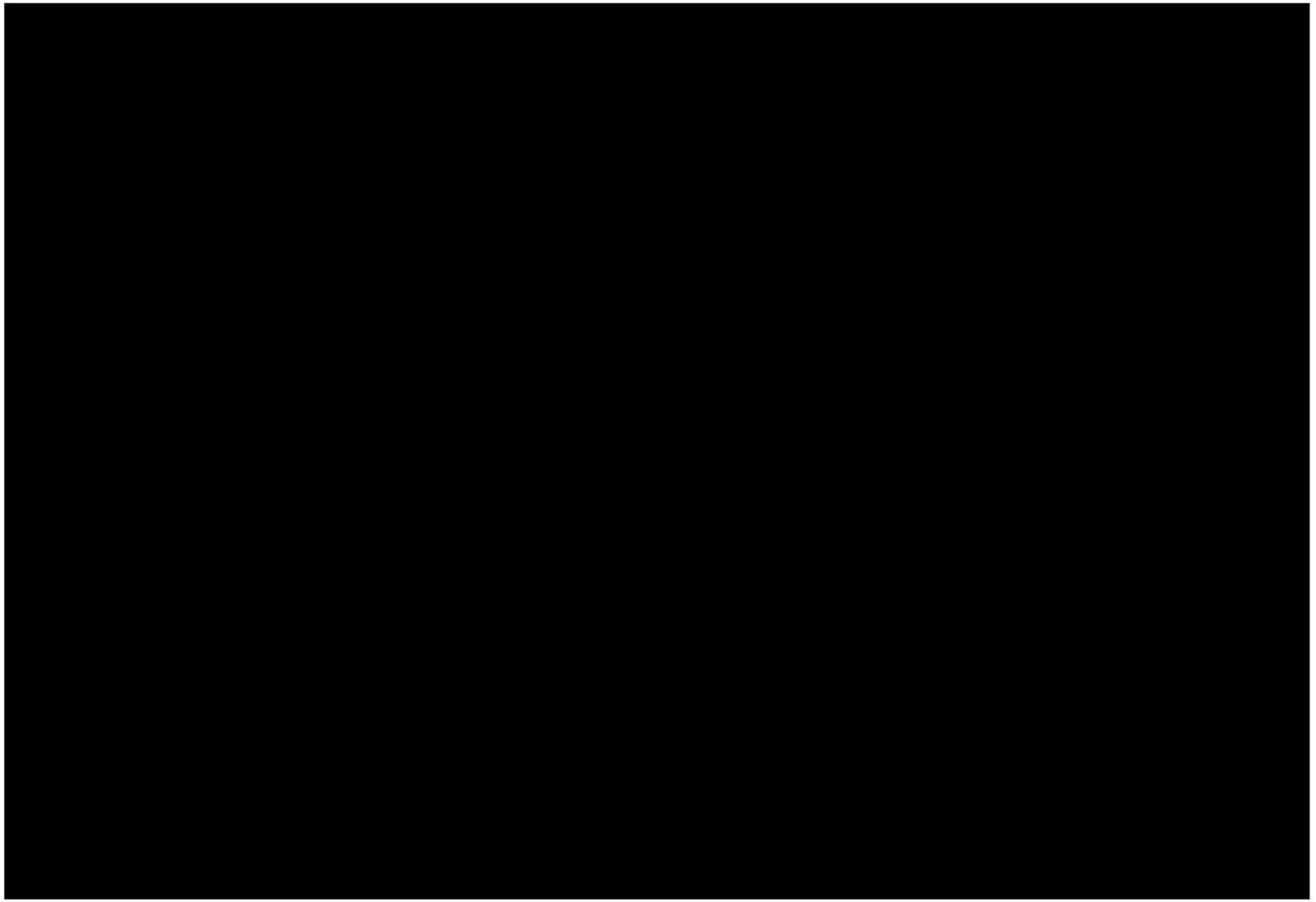

Schedule 3

Performance

1 Performance Levels and Reporting Requirements

1.1 Subject to paragraph 4.1, the Manufacturer shall:

(a) provide the Services in such a manner so as to meet or exceed the monthly Target Performance Level for each KPI; and

(b) comply with the provisions of paragraph 2 in relation to the monitoring and reporting on its performance against the KPIs.

1.2 The Authority acknowledges that the Target Performance Levels for each KPI have been accepted by the Manufacturer on the basis of the assumptions contained in the Statement of Requirements and information currently available from the Authority and a prospective Vaccine Manufacturer as of the date of this Agreement, and as such may need to be revised if such Target Performance Levels are manifestly unsuitable or not reasonably achievable by the Manufacturer owing to changes in the requirements or specifications for the Services, and the Parties agree to discuss any such revisions in good faith.

2 Performance Monitoring and Performance Review

Performance Monitoring Report

2.1 As part of the Utilisation Report submitted to the Authority within 5 Business Days after the end of each calendar month pursuant to Clause 15.3, the Manufacturer shall include a section summarising the performance by the Manufacturer against each of the KPIs, in such format as agreed between the Parties from time to time and containing, as a minimum, the following information (the "**Performance Monitoring Report**"):

Information in respect of the calendar month just ended

(a) for each KPI the actual performance achieved over the calendar month, and that achieved over the previous 3 calendar months;

(b) a summary of all KPI Failures that occurred during the calendar month;

(c) which KPI Failures remain outstanding and progress in resolving them;

(d) for any KPI Failures, actions taken to resolve the underlying cause and prevent recurrence;

(e) whether any Material KPI Failures occurred during the calendar month, the cause of the relevant failure and the action being taken to reduce the likelihood of recurrence;

(f) the status of any outstanding Rectification Plan processes, including:

(i) whether or not a Rectification Plan has been agreed; and

(ii) where a Rectification Plan has been agreed, a summary of the Manufacturer's progress in implementing that Rectification Plan;

(g) the Service Credits to be applied;

(h) relevant particulars of any impacts on the delivery of the Services as a result of any KPI Failures and/or Material KPI Failures;

(i) such other details as the Authority may reasonably require from time to time;

Information in respect of previous calendar months

(j) a rolling total of the number of KPI Failures that have occurred since the beginning of the Term;

(k) the total amount of Service Credits that have been incurred by the Manufacturer since the beginning of the Term;

Information in respect of the next three months

(l) any scheduled Planned Maintenance in the coming three months.

Performance Review Meeting

2.2 Where requested by the Authority, the Parties shall attend a meeting (held by teleconference or videoconference unless otherwise agreed) to review the Performance Monitoring Report ("**Performance Review Meeting**").

2.3 Performance Review Meetings shall (unless otherwise agreed) take place within 5 Business Days of the request to meet being issued by the Authority.

3 Performance Records

3.1 The Manufacturer shall provide to the Authority such supporting documentation as the Authority may reasonably require in order to verify the level of the performance of the Manufacturer and the calculations of the amount of Service Credits for any specified period.

3.2 The Manufacturer shall ensure that the Performance Monitoring Report and any other document or record reasonably required by the Authority are available to the Authority on the Virtual Library in accordance with the terms of this Agreement.

4 Time periods during which KPIs shall apply

4.1 The KPIs set out in this Schedule 3 shall only apply during the period indicated in the "Period of Application" column in the table at Appendix 1.

Time period during which Availability KPI shall apply

4.2 Subject to paragraph 4.3, the Manufacturer shall be deemed to have met the Target Performance Level for the Availability KPI (and accordingly there shall be no KPI Failures or Service Credits in relation to the Availability KPIs) during the term of any MSA entered into in accordance with Clause 4 (Agreements with Vaccine Manufacturers).

4.3 Where the Authority's consent is sought to extend the term of an MSA, then paragraph 4.2 shall not apply (such that the Manufacturer shall not automatically be deemed to have met the Target Performance Level for the Availability KPI solely as a result of the continuance of the term of such MSA) during the term of any extension to the MSA, to the extent that such extension is required as a result of the Reserved Capacity not being Available during the original term of the MSA due to:

(a) a breach of the MSA by the Manufacturer; or

(b) negligence on the part of the Manufacturer,

but not, for the avoidance of doubt, due to any breach of the MSA by any Vaccine Manufacturer, any negligence on the part of any Vaccine Manufacturer, or any failure by a Vaccine Manufacturer to deliver on time any Bulk Vaccine. Notwithstanding anything to the contrary under this Agreement, no Service Credit shall be applied under any circumstances if the Manufacturer cannot meet the Target Performance Level for the Availability KPI as a result of any breach of the MSA by any Vaccine Manufacturer, any negligence on the part of any Vaccine Manufacturer, or any failure by a Vaccine Manufacturer to deliver on time any Bulk Vaccine.

4.4 The Manufacturer shall solely be required to measure, meet and report performance against the Availability KPI during the Term from 17 August 2020 onwards and solely where:

(a) an MSA is not in place; and

(b) during the term of any extension to an MSA which meets the requirements of paragraph 4.3.

4.5 Where a Material KPI Failure occurs in respect of the Availability KPI, the Parties acknowledge and agree that this shall be a material breach of this Agreement.

5 KPIs

5.1 Appendix 1 sets out the KPIs which the Parties have agreed shall be used to measure the performance of the Services by the Manufacturer.

6 KPI Failure

6.1 If a KPI Failure occurs in any calendar month then:

(a) the Manufacturer shall notify the Authority in the relevant Performance Monitoring Report of the action (if any) it will take to rectify the KPI Failure and/or prevent the KPI Failure from recurring in accordance with paragraph 2; and

(b) if such KPI Failure is in relation to the Availability KPI, then paragraph 9 shall apply.

7 Material KPI Failure

7.1 If the Manufacturer's performance of the Services results in:

(a) a score (without a Valid Reason and calculated in accordance with the table at Appendix 1) of less than [redacted] against the Availability KPI in any calendar month;

(b) the number of KPI Failures equalling [redacted] in any calendar month;

(c) a KPI Failure against the same KPI in any [redacted] calendar months across a [redacted] calendar month period;

then this shall constitute a "**Material KPI Failure**".

7.2 If a Material KPI Failure occurs then the Manufacturer shall comply with paragraph 8.

8 Rectification Plan Process

8.1 Where a Material KPI Failure occurs, the Authority shall request a Performance Review Meeting to discuss with the Manufacturer:

(a) the impact of the Material KPI Failure on the delivery of the Services;

(b) the reasons for the Material KPI Failure and what actions can be taken to mitigate and minimise the risk of any future performance failure against the relevant KPIs; and

(c) whether a Rectification Plan is required in relation to the Material KPI Failure.

8.2 Where the Authority determines, in its sole discretion, that a Rectification Plan is required in relation to the Material KPI Failure:

(a) the Parties shall make all reasonable endeavours at the Performance Review Meeting held pursuant to paragraph 8.1 to agree the actions to be taken to rectify the Material KPI Failure; and

(b) within 5 Business Days after the Performance Review Meeting, the Manufacturer shall submit a "**Draft Rectification Plan**" to the Authority detailing:

(i) the actions to be carried out by the Manufacturer to mitigate and minimise the risk of any future performance failure against the relevant KPIs;

(ii) a named individual responsible for implementing each action; and

(iii) the date by which each action shall be completed.

8.3 Within 5 Business Days of receipt of the Draft Rectification Plan the Authority shall either:

(a) notify the Manufacturer that the Draft Rectification Plan is accepted by the Authority; or

(b) notify the Manufacturer of the amendments that it requires to be incorporated into the Draft Rectification Plan.

8.4 If the Authority fails to notify the Manufacturer in accordance with paragraph 8.3 then the Authority shall be deemed to have accepted the Draft Rectification Plan.

8.5 Within 5 Business Days of receiving any proposed amendments to the Draft Rectification Plan pursuant to paragraph 8.3, the Manufacturer shall either:

(a) notify the Authority that its amendments have been accepted; or

(b) discuss what changes to any proposed amendments would be required for the Manufacturer to accept the amendments and the Parties shall make reasonable endeavours to agree such changes.

8.6 Where the Parties are not able to agree the Rectification Plan, the matter shall be referred to senior representatives of the Parties as soon as reasonably practicable for resolution. If these representatives cannot resolve the issue within 10 Business Days then the matter shall be referred to the Dispute Resolution Procedure.

8.7 If the Manufacturer fails to notify the Authority in accordance with paragraph 8.5 then the Manufacturer shall be deemed to have accepted the proposed amendments.

8.8 Where the Draft Rectification Plan is agreed or determined pursuant to paragraphs 8.3 to 8.7 it shall become the "**Rectification Plan**".

8.9 The Manufacturer shall comply with the Rectification Plan and implement it as soon as reasonably practicable in order to meet the agreed dates for completing the agreed actions.

Rectification Plan Failure Notice Stage

8.10 If the Manufacturer fails without a Valid Reason to implement a Rectification Plan in accordance with paragraph 8.9 then the Authority may issue a Rectification Plan Failure Notice to the Manufacturer in accordance with paragraph 8.11.

8.11 A Rectification Plan Failure Notice served on the Manufacturer shall:

(a) specify that it is a Rectification Plan Failure Notice; and

(b) specify which agreed actions in the Rectification Plan have not been completed by the agreed date.

8.12 Where the Manufacturer fails to complete the agreed action which is the subject of a Rectification Plan Failure Notice within 10 Business Days of receipt of the Rectification Plan Failure Notice, then the Parties acknowledge and agree that this shall constitute a material breach of this Agreement.

9 Service Credits

9.1 Where a KPI Failure occurs in relation to the Availability KPI, a Service Credit shall be applied in accordance with the table at Appendix 1.

For example:

[redacted]

[redacted]

9.2 [redacted]

(a) [redacted]

(b) [redacted]

9.3 [redacted]

9.4 [redacted]

(a) [redacted]

(b) [redacted]

9.5 [redacted]

(a) [redacted]

(b) [redacted]

9.6 [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

9.7 [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

[redacted]

9.8 [redacted]

10 [redacted]

10.1 [redacted]

(a) [redacted]

(b) [redacted]

(c) [redacted]

[redacted]

10.2 [redacted]

11 [redacted]

11.1 [redacted]

[redacted]

11.2 [redacted]

12 Calendar month

12.1 Save in respect of the definitions of "Relevant Monthly Availability Period" or otherwise in connection with the Availability KPI (which shall only be calculated and measured from 17 August 2020 to 31 August 2020, and then for each calendar month onwards), references to "calendar months" throughout this Schedule 3 shall be read as "part calendar months" if the beginning and/or end of Service delivery does not align with calendar months.

Appendix 1

KPIs

KPI	Measure	Target Performance Level	Service Credit applicable	Frequency of Reporting	Period of Application
CAPACITY					
Availability	% Availability	[redacted]	[redacted]	Monthly	From 17 August 2020, subject to and as set out at paragraphs 4.2 to 4.4
Reporting	Accuracy and punctuality of Utilisation Report	[redacted]	[redacted]	Monthly	After the Effective Date throughout the remainder of the Term
QUALITY					

KPI	Measure	Target Performance Level	Service Credit applicable	Frequency of Reporting	Period of Application
MHRA major observations	Resolution of major observations related to sterile injectable manufacturing and other areas related to the Reserved Capacity	[redacted]	[redacted]	Monthly	After the Effective Date and throughout the remainder of the Term
Quality Systems: Deviations	Resolution of deviations / OOS	[redacted]	[redacted]	Monthly	After the Effective Date throughout the remainder of the Term
Quality Systems: Non-Conformance	Critical non-conformance impacting sterility	[redacted]	[redacted]	Monthly	After the Effective Date throughout the remainder of the Term
TURN AROUND					
Change over	Average time between batches for cleaning and set up	[redacted]	[redacted]	Monthly	Solely during the term of any MSA entered into in accordance Clause 4

KPI	Measure	Target Performance Level	Service Credit applicable	Frequency of Reporting	Period of Application
Quality release cycle time	Time from batch completion to COC (certification of conformance)	[redacted]	[redacted]	Monthly	Solely during the term of any MSA entered into in accordance Clause 4

Schedule 4

Financial Reports, Records and Audit Rights

1 FINANCIAL TRANSPARENCY OBJECTIVES

1.1 The Manufacturer acknowledges that the provisions of this Schedule are designed (inter alia) to facilitate, and the Manufacturer shall co-operate with the Authority in order to achieve, the following objectives:

(a) for the Authority to understand any payment sought from it by the Manufacturer including an analysis of any Modification Work Cost, Remediation Work Costs, payment for Materials and any other costs for which the Authority is responsible for paying incurred by the Manufacturer in providing the Services, bearing in mind the Authority's obligation to ensure any costs to be paid for by the Authority are:

(i) expected to be incurred in the conduct of delivering the Agreement, able to withstand public scrutiny and which can be supported by sufficient justification on the basis that the inclusion of the cost should be fair and equitable ("**Appropriate**");

(ii) incurred directly or indirectly by the Manufacturer for the fulfilment of the Agreement and necessary to fulfil the requirements of the Agreement, and applied to the Agreement on a basis that is consistent with the Manufacturer's overarching cost accounting practices and not able to be recovered in any way from another contract, whether past, existing or proposed ("**Attributable**"); and

(iii) by their nature do not exceed what might be expected to be incurred in the normal delivery of the Agreement, whether under competitive tendering conditions or as a single source contract, and indicators of this include, but are not limited to:

(A) empirical evidence, where this is possible;

(B) whether the cost is consistent with any available sector/market benchmarks;

(C) whether the quantum of the cost is consistent with good business practice; and

(D) whether the costs deliver value for money for the UK taxpayer,

("**Reasonable**");

(b) for both Parties to be able to review, address issues with and re-forecast progress in relation to the provision of the Services;

(c) for the Parties to challenge each other with ideas for efficiency and improvements; and

(d) to enable the Authority to demonstrate that it is achieving value for money for the tax payer relative to current market prices,

(together the "**Financial Transparency Objectives**").

2 OPEN BOOK DATA

2.1 The Manufacturer acknowledges the importance to the Authority of the Financial Transparency Objectives and the Authority's need for complete transparency in the way in which the payments under the Agreement are calculated.

2.2 During the Term, and for a period of seven (7) years following the end of the Term, the Manufacturer shall:

(a) maintain and retain the Open Book Data; and

(b) disclose and allow the Authority and/or the Audit Agents access to the Open Book Data.

3 PROVISION OF THE FINANCIAL REPORTS

3.1 The Manufacturer shall provide during the Term the following financial reports to the Authority, in the frequency specified below:

Financial Report	When to be provided
Quarterly Contract Report	Within 1 month of the end of each Contract Quarter
Annual Contract Report	Within 1 month of the end of the first 12 months of the Term to which that report relates
Final Reconciliation Report	Within 3 months after the end of the Term

3.2 Each Financial Report shall:

(a) be completed by the Manufacturer using reasonable skill and care;

(b) include details of all costs and payments under this Agreement during the relevant period;

(c) include details of any costs, payments, invoices, orders and deliveries in relation to any MSA during the relevant period;

(d) incorporate and use the same defined terms as are used in this Agreement;

(e) quote all monetary values in pounds sterling;

(f) quote all costs as exclusive of any VAT; and

(g) quote all costs and payments based on prices approved in accordance with the Agreement.

3.3 Each Annual Contract Report and the Final Reconciliation Report shall be certified by the Manufacturer's chief financial officer or director of finance (or equivalent as agreed in writing by the Authority in advance of issue of the relevant Financial Report), acting with express authority, as:

(a) being accurate and not misleading;

(b) having been prepared in conformity with generally accepted accounting principles within the United Kingdom;

(c) being a true and fair reflection of the information included within the Manufacturer's management and statutory accounts; and

(d) compliant with the requirements of Paragraph 3.2.

3.4 During the Term, and for a period of eighteen (18) months following the end of the Term, the Manufacturer shall make available the Financial Representative at reasonable times and on reasonable notice to answer any queries that the Authority may have on any of the Financial Reports and/or Open Book Data.

3.5 If the Manufacturer becomes aware of the occurrence, or the likelihood of the future occurrence, of an event (other than any event that is the subject of the measures in Clause 30 (Measures in a Crisis) of the Agreement) which will or may have a material effect on the following:

(a) the costs incurred (or those forecast to be incurred) by the Manufacturer; and/or

(b) the forecast payments for the remainder of the Term, the Manufacturer shall, as soon as practicable, notify the Authority in writing of the event in question detailing the actual or anticipated effect. For the avoidance of doubt, notifications

provided in accordance with this Paragraph 3.5 shall not have the effect of amending any provisions of this Agreement.

4 DISCUSSION OF QUARTERLY CONTRACT REPORTS AND FINAL RECONCILIATION REPORT

4.1 Following the delivery by the Manufacturer of each Quarterly Contract Report, the Parties shall meet to discuss its contents within ten (10) Business Days of receipt (or such other period as the Parties shall agree). The Financial Representative shall attend the meeting.

4.2 Following the delivery by the Manufacturer of the Final Reconciliation Report, the Parties shall meet to discuss its contents within twenty (20) Business Days of receipt (or such other period as the Parties shall agree). The Financial Representative shall attend the meeting.

5 AUDIT RIGHTS

5.1 The Authority, acting by itself or its Affiliates, shall have the right during the Term and for a period of 18 months thereafter, to assess compliance by the Manufacturer with its obligations under this Agreement, including for the following purposes:

(a) to verify the integrity and content of any Financial Report;

(b) to verify the accuracy of the payments and any other amounts payable by the Authority under this Agreement (and proposed or actual variations to such costs and payments), including that such costs are Appropriate, Attributable and Reasonable;

(c) to verify the accuracy of the payments and any other amounts payable by the Vaccine Manufacturer to the Manufacturer in relation to the use of the Reserved Capacity (and proposed or actual variations to such costs and payments), including that such costs are Appropriate, Attributable and Reasonable in relation to the supply of goods and services to the Vaccine Manufacturer;

(d) to verify the Open Book Data;

(e) to verify the Manufacturer's compliance with this Agreement and applicable Law;

(f) to conduct an environment, health, safety and sustainability audit of the Manufacturer to monitor Manufacturer's compliance with applicable environmental laws and regulations;

(g) to identify or investigate actual or suspected fraud, impropriety or accounting mistakes or any breach or threatened breach of security and in these

circumstances the Authority shall have no obligation to inform the Manufacturer of the purpose or objective of its investigations;

(h) to identify or investigate any circumstances which may impact upon the financial stability of the Manufacturer or its ability to perform the Services;

(i) to obtain such information as is necessary to fulfil the Authority's obligations to supply information for parliamentary, ministerial, judicial or administrative purposes including the supply of information to the Comptroller and Auditor General;

(j) to review any books of account and the internal contract management accounts kept by the Manufacturer in connection with this Agreement;

(k) to carry out the Authority's internal and statutory audits and to prepare, examine and/or certify the Authority's annual and interim reports and accounts;

(l) to enable the National Audit Office to carry out an examination pursuant to Section 6(1) of the National Audit Act 1983 of the economy, efficiency and effectiveness with which the Authority has used its resources;

(m) to verify the accuracy and completeness of any management information delivered or required by this Agreement;

(n) to review any performance monitoring reports and/or other records relating to the Manufacturer's performance of the Services and to verify that these reflect the Manufacturer's own internal reports and records; and/or

(o) to review the Manufacturer's compliance with the Statement of Requirements.

5.2 Except where an audit is imposed on the Authority by a regulatory body or where the Authority has reasonable grounds for believing that the Manufacturer has materially breached its obligations under this Agreement, the Authority may not conduct an audit of the Manufacturer more than twice in any twelve (12) month period during the Term.

5.3 Nothing in this Agreement shall prevent or restrict the rights of the Comptroller and/or Auditor General and/or their representatives from carrying out an audit, examination or investigation of the Manufacturer and/or any of the authorised sub-contractors for the purposes of and pursuant to applicable Law.

6 CONDUCT OF AUDITS

6.1 The Authority shall during each audit comply with the reasonable security, sites, systems and facilities operating procedures of the Manufacturer and ensure that the conduct of

each audit does not unreasonably disrupt the Manufacturer or delay the provision of the Services.

6.2 Subject to the Authority's obligations of confidentiality, the Manufacturer shall on demand provide the Authority and the Audit Agents with all reasonable co-operation and assistance in relation to each audit, including:

(a) all information requested by the Authority within the permitted scope of the audit; and

(b) reasonable access to any sites and to any equipment used (whether exclusively or non-exclusively) in the performance of the Services, which shall take place during the normal business hours of the Manufacturer on a Business Day.

6.3 The Authority shall provide reasonable notice of its intention to conduct an audit, which, except where an audit is imposed on the Authority by a regulatory body or where the Authority has reasonable grounds for believing that the Manufacturer has not complied with its obligations under this Agreement, shall be no less than ten (10) Business Days.

6.4 Each audit shall be of a reasonable duration in relation to the issues being assessed, which subject to:

(a) the Manufacturer's compliance with its obligations under this Schedule; and

(b) no material breach of the Agreement by the Manufacturer being identified in the course of the audit,

is envisaged to be no longer than twenty (20) Business Days.

6.5 The Parties agree that they shall bear their own respective costs and expenses incurred in respect of compliance with any audit under this Schedule 4, unless the audit identifies a material breach of the Agreement by the Manufacturer in which case the Manufacturer shall reimburse the Authority for all the Authority's reasonable costs incurred in connection with the audit.

7 RESPONSE TO AUDITS

7.1 If an audit undertaken pursuant to this Schedule identifies that:

(a) the Manufacturer has committed a breach of the Agreement, the Authority may (without prejudice to any rights and remedies the Authority may have) require the Manufacturer to correct such breach as soon as reasonably practicable;

(b) there is an error in a Financial Report, the Manufacturer shall promptly rectify the error;

(c) the Authority has overpaid any payments, the Manufacturer shall pay to the Authority:

(i) the amount overpaid; and

(ii) solely to the extent that such overpayment has resulted from a miscalculation or fault of the Manufacturer, interest on the amount overpaid at the rate of two per cent (2%) above the base rate of Barclays Bank PLC for the time being in force, accruing on a daily basis from the date of overpayment by the Authority up to the date of repayment by the Manufacturer;

(d) the Authority has underpaid any payments, the Authority shall pay to the Manufacturer:

(i) the amount underpaid; and

(ii) solely to the extent that such overpayment has resulted from a miscalculation or fault of the Authority, interest on the amount overpaid at the rate of two per cent (2%) above the base rate of Barclays Bank PLC for the time being in force, accruing on a daily basis from the date of underpayment by the Authority up to the date of repayment by the Authority.

8 RECORDS

8.1 The Manufacturer shall retain and maintain all the records (including superseded records) referred to in Appendix 1 to this Schedule (together "**Records**"):

(a) in accordance with the requirements of The National Archives and Good Industry Practice; and

(b) in chronological order;

(c) in a form that is capable of audit; and

(d) at its own expense.

8.2 The Manufacturer shall make the Records available for inspection to the Authority on request, subject to the Authority giving reasonable notice.

8.3 The Manufacturer shall, during the Term and a period of at least seven (7) years following the expiry or termination of this Agreement, maintain or cause to be maintained complete and accurate documents and records in relation to the provision of the Services including but not limited to all Records.

9 VIRTUAL LIBRARY

9.1 The Authority shall, no later than twenty (20) Business Days after the date of the Agreement and without charge to the Manufacturer, create a Virtual Library on which the Manufacturer shall (subject to any applicable legislation governing the use or processing of personal data) make information about this Agreement available in accordance with the requirements outlined in this Schedule.

9.2 The Manufacturer shall upload complete and accurate information specified in Appendix 1 (Records) to this Schedule by the date required under the Agreement onto the Virtual Library.

9.3 Upon any document being uploaded to the Virtual Library, the Manufacturer shall email on the same date as the upload, a copy of the document to the nominated Authority email address at:

9.4 Except for notices under Clause 41 (Notices), where the Manufacturer is under an obligation to provide information to the Authority in a provision under this Agreement, then the Manufacturer's upload of that information onto the Virtual Library shall satisfy the Manufacturer's obligation to provide the Authority with that information provided that the Authority has access in accordance with this paragraph 9 and the uploaded information meets the requirements more particularly specified in the relevant provision.

9.5 In order to maintain the integrity of the historical archive of the information and documentation and for the purposes of maintaining a clear audit trail, the Manufacturer shall not delete or overwrite any information that has been stored in the Virtual Library, except for the purposes of maintenance (provided no information is lost during maintenance) or to enable the Manufacturer to comply with Data Protection Legislation.

9.6 The Manufacturer shall use commercially reasonable endeavours to ensure that the information uploaded to the Virtual Library is accurate, complete, up-to-date and in accordance with this Agreement at the date of upload.

9.7 Where the Manufacturer becomes aware that any of the information provided on the Virtual Library is materially inaccurate, incomplete or out of date (other than in respect of historical versions of documents) the Manufacturer shall provide an update to the information within 14 calendar days.

9.8 For the avoidance of doubt, the cost of any redactions, access restrictions or compliance with the Data Protection Legislation in respect of the information hosted on the Virtual Library shall be at the Manufacturer's own cost and expense.

Appendix 1

Records

1 This Agreement, its Schedules and all amendments to such documents.

2 All other documents which this Agreement expressly requires to be prepared in connection with the provision of the Services or the Manufacturer's obligations under this Agreement, including but not limited to any:

(a) Financial Reports;

(b) Demand Forecast Report;

(c) CCN and any other document prepared pursuant to the Change Control Procedure;

(d) Utilisation Report;

(e) Performance Monitoring Report;

(f) documents prepared by the Manufacturer in support of claims for payment;

(g) copies of consent given by the Authority relating to agreements between the Manufacturer and any Vaccine Manufacturer;

(h) invoices and records related to VAT sought to be recovered by the Manufacturer;

(i) records required to be retained by the Manufacturer by applicable Law, including in relation to health and safety matters, in each case that are material in connection with the provision of the Services or the Manufacturer's obligations under the Agreement;

(j) documents relating to the insurances to be maintained under this Agreement and any claims made in respect of them;

(k) formal notices, reports or submissions made by the Manufacturer to the Authority in connection with the provision of the Services; and

(l) certificates, licences or registrations from any Administrative Entity in each case obtained by the Manufacturer in relation to the provision of the Services.

Schedule 5

Price, Payment and Invoicing

1 BASE FEE

1.1 In consideration for the Manufacturer's provision of the Services, the Authority shall pay the Manufacturer the Base Fee.

1.2 The Parties recognise that in order for the Manufacturer to prepare to deliver the Services from the Effective Date and maintain a state of readiness throughout the Term, the Manufacturer will incur certain expenditure regardless of the volume of Product that is required by the Authority.

1.3 In order to allow the Manufacturer to undertake the activities contemplated by paragraph 1.2 the Authority shall pay the Manufacturer an annual fee of [redacted] (pro rata where expressly provided herein) in consideration for the Services for the duration of the Term (the "**Base Fee**").

1.4 The Base Fee shall operate as:

(a) a rental payment in consideration for the Reserved Capacity at the Manufacturing Site; and

(b) as a credit for Product Manufactured at the Reserved Capacity by the Manufacturer.

1.5 The Base Fee shall be payable from the Effective Date in equal instalments in advance of each Contract Quarter, save that the Base Fee payable for the first Contract Quarter (from 1 August 2020 to 31 October 2020) shall be payable upon the occurrence of the Effective Date.

Base fee payable if Agreement terminates early

1.6 For the avoidance of doubt:

(a) subject to paragraph 1.6(b) below, if the Agreement is terminated early in accordance with Clause 38 (Term and Termination) then the Base Fee for the period from the start of the final Contract Quarter until the termination date (which period might be shorter than a calendar quarter) (the "**Residual Period**") shall be payable in advance of the Residual Period and calculated on a pro-rata basis;

(b) if the Agreement is terminated early in accordance with Clause 38.2(a) due to a material breach by the Authority, then Clause 39.4 shall apply to determine the amount of any Base Fee payable.

For example: If the Agreement is due to terminate on 31 January 2022 for a reason that is not attributable to breach of the Agreement by the Authority, then the Authority would pay in advance of 1 January 2022 the pro-rated Base Fee for the thirty one (31) days from 1 January to 31 January 2022, being [redacted] (calculated as [redacted] 365 *31).

Product Conversion Fee

1.7 A set unit fee for each Product item that the Manufacturer may deliver shall be agreed with the Vaccine Manufacturer and shall reflect a fair and reasonable market rate.

1.8 Where the Product is the AZ Vaccine, the unit fee is envisaged to be [redacted] subject to the assumptions and qualifications in the Manufacturer's Proposal.

1.9 Additional costs that may arise in connection with services not contemplated as within the scope of the Services, as set out in the Statement of Requirements at the date of the Agreement, shall be borne by the Authority to the extent such additional services are requested by the Authority and the allocation of costs is agreed by the Parties in accordance with Clause 25 (Change Control).

1.10 In each Contract Quarter or Residual Period, the Base Fee available in respect of that Contract Quarter or Residual Period (which shall include the instalment of the Base Fee paid in respect of that Contract Quarter or Residual Period plus any surplus Base Fee rolled over from the previous Contract Quarter in accordance with paragraph 1.13) ("**Available Base Fee**") shall be used as credit to satisfy the value of invoices for Product which are issued to the Vaccine Manufacturer in respect of that Contract Quarter or Residual Period.

1.11 If the value of Product invoiced by the Manufacturer in respect of any given Contract Quarter or Residual Period ("**Quarter Product Value**") exceeds the Available Base Fee in respect of that Contract Quarter or Residual Period by a given amount (the "**Product Conversion Fee**"), then, subject to any agreement otherwise pursuant to paragraph 1.16 of this Schedule, the Vaccine Manufacturer shall pay this Product Conversion Fee to the Manufacturer in accordance with the terms of the MSA.

1.12 For the avoidance of doubt if the Quarter Product Value does not exceed the Available Base Fee in respect of that Contract Quarter or Residual Period, then:

(a) no Product Conversion Fee shall be payable to the Manufacturer for that period; and

(b) subject to any Service Credits calculated pursuant to Schedule 3 (Performance), the Manufacturer shall not be obliged to repay any of the Base Fee.

1.13 If in any Contract Quarter the Quarter Product Value is less than the Available Base Fee in respect of that Contract Quarter, any surplus Available Base Fee shall be rolled over as credit into the next Contract Quarter (or the Residual Period), thereby increasing the next Available Base Fee in respect of the next Contract Quarter (or Residual Period) by the amount of any surplus. There shall be no limit to the number of occasions or value of any surplus Available Base Fee which can be rolled over into the next Contract Quarter.

For example [redacted]

[redacted]

Final Reconciliation

1.14 At the end of the Term the Manufacturer and the Vaccine Manufacturer shall undertake a reconciliation in accordance with the terms of the MSA to ensure that:

(a) the Vaccine Manufacturer has paid for all Product provided by the Manufacturer; and

(b) the Vaccine Manufacturer has not overpaid for Products provided by the Manufacturer,

in accordance with the principles that:

(i) the Manufacturer shall always be paid and retain the higher of the Total Base Fee and the Total Product Value;

(ii) if the Total Product Value is lower than the Total Base Fee but, as a result of quarterly variation, the Vaccine Manufacturer has paid the Manufacturer some Product Conversion Fees (in addition to the full amount of the Total Base Fee), then the Manufacturer shall reimburse to the Vaccine Manufacturer the amount of such Product Conversion Fees; and

(iii) if the sum of the Total Base Fee and the Total Product Conversion Fee is greater than the Total Product Value, the Manufacturer shall reimburse to the Vaccine Manufacturer the amount by which the Total Product Value is less than the sum of the Total Base Fee and the Total Product Conversion Fee.

For example in relation to paragraph 1.14(b)(ii):

[redacted]

For example in relation to paragraph 1.14(b)(iii)

[redacted]

Contract Quarter	Product Value (£m)	Base Fee (£m)	Product Conversion Fee(£m)	Total payment to Manufacturer (£m)
[redacted]				

1.15 For the avoidance of doubt, subject to any Service Credits calculated pursuant to Schedule 3 (Performance), the Manufacturer shall always be paid at least an amount equal to the Total Base Fee by the Authority under this Agreement.

1.16 Where the Parties agree that the Authority shall pay the Product Conversion Fee to the Manufacturer, then the Authority shall pay the Product Conversion Fee to the Manufacturer and the Parties shall calculate and pay any final reconciliation payment in accordance with paragraphs 1.7 to 1.15 of this Schedule, provided that references to the Vaccine Manufacturer shall be read as references to the Authority.

Invoicing

1.17 The Manufacturer may submit invoices for:

(a) any instalment of the Base Fee no earlier than ten (10) Business Days before the start of each Contract Quarter (or in the case of the first instalment of the Base Fee, on or after the Effective Date); and

(b) all other items for which the Authority is obliged to pay pursuant to the Agreement, including Materials, Modification Work Costs and Remediation Work Costs, at times or intervals as agreed by the Authority in the Agreement or otherwise in due course after the relevant costs have been incurred.

1.18 The Manufacturer shall provide the Authority with a copy of any invoice it submits to the Vaccine Manufacturer under the MSA within five (5) Business Days of issuing any such invoice to the Vaccine Manufacturer.

1.19 The Manufacturer shall ensure that any invoice it submits sets out:

(a) in relation to copies of invoices submitted to a Vaccine Manufacturer:

(i) the name of the Vaccine Manufacturer;

(ii) the amount of Product delivered in the month to which the invoice relates;

(iii) the value of the Product delivered in the month to which the invoice relates;

(iv) the aggregate total of Product delivered in the Contract Quarter or Residual Period to which the invoice relates;

(v) the Available Base Fee in the Contract Quarter or Residual Period to which the invoice relates;

(vi) the calculation of any Product Conversion Fee payable by the Vaccine Manufacturer for the Contract Quarter or Residual Period to which the invoice relates, as calculated at the date of the invoice;

(b) in relation to any other invoices submitted to the Authority:

(i) the Authority's Purchase Order number;

(ii) the amount to be invoiced;

(iii) a description of the items.

1.20 In relation to invoices submitted to the Authority pursuant to paragraph 1.17, the Authority shall pay any undisputed amount after receiving a correctly submitted invoice as set out in paragraphs 1.17 and 1.19. Such payment shall be made within thirty (30) calendar days of receipt of the correctly submitted invoice.

1.21 Save as provided in Clause 30 (Measures in a Crisis) or otherwise expressly provided in this Agreement, the Manufacturer shall not be entitled to charge for the supply of any goods or services that are not part of the Services agreed within the Agreement, unless the Agreement has been properly varied in advance in accordance with the Change Control Procedure.

1.22 If the Manufacturer believes that payment for a correctly submitted invoice is overdue then the Manufacturer should, in the first instance, contact the Authority's representative identified at Clause 41 (Notices). If the problem is not resolved to the Manufacturer's satisfaction, the Manufacturer should write to the Head of Procurement at the Department for Business, Energy and Industrial Strategy setting out its case. The Head of Procurement shall ensure that the complaint is dealt with by an official who is independent of the main contact and that the Manufacturer is not treated adversely in future for having made a complaint.

1.23 For the purpose of calculating any statutory interest under the Late Payment of Commercial Debts (Interest) Act 1998, the relevant date for the payment of the debt (including, for the avoidance of doubt, any late payment of the Base Fee) shall be deemed to be the last day of a period of 30 calendar days commencing on the day when the Authority received the invoice.

Schedule 6

Modification Works and Remediation Works

1 MODIFICATION WORKS

1.1 Where it is agreed that the Authority shall bear the cost of Modification Works pursuant to Clause 9 (Modification Works), the Manufacturer shall:

(a) complete any project activity to modify the Manufacturing Site to handle mRNA or Adeno (BSL1) viral vectors (which for the avoidance of doubt shall not include modifications required to meet BSL2 requirements, which BSL2 requirements the Manufacturer shall not be required to meet under this Agreement under any circumstances) to the standard required to comply with any applicable Law or regulation, including in relation to GMO, GMP and health and safety, in each case to the extent applicable to the Manufacturer's performance of the Services (the "**Modification Works**");

(b) make reasonable endeavours to notify the Authority as soon as reasonably practicable, if the Manufacturer becomes aware, based on the information available to the Parties at the time regarding the Services, of any changes which need to be made to the forecast estimate of potential Modification Works which are set out in Appendix 1 (Forecast Estimate of Modification Works) to this Schedule 6 in order to provide a fair and reasonable estimate of the required Modification Works;

(c) before incurring any costs associated with any Modification Works, obtain the Authority's consent (such consent not to be unreasonably withheld or delayed, and which, subject to any suspension of deemed approval pursuant to paragraph 2.3, shall be deemed to be given if the costs are less than [redacted] to such works being undertaken, which shall require the Manufacturer to provide the Authority with the following information with sufficient notice to allow the Authority a reasonable time period, bearing in mind the cost, complexity and the Authority's prior knowledge of the relevant works, within which to review the information:

(i) a breakdown of the costs to be incurred in performing the relevant Modification Works;

(ii) such evidence as the Authority may require to satisfy the Authority that the relevant cost is Appropriate, Attributable and Reasonable; and

(iii) that the relevant Modification Works are being undertaken solely to facilitate the Manufacturer's performance of the Services;

(d) where the Manufacturer receives deemed approval for any Modification Works, provide the information required under paragraphs 1.1(c)(i) - 1.1(c)(iii) in relation to such Modification Works to the Authority as soon as reasonably practicable and in any event within ten (10) Business Days of incurring the relevant Modification Work Costs; and

(e) subject to paragraph 1.3, once the relevant Modification Work has been performed, provide a valid invoice to the Authority in relation to such works.

1.2 The Authority shall:

(a) subject to:

(i) paragraphs 1.3, 1.4 and 1.5 of this Schedule; and

(ii) the Manufacturer complying with its obligations at paragraphs 1.1(c), 1.1(d) and 1.1(e) of this Schedule;

pay the Manufacturer the approved Modification Work Costs (for the avoidance of doubt, if any portion of the Modification Work Costs are not agreed in accordance with paragraph 1.1 then only the undisputed portion of such costs shall be payable by the Authority);

1.3 Neither the Authority nor the Vaccine Manufacturer shall be liable for such portion of the aggregated Modification Work Costs agreed pursuant to this Schedule that is below [redacted] and such costs shall be borne by the Manufacturer. The Manufacturer shall ensure that any MSA that it enters into with a Vaccine Manufacturer shall provide for the same. For avoidance of doubt, any Modification Work Costs borne by the Manufacturer under this Agreement or any MSA shall be aggregated and count towards the threshold in the first sentence of this paragraph 1.3, which is a single threshold that only applies once in respect of aggregated Modification Work Costs arising under this Agreement and all MSAs collectively.

1.4 The Modification Work Costs payable by the Authority shall apply only:

(a) in respect of the Manufacturer's costs on a pass through basis and shall not include any element of a management fee or other margin for the benefit of the Manufacturer;

(b) in respect of the Manufacturer's Appropriate, Attributable and Reasonable costs (demonstrated in accordance with paragraph 1.1 of this Schedule); and

(c) where the Modification Work Costs are not being paid under a separate agreement with the Vaccine Manufacturer.

1.5 For the avoidance of doubt, where the Manufacturer enters into an agreement with the Vaccine Manufacturer whereby the Vaccine Manufacturer pays for all or part of any Modification Works to the Manufacturing Site, the Manufacturer shall not claim for, or be due any payments from the Authority, in respect of such Modification Works.

2 AUDIT AND REVIEW OF MODIFICATION WORK COSTS

2.1 At the end of each month, the Parties shall review the Modification Work Costs, including:

(a) any difference in value between the actual approved Modification Work Costs and the latest forecast of estimated Modification Work Costs;

(b) the number and type of Modification Works for which the Manufacturer has sought approval (or received deemed approval) which had not been previously notified to the Authority pursuant to paragraph 1.1(b) of this Schedule; and

(c) the number and value of Modification Work Costs which have received deemed approval in the relevant period and during the Term to date.

2.2 The Authority shall notify the Manufacturer if, following the review, it requires changes to the regime for approving and paying for Modification Works and the Parties shall meet as soon as reasonably practicable in order to work together in good faith to agree any such changes pursuant to the Change Control Procedure within ten (10) Business Days or such other period as is agreed between the Parties.

2.3 If the Parties are unable to agree changes to this Schedule within ten (10) Business Days of a request from the Authority, or are unable to agree a time period within which to agree such changes, pursuant to paragraph 2.2, the Authority may, in its absolute discretion, suspend the ability of the Manufacturer to receive deemed approval for Modification Works until such time as the Parties have agreed any changes to this Schedule in accordance with paragraph 2.2.

3 REMEDIATION WORKS

3.1 Where it is agreed that the Authority shall bear the cost of Remediation Works pursuant to Clause 10 (Remediation Works), the Manufacturer shall:

(a) subject to paragraph 3.2, procure any necessary Remediation Works;

(b) before incurring any costs associated with any Remediation Works, obtain the Authority's consent (such consent not to be unreasonably withheld or delayed) to such works being undertaken, which shall require the Manufacturer to provide the Authority with the following information with sufficient notice to allow the Authority a reasonable time period, bearing in mind the cost, complexity and the

Authority's prior knowledge of the relevant works, within which to review the information:

(i) a breakdown of the costs to be incurred in performing the relevant Remediation Works;

(ii) such evidence as the Authority may require to satisfy the Authority that the relevant cost is Appropriate, Attributable and Reasonable; and

(iii) that the relevant Remediation Works are being undertaken to restore the Manufacturing Site to the condition that it was in prior to the relevant Modification Works being carried out (and not in any superior condition);

(c) once the relevant Rectification Work has been performed, provide a valid invoice to the Authority in relation to such activity.

3.2 Before the end of the Term, the Parties shall review the Modification Works undertaken pursuant to this Schedule and identify whether any of the equipment (wholly or partially paid for by the Authority) installed in the Manufacturing Site serves to enhance the Manufacturing Site, enabling or going some way to enabling the Manufacturer to deliver services to other customers and the Manufacturer shall identify whether any equipment will be retained by the Manufacturer after the Term. Where the Parties intend for any such equipment to be retained by the Manufacturer, the Parties will obtain a valuation of the equipment before agreeing the terms (including price) of the sale or lease of the equipment from the Authority to the Manufacturer. If the Parties fail to agree terms, the Authority may choose to remove the equipment from the Manufacturing Site as part of the Remediation Works.

3.3 The Authority shall, subject to the Manufacturer complying with its obligations at paragraph 3.1, pay the Manufacturer the Remediation Work Costs (for the avoidance of doubt, if any portion of the Remediation Work Costs are not agreed in accordance with paragraph 3.1 then only the undisputed portion of such costs shall be payable by the Authority).

3.4 The Remediation Work Costs payable by the Authority shall apply only:

(a) in respect of the Manufacturer's costs on a pass through basis and shall not include any element of a management fee or other margin for the benefit of the Manufacturer;

(b) in respect of the Manufacturer's Appropriate, Attributable and Reasonable costs (demonstrated in accordance with paragraph 3.1(b)); and

(c) where the Remediation Work Costs are not being paid under a separate agreement with the Vaccine Manufacturer.

3.5 For the avoidance of doubt, where the Manufacturer enters into an agreement with the Vaccine Manufacturer whereby the Vaccine Manufacturer pays for all or part of any Remediation Works to the Manufacturing Site, the Manufacturer shall not claim for, or be due any payments from the Authority, in respect of such Remediation Works for which the Vaccine Manufacturer is obligated to pay.

Appendix 1

Forecast Estimate of Modification Works

Enabling Cost Component	Cost Estimate
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Total	[redacted]
Total incl. VAT	[redacted]

Schedule 7

Materials

Part A

Application of Schedule 7 (Materials)

1 For the avoidance of doubt, this Schedule 7 (Materials) shall only apply to the extent that the Parties agree pursuant to Clause 12 (Materials) that:

(a) Bulk Vaccine; or

(b) Elective Materials

are procured or provided by the Authority under this Agreement.

Part B

Bulk Vaccine

1 Provision of Bulk Vaccine

1.1 The Bulk Vaccine shall be provided by:

(a) the Vaccine Manufacturer pursuant to an MSA and Quality Agreement; or

(b) the Authority, subject to the terms of this Agreement being amended in accordance with Clause 6.1(d), (or such other agreement as the Parties may agree).

1.2 Further details regarding the Bulk Vaccine, including the delivery, transfer, risk, quality, inspection, testing, storage and use of the Bulk Vaccine shall be specified in the relevant agreements and amendments referred to at paragraph 1.1 of this Schedule 7 Part B.

Part C

Elective Materials

1 Manufacturer notifies the Authority of the need for Elective Materials

1.1 Where the Manufacturer requires Elective Materials to Manufacture the Products and the Manufacturer is unable to procure the relevant Materials required under the relevant MSA and Quality Agreement, the Manufacturer shall give notice to the Authority as soon as reasonably practicable, specifying:

(a) details of why the relevant Materials cannot be procured as specified under the relevant MSA;

(b) the type and volume of any Elective Materials required;

(c) the date by which the relevant Elective Materials would be required in order to meet any relevant forecasts for Manufacture of the Product;

(d) details of the supplier(s) from which the Manufacturer recommends, in accordance with Good Industry Practice and the requirements in the MSA and Quality Agreement, the Elective Materials should be procured as suitably qualified and technically able to provide the Elective Materials;

(e) details of the price payable for the Elective Materials and evidence that such prices are on reasonable market terms; and

(f) expected lead times for delivery of the Elective Materials.

2 Authority decides which Party should procure Elective Materials

2.1 Where the Manufacturer informs the Authority that Elective Materials are required in accordance with paragraph 1.1 of this Part C and the Authority agrees the relevant Materials shall be procured by the Authority, then the Authority shall, at its sole discretion, either:

(a) procure the Elective Materials and provide these to the Manufacturer at the Authority's cost; or

(b) as soon as reasonably practicable, and within a reasonable period in advance of the date on which the Manufacturer requires the relevant Elective Materials, instruct the Manufacturer to procure the Elective Materials at the Authority's cost.

3 Authority approval

3.1 Where the Authority instructs the Manufacturer to procure the Elective Materials in accordance with paragraph 2.1(b) of this Part C, the Authority shall provide the

Manufacturer with written notice confirming the relevant details provided by the Manufacturer under paragraph 1.1 of this Part C and notice shall be taken as the Authority's approval of the purchase of the Elective Materials by the Manufacturer.

3.2 Prior to entering into this Agreement the Authority approved the purchase by the Manufacturer of the Elective Materials set out at Appendix 1 (Approved Elective Materials) to this Schedule 7 (Materials).

4 Monthly reporting

4.1 The Manufacturer shall notify the Authority on a monthly basis of deliveries of Elective Materials received from third party suppliers.

5 Invoicing

5.1 The Manufacturer shall be entitled to invoice the Authority on a monthly basis for Elective Materials delivered to the Manufacturer which:

(a) the Manufacturer has:

(i) purchased in accordance with this Part C; and

(ii) tested, inspected and accepted in accordance with paragraph 10.1 of this Part C; and

(b) the Authority has approved under paragraphs 3.1 or 3.2 of this Part C.

6 Title

6.1 Title to the Elective Materials purchased pursuant to this Part C shall at all times remain with and vest in the Authority until such time as the Elective Materials are incorporated into a Product, at which time the title shall transfer to the party which owns the title in the Product.

7 Risk

7.1 Risk in the Elective Materials shall remain with the Manufacturer from the point when the Elective Materials are delivered to the Manufacturer until the Elective Materials are:

(a) incorporated into a Product, at which time risk shall pass to the party which holds risk in the Product; or

(b) collected by the Authority pursuant to Clause 39.5 on termination or expiry of this Agreement.

8 Insurance

8.1 The Manufacturer:

(a) shall insure all Elective Materials against loss or damage due to fire, flood, theft and such other risks as appropriate for the relevant replacement values at all times whilst risk in such Elective Materials remains with the Manufacturer; and

(b) shall only use the Elective Materials for the Manufacture and supply of Product under this Agreement.

9 Storage of Elective Materials

9.1 The Elective Materials procured under this Part C shall at all times be segregated from other goods and materials in the possession of the Manufacturer, and there must be systems in place to ensure the materials cannot be used for any purpose other than the agreed Services.

9.2 The Manufacturer shall do all such other acts and things at its own expense as the Authority may reasonably request to protect the Elective Materials procured under this Part C against any persons having claims against the Manufacturer.

9.3 The Manufacturer shall, upon the Authority giving reasonable notice, allow authorised representatives of the Authority access to the Manufacturing Site during normal business hours to inspect the Manufacturer's facilities, records and procedures relevant to the Elective Materials procured under this Part C in order to ascertain the Manufacturer's adherence to the requirements of this paragraph 9.

10 Evaluation of Elective Materials

10.1 In accordance with the requirements of the MSA and Quality Agreement, the Manufacturer shall be responsible for selecting and specifying all Elective Materials to ensure that they are Fit for Purpose and for testing the materials upon receipt to ensure that they comply with the specifications.

10.2 If the Elective Materials, upon testing, are deemed to be faulty or do not meet the specifications established in the purchase order, it is the responsibility of the Manufacturer to work with the supplier to resolve the situation.

10.3 If the Manufacturer determines following use in the Manufacture of the Products that the relevant Elective Materials are not Fit for Purpose and this is the result of failure of the Manufacture to either specify the correct Elective Materials as required per the MSA or comply with its obligations pursuant to paragraph 10.2 above, then if the relevant Elective Materials were procured by:

(a) the Manufacturer in accordance with paragraph 2.1(b) of this Part C, the Manufacturer shall rectify the relevant defects at its own cost;

(b) the Authority in accordance with paragraph 2.1(a) of this Part C, then paragraph 11 of this Part C shall apply.

11 Defective Elective Materials procured by the Authority

11.1 This paragraph 11 shall only apply to Elective Materials procured by the Authority in accordance with paragraph 2.1(a) of this Part C, not those Elective Materials procured by the Manufacturer.

11.2 The Manufacturer shall notify the Authority promptly in writing (and in any case within ten (10) Business Days after delivery) if, after having carried out the applicable evaluations (such as analysis, testing or use) of Elective Materials in accordance with paragraph 10.1 (or otherwise), the Manufacturer considers that any Elective Materials delivered are not Fit for Purpose, and shall provide evidence including copies of any relevant analysis records.

11.3 Upon the Authority receiving notification pursuant to paragraph 11.2, the Parties will use all reasonable endeavours to agree (each acting in good faith) whether or not the Elective Materials in question are compliant and:

(a) the Authority will be entitled to all information regarding the specification and selection rationale for the Elective Materials and at reasonable times to inspect and/or analyse the delivery in question if requested;

(b) the Manufacturer shall not use any of the Elective Materials in question in the Manufacture of Product until the matter has been resolved in accordance with this paragraph 11; and

(c) at the Manufacturer's request, the Authority shall deliver to the Manufacturer replacement Elective Materials as soon as practicable, using all reasonable endeavours to enable continuity of the Manufacturer's Manufacture of the relevant Products.

11.4 If the Parties do not agree on whether the Elective Materials in question are compliant under paragraph 11.3, the provisions of paragraphs 11.6 and 11.7 shall apply.

Consequences of Manufacturer failure to test Elective Materials

11.5 Where the Manufacturer fails:

(a) to correctly specify the Elective Materials in accordance with paragraph 10.1;

(b) to comply with its obligations pursuant to paragraph 10.2; or

(c) to notify the Authority of any alleged defect as required in accordance with paragraph 11.2;

and any such Elective Materials thereafter prove to be defective, the Manufacturer shall:

(i) bear the costs of replacement of such defective Elective Materials and any Products rendered defective as a result; and

(ii) at the Authority's option, take all necessary action (promptly and at its own expense), to rework, reprocess or destroy any:

(A) defective Elective Materials; or

(B) Products rendered defective because of such defective Elective Materials.

Resolution of disputes regarding alleged defects in Elective Materials

11.6 Without prejudice to Clause 55 (Dispute Resolution Procedure), the Parties shall use all reasonable endeavours to resolve any dispute that may arise pursuant to this paragraph 11. However, if within thirty (30) calendar days after being notified of delivery of Elective Materials deemed to be not Fit for Purpose the Parties fail to agree whether such Elective Materials are defective or may be rejected for any reason, then:

(a) in the case of a rejection for quality reasons, the dispute shall be determined by an Independent Laboratory and the decision of the Independent Laboratory shall be final and binding on the Parties. The Independent Laboratory shall act as an expert and not as an arbitrator and (unless the Independent Laboratory otherwise determines) its fees shall be borne by the Party against whom the Independent Laboratory's decision is given; and

(b) in the case of a rejection for any other reasons, the matter shall be resolved according to the dispute resolution procedure set out in Clause 55 (Dispute Resolution Procedure).

11.7 If the Independent Laboratory finds that the Manufacturer was not entitled to reject a delivery of Elective Materials in accordance with this paragraph 11, then the Manufacturer shall:

(a) proceed to use such Elective Materials in the Manufacture of Product; and

(b) reimburse the Authority for any reasonable costs associated with additional testing of the Elective Materials and for all other costs associated with expediting shipment and manufacture of replacement Elective Materials, that may have occurred pursuant to this paragraph 11.

11.8 If the Independent Laboratory finds that the Manufacturer was entitled to reject a delivery of Elective Materials in accordance with this paragraph 11 or if the Authority accepts that

the delivery of Elective Materials does not comply with the requirements of the Quality Agreement, any relevant specifications (including the Specifications), the Product Licence, GMP or is not in Good Condition or suitable for its intended purpose, then:

(a) the Manufacturer shall destroy the defective Elective Materials; and

(b) the Authority shall reimburse the Manufacturer for any reasonable costs associated with the testing and destruction of the Elective Materials.

Appendix 1

Approved Elective Materials

The purchase by the Manufacturer of the Elective Materials set out in the table below has been approved by the Authority prior entering into this Agreement:

Component	Cost Per unit (GBP)	Per Dose	Total Cost (excl. VAT)	Total Cost (incl. VAT @20%)
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Total			[redacted]	[redacted]

Schedule 8

Change Control Notice

SECTION A – CHANGE REQUEST	
Party requesting change	
Date	
Reference number	
Title of Change	
Details of Change	
Suggested amendments to the Agreement	
SECTION B – CHANGE APPROVAL	
Agreed amendments to the Agreement	
Signed by Manufacturer	
Signed by Authority	
Date	

Schedule 9

Manufacture and Supply to Authority

1 DEFECTIVE PRODUCTS

Application

For the avoidance of doubt, this paragraph 1 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 17 (Defective Products). If this paragraph is required, a separate manufacture and supply agreement and quality agreement will be prepared to delineate the responsibilities between the Authority, the Vaccine Manufacturer and the Manufacturer.

1.1 Upon receipt of each Delivery of Product from the Manufacturer, the Authority or its relevant Affiliate shall confirm that the Products Delivered appear to be in satisfactory condition and that the Delivery otherwise complies with the terms of the relevant Firm Order. For the avoidance of doubt, the Authority or its relevant Affiliate shall not be required to carry out any laboratory analysis of the Products Delivered unless otherwise expressly stated in the Quality Agreement.

1.2 Without prejudice to any other remedy under this Agreement, for a period of sixty (60) Business Days after each Delivery, the Authority (or its relevant Affiliate) shall have the right to reject the Delivery (or any part of such Delivery) if, having carried out its obligations under paragraph 1.1, it becomes aware that any Product contained in such Delivery:

(a) has not been Manufactured in accordance with Clause 6.1(f);

(b) is not in Good Condition; or

(c) does not comply with the Specification.

1.3 Products Delivered will be deemed accepted by the Authority (or its relevant Affiliate) if it fails to carry out its obligations pursuant to paragraph 1.1 or if no notification is made to the Manufacturer within the time limit specified in paragraph 1.2, provided that the Manufacturer shall remain liable to the Authority and its Affiliates under the terms of this Agreement for any Latent Defect solely to the extent attributed to the delivery of services being provided under the manufacture and supply agreement by the Manufacturer.

1.4 In the event of a Product rejection pursuant to paragraph 1.2:

(a) the Authority (or its relevant Affiliate) shall notify the Manufacturer in writing, giving reasons for the rejection;

(b) the payment obligation in relation to such Product shall be suspended pending resolution of the dispute;

(c) the Parties and the Vaccine Manufacturer shall immediately endeavour to agree (each Party and the Vaccine Manufacturer acting reasonably and in good faith) whether or not the Product and/or Delivery in question is defective according to the terms of this Agreement;

(d) the Manufacturer shall be entitled at all reasonable times and on written notice to the Authority (or its relevant Affiliate) to inspect and/or analyse the Product(s) in question; and

(e) at the Authority's (or its relevant Affiliate's) request, the Manufacturer, in coordination with the Vaccine Manufacturer, will deliver a replacement delivery of the Product to the Authority or its Affiliate as soon as practicable after notification of the rejection, using all reasonable endeavours to ensure continuity of supply, and the Authority or the relevant the Authority Affiliate shall pay the Manufacturer for such Delivery in accordance with the payment provisions set out in this Agreement.

1.5 Notwithstanding the provisions of paragraph 1.1 to 1.4 of this Schedule, and without prejudice to any other remedy under this Agreement, the Authority (or its relevant Affiliate) shall be entitled to return any Product to the Manufacturer at any time after receiving it and before the Product's expiry date if any Latent Defect becomes evident that can be attributed solely to the services being provided under the manufacture and supply agreement performed by the Manufacturer. If the Authority (or its relevant Affiliate) intends to return any Product pursuant to this paragraph 1.5:

(a) the Authority (or its relevant Affiliate) shall notify the Manufacturer in writing, giving reasons for the return;

(b) the payment obligation in relation to such Product shall be suspended pending resolution of the dispute;

(c) the Parties shall immediately endeavour to agree (each Party acting reasonably and in good faith) whether or not the Product in question is subject to a Latent Defect;

(d) the Manufacturer shall be entitled at all reasonable times and on written notice to the Authority (or its relevant Affiliate) to inspect and/or analyse the Product in question;

(e) at the Authority's (or its relevant Affiliate's) request, the Manufacturer will deliver a replacement Delivery of the Product to the Authority or its Affiliate as soon as

practicable after notification of the return, using all reasonable endeavours to ensure continuity of supply, and the Authority or the relevant Affiliate shall pay the Manufacturer for such Delivery in accordance with the payment provisions set out in this Agreement; and

(f) where the Authority (or its relevant Affiliate) reasonably suspects that any Products subsequently Delivered are likely to have the same (or substantially the same) Latent Defect as the notified Products, the Authority (or its relevant Affiliate) may return such Products even where any such Latent Defect has not yet become evident and, without prejudice to any other remedy under this Agreement, the provisions of paragraph 1.5(a) to 1.5(e) shall apply to any such returned Products.

1.6 Without prejudice to Clause 55 (Dispute Resolution Procedure), the Parties shall use all reasonable endeavours to resolve any dispute that may arise pursuant to this paragraph 1.6. However, if within 30 calendar days after being notified of any:

(a) allegedly defective Delivery of Products;

(b) defective Products; or

(c) Products being returned under paragraph 1.3,

the Parties fail to agree whether any Products supplied by the Manufacturer to the Authority or any relevant Affiliate are defective or may be rejected or returned for any reason, then:

(i) in the case of a rejection or return for quality reasons, the dispute shall be determined by an Independent Laboratory and the decision of the Independent Laboratory shall be final and binding on the Parties. The Independent Laboratory shall act as an expert and not as an arbitrator and (unless the Independent Laboratory otherwise determines) its fees shall be borne by the Party against whom the Independent Laboratory's decision is given; and

(ii) in the case of a rejection or return for any other reasons, the matter shall be resolved according to the Dispute Resolution Procedure set out in Clause 55 (Dispute Resolution Procedure).

1.7 If the Parties agree, or the Independent Laboratory finds, that any Delivery or Products may be rejected and/or returned in accordance with paragraph 1.2 or 1.3 then, without prejudice to any other rights or remedies under this Agreement:

(a) the Manufacturer shall reimburse the Authority (or its relevant Affiliate) for any reasonable costs incurred in disposal of the rejected/returned Product;

(b) the Manufacturer shall promptly reimburse the Authority (or its relevant Affiliate) in respect of any cost (including without limitation freight, clearance, duty, storage and price paid) incurred by the Authority (or its relevant Affiliate) in respect of the rejected/returned Product; and

(c) if no replacement Delivery has already been made in accordance with paragraph 1.2 or 1.3 then, the Authority (or its relevant Affiliate) may elect to give the Manufacturer the opportunity to replace the rejected/returned Product as soon as reasonably practicable with a Delivery of Product which complies with the requirements of this Agreement at no extra cost,

provided that where the Authority (or its relevant Affiliate) considers in its reasonable opinion that the option set out at paragraph 1.7(c) is not practicable, the Manufacturer shall reimburse any monies already paid by the Authority (or its relevant Affiliate) for the rejected/returned Product.

1.8 If the Independent Laboratory finds that the Authority (or its relevant Affiliate) was not entitled to reject/return Products in accordance with paragraph 1.2, then the Authority or its relevant Affiliate shall pay for such Products in accordance with the payment provisions contained in this Agreement and reimburse to the Manufacturer any reasonable costs incurred in carrying out any additional testing of the Products for the purposes of this paragraph 1 (Defective Products).

2 QUALITY ASSURANCE

Application

For the avoidance of doubt, this paragraph 2 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 22 (Quality Assurance). If this paragraph is required, a separate manufacture and supply agreement and quality agreement will be prepared to delineate the responsibilities between the Authority, the Vaccine Manufacturer and the Manufacturer.

2.1 The Manufacturer shall at all times employ a Qualified Person who shall be responsible for confirming by his/her signature on the appropriate Batch Record and certificate of conformance that each batch of Products Manufactured conforms with the Specifications and is manufactured in accordance with GMP. The mechanism for product release responsibilities and the responsibility for the generation of a certificate of analysis will be defined in the Quality Agreement.

2.2 The Manufacturer shall at all times ensure that quality assurance tests specified by the relevant Vaccine Manufacturer are adopted and that reference and retention samples of each batch of Products Manufactured are taken and retained in accordance with the

Quality Agreement and the requirements of GMP. Such samples shall (notwithstanding any termination of this Agreement) be retained by the Manufacturer for the periods prescribed in the Quality Agreement.

2.3 The Manufacturer shall ensure that testing methodology complies with GMP and the Produce Licence.

2.4 The Manufacturer shall institute and maintain process controls during the Manufacture of the Products in accordance with GMP. Further, the Manufacturer shall maintain full records of the manufacturing process as specified in the Quality Agreement. Such records and samples shall be retained by the Manufacturer for such period as may be specified in the Quality Agreement or as otherwise required by applicable Law.

2.5 The Manufacturer shall promptly report any adverse trends to the Vaccine Manufacturer that arise during release testing of the Products.

2.6 The terms of this paragraph 2 shall be supplemented by additional quality specific provisions in the Quality Agreement. In the event of any conflict or inconsistency between the Quality Agreement and the terms of this Agreement on quality related matters, the terms of the Quality Agreement shall prevail.

3 COMPLAINTS AND RECALL PROCEDURES

Application

For the avoidance of doubt, this paragraph 3 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 23 (Complaints and Recall Procedures). If this paragraph is required, a separate manufacture and supply agreement and quality agreement will be prepared to delineate the responsibilities between the Authority, the Vaccine Manufacturer and the Manufacturer.

3.1 The Vaccine Manufacturer shall be responsible in accordance with applicable Laws for the reporting to Regulators of all complaints and product recalls relating to Products. The Manufacturer will promptly advise the Authority and the Vaccine Manufacturer of any occurrence or information which arises out of the Manufacture of Products which has or could be reasonably expected to have adverse regulatory compliance and/or reporting consequences concerning the Products, and provide relevant information to the Authority and Vaccine Manufacturer upon request.

3.2 The Manufacturer shall promptly notify the Authority and the relevant Vaccine Manufacturer upon becoming aware of any problem related to the Manufacture of Product, including where any Product:

(a) or its labelling may have been mistaken for, or applied to, another product;

(b) may be affected by bacteriological or other contamination, significant chemical, physical or other change or deterioration or stability failures;

(c) is the subject of a complaint by a Third Party or Authority; or

(d) may not comply with the Specification.

3.3 If the Vaccine Manufacturer or any Regulator deems that a Product recall is required, the recall strategy shall be developed by the Vaccine Manufacturer and followed by the Manufacturer with strict regard to timing requirements.

3.4 Without prejudice to any other right or remedy under this Agreement, to the extent any action or recall required under this paragraph 3.4 is caused solely by a failure of the Manufacturer to comply with its obligations under this Agreement (including, without limitation, the failure or defect of the Product caused by any of the problems set out in Clauses 3.2(a) to 3.2(d) but solely to the extent such failure or defect is caused by a failure of the Manufacturer to comply with its obligations under this Agreement), the costs of the action or recall shall be paid by the Manufacturer (including, without limitation, a refund to the Authority (or its Affiliate) of the sums paid in respect of the affected Products) provided that the party incurring such costs has used reasonable endeavours to mitigate such costs. In all other cases, the costs of the action or recall shall be borne by the Vaccine Manufacturer.

3.5 Upon notification from the Vaccine Manufacturer that it has received a complaint in respect of any Product which may be due to its Manufacture, the Manufacturer will promptly conduct all such necessary internal investigations as may be necessary to determine the validity of such complaint and report the findings to the Vaccine Manufacturer in compliance with the MSA and Quality Agreement.

4 INSPECTIONS BY AN ADMINISTRATIVE ENTITY

Application

For the avoidance of doubt, this paragraph 4 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 24 (Inspections by an Administrative Entity). If this paragraph is required, a separate manufacture and supply agreement and quality agreement will be prepared to delineate the responsibilities between the Authority, the Vaccine Manufacturer and the Manufacturer.

4.1 If the Manufacturer is notified that any Product in the Manufacturer's possession or the Manufacturing Site will be subject to an inspection by any Administrative Entity, then the Manufacturer shall:

(a) immediately advise the Vaccine Manufacturer and provide relevant information known to the Manufacturer regarding such investigation;

(b) fully cooperate with and allow any such inspection to the extent required by applicable Laws;

(c) ensure that all enquiries related to any Product Manufactured in relation to this Agreement or any Product Licence shall be directed to the Vaccine Manufacturer, and the Manufacturer agrees that the Vaccine Manufacturer (or its Affiliates) shall have the right to be present at any inspection involving any Product;

(d) provide the Vaccine Manufacturer with the opportunity to attend such inspection, in a capacity agreed with the Manufacturer and in a manner that does not interfere with the conduct of the inspection subject to any reasonably imposed confidentiality obligations; and

(e) promptly notify the Vaccine Manufacturer of any observations (or other findings) issued by a Regulator specifically related to the manufacture, generation, processing, storage, transportation, distribution, treatment, disposal or other management of Products or Materials as well as responses to any inspection reports prepared in accordance with this paragraph 4.1.

Notwithstanding the foregoing, nothing in this paragraph 4 shall oblige the Manufacturer to disclose information to the Vaccine Manufacturer or the Vaccine Manufacturer's Affiliates relating to any other customer of the Manufacturer or those customer's products to which the inspection relates, unless such information is of a general nature relating to the Manufacturing Site, services, equipment or personnel also utilised in the Manufacture of the Products, in which case the information shall be disclosed to the Vaccine Manufacturer to the extent required under this paragraph 4.

4.2 If any Administrative Entity takes any action (including any request for information) requiring a response or action by the Manufacturer with respect to any Product, the Manufacture of the Products, the Specifications or any Authority Material, the Manufacturer will consult with the Vaccine Manufacturer regarding whether the response or commitment being required affects the specifications set forth in the Product Licence.

4.3 If the Vaccine Manufacturer is subject to an inspection by any Administrative Entity that relates to the Products or the Manufacturer's performance of its obligations under this Agreement, the Manufacturer shall provide the Authority and such Administrative Entity with access to Manufacturer's records, the Products and those portions of the Manufacturing Site used in the manufacture, generation, storage, testing, treatment, holding, transportation, distribution or other handling or receiving of the Products or Materials as required by this Agreement or otherwise by applicable Law.

4.4 The Vaccine Manufacturer has the right to audit the Manufacturer to confirm compliance with the MSA, Quality Agreement, applicable regulations and GMP subject to and in accordance with the requirements set forth in the Quality Agreement.

5 ORDERING AND FORECASTING PROCESS

Application

5.1 For the avoidance of doubt, this paragraph 5 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 5 (Ordering and Forecasting).

Ordering and Forecasting Process

5.2 On or before the first day of each Contract Quarter during the Term, the Authority and its relevant Affiliates shall provide the Manufacturer with, or with access to, a rolling forecast schedule of quarterly demand for the Products for at least the following Contract Quarter (a "**Forecast Schedule**").

5.3 The Authority and/or its Affiliates shall place corresponding purchase orders [redacted] (each a "**Firm Order**").

5.4 The Authority shall be responsible for placing all Firm Orders with the Manufacturer, and each Firm Order must set out:

(a) the quantity of Product required;

(b) the date for Delivery (subject to paragraph 5.6); and

(c) the Delivery point.

5.5 The Manufacturer shall keep the Authority informed of the standard lead time for the Manufacture of Products and the date for Delivery specified in the Firm Order shall not be sooner than the applicable lead time.

5.6 The Manufacturer shall confirm in writing each Firm Order received from the Authority within five (5) Business Days of receipt. The response shall include confirmation of the Delivery dates and quantity of Product as set out in the relevant Firm Order.

5.7 Upon receipt of confirmation pursuant to paragraph 5.6, each Firm Order will be regarded by the Parties as a binding irrevocable commitment by:

(a) the Authority and/or its Affiliates to purchase from the Manufacturer; and

(b) the Manufacturer to Manufacture and supply to the Authority and its Affiliates,

the relevant quantity of Product according to the requirements set out in such Firm Order.

5.8 It is understood that the remaining months of the Forecast Schedule outside the Firm Order period constitutes an estimate of the future requirements of the Authority and its Affiliates for Product and does not comprise a minimum purchase requirement or any binding commitment by the Authority or its Affiliates to purchase such Product.

5.9 Without prejudice to its other rights and remedies, the Authority may terminate a Firm Order, in whole, or in part with respect to one or more Products, by notice in writing to the Manufacturer at any time, if:

(a) the Products (or any of them):

(i) are not consistently Manufactured to the relevant Specifications and/or the requirements of the Manufacturing Licence and/or Product Licence;

(ii) contain any new or unknown impurities, including new or unknown related substances;

(iii) contain any known impurities over the limits referred to in the Quality Agreement and/or in such quantity that is not permitted by applicable Laws;

(iv) are potentially hazardous; or

(v) may cause untoward reactions in a patient;

(b) regulatory issues arise, including, without limitation, the withdrawal of the Manufacturing Licence, or there are other regulatory considerations which affect the Manufacture and/or commercialisation of the Products;

(c) one or more of the Products is discontinued, or withdrawn from the market for safety, quality or regulatory reasons;

(d) significant quality issues arise in relation to the Manufacture of the Product under this Agreement; and/or

(e) there is a material disruption in supply.

6 DELIVERY

Application

6.1 For the avoidance of doubt, this paragraph 6 shall only apply where the Parties agree that the Authority shall assume some responsibility in relation to the issues set out herein, in accordance with Clause 16 (Delivery of Products).

Delivery

6.2 The Manufacturer shall make the Products available for collection by the Authority at the Delivery Location on the dates and in the quantities specified in the relevant Firm Order.

6.3 Subject to paragraph 6.2 of this Schedule 9 (Manufacture and Supply to Authority), the delivery terms shall be ex-works (EXW) (Incoterms 2020).

6.4 Risk in the Products shall pass from the Manufacturer to the Authority when the Authority collects the Product from the Manufacturer's premises at the Delivery Location.

6.5 For each Delivery, the Manufacturer shall provide the Authority with the corresponding certificate of analysis and any other specified Delivery documentation as defined in the Quality Agreement.

6.6 All Products supplied under this Agreement shall be Delivered with the relevant remaining shelf life specified in the relevant Specification.

6.7 If the Manufacturer is unable, or anticipates that it will be unable, for any reason (including, without limitation, as a result of negligence, fault or omission or an event of Force Majeure) to Deliver in whole or in part the quantities of Product required under any Firm Order, the Manufacturer shall, as soon as it becomes aware of that fact, give written notice to the Authority setting out the reasons for such shortfall or failure.

6.8 Payment by the Authority or its Affiliates for the Products shall not be deemed to constitute acceptance of such Products by the Authority or its Affiliates. Acceptance of Products is subject always to paragraph 1 (Defective Products).