DATED 15th July 2024

(1) THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

(2) ALLOGA UK LIMITED

CO-PACKAGING SERVICES AGREEMENT

Order Form

1. Contract Reference	C297291
2. Authority	THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE, contracting for and on behalf of the Crown (as defined below), and whose principal office is at 39 Victoria Street, London SW1H 0EU United Kingdom
3. Supplier	Alloga UK Limited, whose registered office is at Amber Park, Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2FH
4. The Agreement	This Agreement between the Authority and the Supplier is for the supply of the Services. The Supplier shall supply the Services described below on the terms set out in this Order Form and the attached contract conditions ("**Conditions**") and Annexes. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in the Conditions.
5. Services	Co-packaging Services as described in Annex 1 – Specification.
6. Start Date	15th July 2024
7. Expiry Date	31 March 2025
8. Extension Period	None
9. Charges	The Charges for the Services shall be as set out in the Supplier's Quote - Annex 2.
10. Payment	All invoices must be sent, quoting a valid Purchase Order Number (PO Number), to: [redacted] Addressed to: Secretary of State for Health and Social Care Accounts Payable 39 Victoria Street London SW1H 0EU Payment of undisputed invoices will be made within 30 days of receipt of invoice, which must be submitted promptly by the Supplier. To avoid delay in payment it is important that the invoice is compliant and that it includes a valid PO Number, item number (if applicable) and the details (name, email, and telephone number) of your Authority contact (i.e. Authority Authorised Representative). Non-compliant invoices may be sent back to you, which may lead to a delay in payment. If you have a query regarding an outstanding payment please contact our Accounts Payable team either by email to: [redacted]

	[redacted]) quoting a valid purchase order number (PO)."
11. Progress Meetings and Progress Reports	The Supplier shall attend progress meetings, including to discuss ongoing co-packaging demand, with the Authority at least monthly. The Supplier shall provide the Authority with progress reports as required.
12. Authority Authorised Representative(s)	For general liaison your contact will be [redacted] or, in their absence, [redacted]
13. Supplier Authorised Representative(s)	For general liaison your contact will be [redacted]
14. Address for notices	Authority**:** Supplier: [redacted] or, in their absence, [redacted]
15. Procedures and Policies	For the purposes of the Agreement please see the following code of conduct which sets out the standards and behaviours we expect of suppliers contracted to support the work of the Department of Health and Social Care (DHSC) https://www.gov.uk/government/publications/dhsc-supplier-code-of-conduct/dhsc-supplier-code-of-conduct
16. Incorporated terms and order of precedence	The following documents are incorporated into the Agreement. If there is any conflict, the following order of precedence applies: a) This Order Form b) Conditions c) The following Annexes in equal order of precedence: i. Annex 1 – Specification ii. Annex 2 – Supplier's Quote

Signed for and on behalf of the Authority:	**Signed for and on behalf of the Supplier:**

CONDITIONS

THIS AGREEMENT is made on 15th July 2024 **("Start Date")**

BETWEEN:

(1) **THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE**, contracting for and on behalf of the Crown (as defined below), and whose principal office is at 39 Victoria Street, London SW1H 0EU United Kingdom (the "**Authority**") and

(2) **ALLOGA UK LIMITED,** whose registered office is at Amber **Park**, Berristow Lane, South Normanton, Alfreton, Derbyshire, DE55 2FH ("**Supplier**"),

Authority and the Supplier, each a "**Party**", collectively the "**Parties**".

BACKGROUND:

(A) The Authority has purchased a quantity of Patient Courses of the pharmaceutical product known as molnupiravir (brand name Lagevrio) an antiviral treatment for Covid 19 from Merck Sharp & Dohme (**MSD**) pursuant to a supply agreement, as part of its preparatory measures to counter the COVID-19 pandemic in the United Kingdom of Great Britain and Northern Ireland.

(B) A batch specific variation extending the shelf life of Lagevrio has been agreed with the Medicines and Healthcare Products Regulatory Agency. A proportion of the remaining stock now requires co-packaging to change the expiry date of the Product in order to supply to community pharmacies and NHS hospitals and trusts in accordance with any Dear Healthcare Professional Letters and Dear Patient Letter, as appropriate. To guarantee that the patient receives an explanation of the shelf-life extension, the Dear Patient Letter will be co-packed with the Product, while the Dear Healthcare Professional Letter will be supplied with the delivery to the pharmacy or NHS Hospital.

IT IS AGREED AS FOLLOWS:

1. **INTERPRETATION**

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

"Affiliates"	in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;
"**Agreement**"	means the contract between (i) the Authority and (ii) the Supplier which is created by the Supplier's

	counter signing the Order Form, these Conditions and the Annexes;
"**Authorisation**"	means a marketing authorisation, which is legally required under applicable Laws, regulations or administrative decisions to import, promote, distribute, market and sell any of the Products in a country of the Territory;
"Beneficiary"	is a Party having (or claiming to have) the benefit of an indemnity under this Contract;
"Change of Control"	means the sale to and purchase by a third party of more than fifty per cent (50%) of the voting share capital of a company but excludes the listing of all or part of the share capital of a company on a recognised investment exchange as defined by the Financial Services and Markets Act 2000;
"Charges"	means the charges for the Services as specified in Annex 2 – Supplier's Quote;
"Claim"	means any claim which it appears that a Beneficiary is, or may become, entitled to indemnification under this Contract;
"**Commercially Reasonable Endeavours**" or "**CRE**"	means in relation to the Authority, reasonable activities and reasonable degree of effort the Authority would undertake or use to enforce its rights under the Supply Agreement, having due regard to all its obligations, policies and objectives;
"Compliance Officer"	means the person(s) appointed by the Supplier who is responsible for ensuring that the Supplier complies with its obligations under the Law;
''Conflict of Interest"	a conflict between the financial or personal duties of the Supplier or the Supplier Staff and the duties owed to the Authority under the Contract, in the reasonable opinion of the Authority;

"Contract"	means this Agreement;
"Contract Period"	means the term of the Agreement from the Start Date until the expiry or termination of the Agreement;
"**Contracting Authority**"	means any contracting authority as defined in regulation 3 of the Public Contracts Regulations 2015 (SI 2015/102) (as amended), other than the Authority;
"**Crown Body**"	means the government of the United Kingdom (including the Northern Ireland Assembly and Executive Committee, the Scottish Government and the National Assembly for Wales), including, but not limited to, government ministers and government departments and particular bodies, persons, commissions or agencies from time to time carrying out functions on its behalf;
"**Dear Healthcare Professional Letter**" or "**DHCP Letter**"	means the communications to healthcare professionals regarding the change to expiry date of the Products to be supplied by the Supplier pursuant to the Specification and in accordance with current good pharmacovigilance practice (cGVP) Module XV (Safety communication) and the MHRA Guidance Note on Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority dated 21 December 2020 (and as may be updated from time to time);
"**Dear Patient Letter**"	[means the communications regarding the change to expiry date of the Products to be provided to the Patient pursuant to the Specification and in accordance with current good pharmacovigilance practice (cGVP) Module XV (Safety communication) and the MHRA

	Guidance Note on Exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority dated 21 December 2020 (and as may be updated from time to time)];
"Default"	means any breach of the obligations of the Supplier (including abandonment of the Agreement in breach of its terms) or any other default (including material default), act, omission, negligence or statement of the Supplier, of its Subcontractors or any Supplier Staff howsoever arising in connection with or in relation to the subject-matter of the Agreement and in respect of which the Supplier is liable to the Authority;
"**DSUR**"	means a development safety update report, prepared in accordance with applicable law and the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use ICH Harmonised Tripartite Guideline: Development Safety Update Report E2F (17 August 2010);
"**FOI Legislation**"	means the Freedom of Information Act 2000 and the Environmental Information Regulations 2004;
"**Force Majeure Event**"	means an event beyond the control of a Party (or any person acting on its behalf), which by its nature could not have been foreseen by such Party (or such person), or, if it could have been foreseen, was unavoidable, and includes acts of God, storms, floods, pandemic, epidemic, riots, fires, sabotage, civil commotion or civil unrest, interference by civil or military authorities, acts of war (declared or undeclared) or armed hostilities or other national or international calamity or one or more acts of terrorism or failure of energy sources;

"**cGDP**" or "**current Good Distribution Practices**"	means the principle and guidelines of Good Distribution Practice as defined and in accordance with Directives 2001/83/EC on the distribution of medicines in the European Union and the Guidelines on the Good Distribution Practice of medicinal products for human use, and any other relevant legislation, regulations, standards or guidance, as such legislation, regulations, standards and guidance in respect to the distribution of the Product for the intended Territory as may be amended and implemented in the Territory from time to time;
"**cGMP**" or "**current Good Manufacturing Principles**"	means Good Manufacturing Practice in accordance with Directive 2003/94/EC, Volume 4 of the Rules Governing Medicinal Products in the European Union and any other relevant legislation, regulations, standards or guidance, as such legislation, regulations, standards and guidance in respect to the manufacture of the Product for the intended Territory as may be amended and implemented in the Territory from time to time and in such other requirements as agreed between the Parties in writing and set out in the QTA;
"**Good Industry Practice**"	means standards, practices, methods and procedures conforming to the Law and the exercise of the degree of skill and care, diligence, prudence and foresight which would reasonably and ordinarily be expected from a skilled and experienced person or body engaged within the relevant industry or business sector;
"Indemnifier"	a Party from whom an indemnity is sought under this Agreement;
"**Insolvency Event"**	means in respect of a person: (a) if that person is insolvent; (b) where that person is a company, LLP or a partnership, if an order is made or a resolution is passed for the winding up of the person (other than voluntarily for the purpose of solvent amalgamation or reconstruction);

	(c) if an administrator or administrative receiver is appointed in respect of the whole or any part of the person's assets or business; (d) if the person makes any composition with its creditors; or (e) takes or suffers any similar or analogous action to any of the actions detailed in this definition as a result of debt in any jurisdiction;
"**Intellectual Property**"	means, without limitation, all patents, copyright, design rights, registered designs, trademarks, know-how, database rights, supplementary protection certificates, confidential formulae and any other intellectual property rights and the rights to apply for patents and trademarks and registered designs, technology, know-how, recipes, clinical data, data, processes, trade secrets, inventions, business information, technical information, methods, marketing information and materials, business plans, proprietary data, formulae, techniques, specifications, research and development data, non-public information and confidential information and rights to limit the use or disclosure of any of the foregoing by any person;
"**Law**"	any law, subordinate legislation within the meaning of section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of the European Union (Withdrawal) Act 2018 as amended by European Union (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Supplier is bound to comply;
"**Manufacturer**"	means MERCK SHARP & DOHME (UK) LIMITED:
"MHRA"	means the UK Medicines and Healthcare products Regulatory Agency;

"MIA"	means Manufacturer's Importer's Authorisation valid in the Territory and granted by the relevant regulatory authority;
"National Insurance"	contributions required by the Social Security Contributions and Benefits Act 1992 and made in accordance with the Social Security (Contributions) Regulations 2001 (SI 2001/1004);
"Order"	means an order for the Services submitted by the Authority in accordance with clause 5 [and "Order Form" shall have the same meaning];
''**Patient Courses**''	means one patient treatment course of the Product, unless otherwise stipulated under the Authorisation and which may be referred to as "units" by the Manufacturer;
"**Product Adjustment**"	means adjustments made by the Supplier from time to time, through the routines of inventory management, to stock levels in the Supplier UK Repack Facility to maintain synchronisation with IT system held stock levels and which are made to the Supplier's system using the clearly identifiable codes: 'DAMAGE' for stock damaged in the Supplier's UK Repack Facility attributable to Supplier's handling and 'PHY COUNT' for all such other adjustments. The Product Adjustments may be positive/Product gains (if Products are 'found') or negative/Product write-offs (if Products are 'lost' or damaged). For clarification, a PHY COUNT adjustment will be due to stock discovered to be lost or found following a physical count of a storage location and typically attributable to an error during order assembly.
"Product Information"	means product information as defined in clause 10.1 of this Agreement;
"**Product**''	means the pharmaceutical product known as molnupiravir (brand

	name Lagevrio) an antiviral for Covid 19, made by the Manufacturer;
"**Qualified Person**"	means the person responsible certifying that each batch of a medicinal product meets all required provisions to be placed on the market and meets the Authorisation;
"QTA"	means the Quality Technical Agreement at Annex 3 of this Agreement;
"Replacement Services"	means any services which are substantially similar to any of the Services and which the Authority receives in substitution for any of the Services, whether those goods are provided by the Authority internally and/or by any third party;
"Replacement Supplier"	any third party provider of Replacement Services appointed by or at the direction of the Authority from time to time or where the Authority is providing Replacement Services for its own account, shall also include the Authority;
"**Representative**"	means a Party's officers, employees, agents and advisors;
"Rectification Plan"	means the Supplier's plan (or revised plan) to rectify its breach which shall include: (a) full details of the material Default that has occurred, including a root cause analysis; (b) the actual or anticipated effect of the material Default; and (c) the steps which the Supplier proposes to take to rectify the material Default (if applicable) and to prevent such material Default from recurring, including timescales for such steps and for the rectification of the material Default (where applicable);
"**SmPC**"	means Summary of medical Product Characteristics;

"**Specification"**	means the specification for the Services to be supplied by the Supplier to the Authority (including as to quantity, description and quality) as set out at Annex 1;
"Start Date"	means the start date of the Agreement set out in the Order Form;
"Sub-Contract"	any contract or agreement (or proposed contract or agreement), other than the Contract, pursuant to which a third party: (a) provides the Services (or any part of them); (b) provides facilities or services necessary for the provision of the Services (or any part of them); and/or (c) is responsible for the management, direction or control of the provision of the Services (or any part of them);
"Subcontractor"	any person other than the Supplier, who is a party to a Sub-Contract and the servants or agents of that person;
"**Supplier UK Repack Facility**"	means the Supplier facilities used for the provision of the Services,, located at AP5, South Normanton, DE55 2JX;
"Supplier Staff"	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor engaged in the performance of the Supplier's obligations under the Contract;
"**Supply Agreement**"	means the agreement for the supply of the Product entered into by the Authority and the Manufacturer dated 20 December 2021;
"**Territory**"	means the United Kingdom of Great Britain and Northern Ireland;

"Worker"	any one of the Supplier Staff which the Authority, in its reasonable opinion, considers is an individual to which Procurement Policy Note 08/15 applies in respect of the Services;
"Working Day"	means any day other than a Saturday or Sunday or public holiday in England and Wales.

1.2 Clause headings shall not affect the interpretation or construction of this Agreement. References to Clauses and Annexes are to the Clauses and Annexes of this Agreement.

1.3 Unless the context otherwise requires, words in the singular include the plural and, in the plural, include the singular and a reference to one gender shall include a reference to all other genders.

1.4 Reference to a person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) and that person's legal and personal representatives, successors and permitted assigns.

1.5 A reference to a statute, statutory provision or subordinated legislation is a reference to it as it is in force from time to time. A reference to a statute or statutory provision shall include any subordinate legislation made from time to time under that statute or statutory provision.

1.6 Any words following the terms **including**, **include**, **in particular** or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

2. PURPOSE OF THIS AGREEMENT

2.1 This Agreement is a services agreement governing the co-packaging of the Product by the Supplier for the Authority, as detailed in the Specification.

2.2 The Supplier shall provide the Services to the Authority in accordance with this Agreement.

2.3 The Order Form is an offer by the Authority to purchase the Services subject to and in accordance with the terms of the Agreement.

2.4 The Supplier is deemed to accept the offer in the Order Form when the Authority receives a copy of the Order Form signed by the Supplier.

2.5 The Supplier warrants and represents that the Supplier's quote and all statements made and documents submitted to the Authority are and remain true and accurate.

3. COMMENCEMENT AND TERM

3.1 This Agreement shall commence on the Start Date and shall, unless terminated in accordance with the provisions of Clause 15, remain in force until 31 March 2025 [the **Term**].

4. SERVICES

4.1 The Supplier shall supply the Services as set out in Annex 1 (Specification) in the Territory. The Services shall be carried out in response to specific instructions from the Authority on volumes to be co-packaged, and under the Supplier's MIA. The Product shall then be released back to the Authority with a new product code under the Supplier's Qualified Person release process.

4.2 The Supplier must provide the Services: (i) in accordance with this Agreement including the Specification and the QTA; (ii) using reasonable skill and care; (iii) using Good Industry Practice; (iv) using its own policies, processes, and internal quality control measures as long as they don't conflict with the Agreement; (v) on the dates agreed; and (vi) in compliance with all Law, including obtaining and maintaining all necessary licences and consents.

4.3 The Supplier must ensure that:

4.3.1 the Product is handled in accordance with any instructions from the Authority, the Manufacturer and/or any regulatory authority in accordance with applicable Laws;

4.3.2 all facilities used in the storage and handling of the Product are kept in a state and condition necessary to enable the Supplier to comply with its obligations in accordance with this Agreement and in accordance with applicable Laws;

4.3.3 the handling of the Products means that they remain in good and useable condition;

4.3.4 where the Product is required to be stored at a certain temperature, the Supplier shall provide, or shall procure the provision of, complete and accurate temperature records for the duration of the Service;

4.3.5 the Supplier handles the Products in accordance with the instructions from the Authority set out in the Specification or as otherwise notified by the Authority to the Supplier;

4.3.6 services are carried out in accordance with the QTA;

4.3.7 sufficient resources and appropriate expertise are allocated to performance of the Services;

4.3.8 all reasonable care is taken to ensure performance does not disrupt the Authority's operations, employees, or other contractors; and

4.3.9 all Services, and anything used to deliver the Services, are of good quality and free from defects.

4.4 The Supplier shall be responsible for purchasing any Packaging Materials required for the Services, but it shall not be required to use a specific supplier unless agreed by the Parties in writing.

4.5 The Supplier may procure all Packaging Materials, based on the Authority's forecast.

4.6 Where the Supplier purchases Packaging Materials in accordance with the Authority's forecast the Authority shall underwrite the cost of any surplus or obsolete Packaging Materials provided that the Supplier does not purchase than more than the forecasted materials or exceed any minimum order quantities.

4.7 Any damaged Product, damaged Packaging Materials or surplus Packaging Materials will be disposed of as agreed with the Authority and, at the Supplier's cost.

4.8 The Supplier shall not unnecessarily delay the disposal of surplus or damaged Packaging Material.

4.9 The Authority is entitled to withhold payment for partially delivered or undelivered Services, but doing so does not stop it from using its other rights under the Agreement but for the avoidance of doubt the Authority shall not withhold payment for any portion of the Services that has been delivered in accordance with all obligations under this Agreement.

4.10 Late provision of the Services will be a Default of the Agreement.

4.11 The Authority retains title to the Products during the provision of the Service. Title to the Products does not pass to the Supplier at any stage of the Agreement.

4.12 From time-to-time additional tasks falling outside of those envisaged in the Services may be undertaken, by agreement of the Parties. Except where otherwise agreed, all additional services provided by the Supplier will be subject to the terms and conditions contained in this Agreement. The cost of providing such additional services shall be paid for separately by the Authority and such costs shall not form part of the Charges.

5. ORDERS AND FORECASTING

5.1 The Authority shall provide the Supplier with written, rolling, monthly forecasts of its requirements for the Products on a quarterly basis for the proceeding twelve (12) months during the Term (each a "**Forecast**"). The Forecasts shall provide an estimate of the volumes of Product to be re-packaged, specify the Delivery Dates and other requirements for the Product as detailed in the Specification.

5.2 The Authority shall, on an on-going basis, during the Term of this Agreement, submit Orders for the Services

5.3 Each Order shall be given in written form (including electronic transmission), specify the volume of Product to be repackaged required and specify the date on which the Product is to be delivered (the '**Delivery Date**') as well as any other information which is relevant to the Order.

5.4 Within ten (10) business days of receipt of an Order, the Supplier shall confirm its acceptance or objection to such Order, including the Delivery Date. If the Supplier does not confirm such Order within the ten (10) business day period, it shall be deemed that the Order is accepted by the Supplier.

6. QUALITY ASSURANCE

6.1 The Authority will:

6.1.1 ensure the Patient Courses of Product are stored and in accordance with this Agreement and all applicable laws in the Territory, including cGDP; and

6.2 The Authority shall use its CRE to:

6.2.1 obtain any reasonable information and documentation, including the Product's SmPC which the Supplier requires to provide the Services; and

6.2.2 promptly inform the Supplier upon becoming aware of any claim brought by any third party in relation to the Product,

but the Authority acknowledges that if the Supplier is prevented, hindered or delayed in or from performing any of its obligations under this agreement by the Authority's failure to comply with its obligations or procure the information and resources set out in this clause 6.2, the Supplier shall not be in breach of this Agreement or otherwise liable for any such failure or delay in the performance of such obligations to the extent that they are caused by the Authority. The time for performance of the Supplier's obligations shall be extended accordingly.

6.3 In the event of a recall or withdrawal of the Product, the Authority will use its CRE to:

6.3.1 ensure the Supplier is promptly notified of the recall or withdrawal of the Product;

6.3.2 procure the Manufacturer collects and destroys of all recalled or withdrawn Product in the possession of the Supplier;

6.3.3 procure reimbursement for all reasonable, itemized, direct out-of-pocket costs and expenses actually incurred by the Supplier in relation to the recall or withdrawal of the Product.

6.4 The Supplier shall:

6.4.1 ensure all Patient Courses of Product are stored, handled, co-packaged, transported and released by, and on behalf of, the Supplier in accordance with this Agreement and all applicable Laws, including cGDP and cGMP, and the Authorisation;

6.4.2 upon transfer of the Product to the Supplier UK Repack Facility, inspect the Patient Courses of Product transferred and all supplied documentation and promptly notify the Authority in writing:

(a) within five (5) Working Days of transfer of any defects and/or damage to any of the Patient Courses of Product that are reasonably ascertainable from a visual inspection of such Patient Courses of Product and/or a review of the supplied documentation; or

(b) where such defects and/or damage were not reasonably ascertainable from a visual inspection of the Patient Courses of Product and a review of the supplied documentation upon transfer, prior to expiration of the shelf life and within five (5) Working Days of any defects and/or damage to any of the Patient Courses of Product being detected by, or notified to, the Supplier;

6.4.3 promptly inform the Authority of all information of which the Supplier becomes aware relating to the safety and/or efficacy of the Product;

6.4.4 comply with all reasonable requests for information and assistance made by, or on behalf of, the Authority in relation to defective or damaged Patient Courses of Product;

6.4.5 prepare, keep for three years after creation unless agreed otherwise and make available to the Authority: Batch records and, where instructed to do so, retained samples of finished Product and packaging materials, and information to show that the Supplier has and had at all relevant times all the necessary licences to provide the Services.

7. SUPPLIER STAFF

7.1 The Supplier Staff involved in the performance of the Agreement must:

7.1.1 be appropriately trained and qualified;

7.1.2 be vetted using Good Industry Practice; and

7.2 The Supplier indemnifies the Authority against all claims brought by any person employed by the Supplier caused by an act or omission of the Supplier or any Supplier Staff.

8. LIMITATION OF LIABILITY

8.1 Risk of loss or damage to the Products shall be with the Supplier whilst in the custody of the Supplier only to the extent expressly accepted by the Supplier pursuant to the terms of this Agreement.

8.2 At the end of each Agreement Year, the Supplier shall aggregate the value of Product Adjustments, in relation to the Services provided in accordance with this Agreement, and in respect of that Agreement Year. Where the aggregate Product Adjustments in that Agreement Year is a negative number, the Supplier shall pay to the Authority an amount equal to the Product Cost (as defined in Clause 8.3), but only to the extent that the value in that Agreement Year at Product Cost of such negative Product Adjustment is greater than 0.20% of the total value at Product Cost of all the Products subject to Services provided in accordance with this Agreement and during that Agreement Year.

8.3 "Product Cost" is, in relation to the Products, the actual cost to the Authority of manufacturing or purchasing a replacement for the Product that has been classified as a negative Product Adjustment. For the avoidance of doubt, Product Cost shall include but shall not be limited to transport costs.

8.4 Subject to Clauses 8.2, 8.4, 8.5 and 8.6, the Supplier shall be liable for, any Products damaged or lost in the Supplier UK Repack Facility (from the point when the a Services commence to the point at which they are completed) to the extent that such damage or loss is caused by the Supplier's breach of this Agreement. Notwithstanding any other provision of this Agreement except Clause 8.6, the Supplier's total liability to the Authority in respect of its acts or omissions in each Agreement Year shall be limited to an amount equal:

8.4.1 in the first Agreement Year, to the Charges paid or payable in that Agreement Year at the date of the act or omission in question; and

8.4.2 in subsequent Agreement Years, the Charges payable by the Authority in that Agreement Year,

and the relevant date for determining whether the maximum level of liability has been exceeded is the date of the act or omission giving rise to the liability.

8.5 Subject to Clause 8.6, the Supplier shall not be liable under or in connection with this Agreement for any reason, whether in contract, tort (including negligence), restitution, breach of statutory duty or misrepresentation or otherwise) for any :

a) consequential loss; direct or indirect loss of profit;

b) loss of goodwill;

c) loss of business or opportunity;

d) interest cost;

e) special damage; or

f) indirect damage.

8.6 Notwithstanding any other provision of this Agreement, neither Party excludes nor limits liability:

8.6.1 for death or injury to persons to the extent caused by its or its employees' or Subcontractors' negligent acts or omissions;

8.6.2 for fraud or fraudulent misrepresentation;

8.6.3 to the extent otherwise prevented by law.

8.7 Neither Party, to the extent permitted by law, has any implied obligation, duty or liability in contract, tort or otherwise other than those expressly stated in this Agreement.

8.8 The Supplier shall not be liable for any failure to perform or for any delay in the performance of any of the Services to the extent that such failure or delay is caused or contributed to by the Authority.

8.9 The Authority shall indemnify and hold harmless the Supplier, its officers, directors and employees from and against any and all claims from any third party arising as a result of any actual or alleged defectiveness of the Products or any claim that any of the Products infringe the Intellectual Property rights of any third party, save in each case in circumstances where and to the extent that such claim arises as a result of any act or omission and/or negligence of the Supplier or as a result of any failure by the Supplier to perform its obligations under this Agreement.

9. INSURANCE

9.1 The minimum levels of insurance to be taken out and maintained by the Supplier are as follows (subject to specific exceptions in the policies):

Employers Liability Insurance

£10,000,000 in respect of any one claim or series of claims arising out of one event.

Public Liability

£20,000,000 any one occurrence

Product Liability

£20,000,000 any one occurrence and in the aggregate.

10. CONFIDENTIALITY

10.1 Each Party undertakes that for the duration of this Agreement and thereafter it will keep confidential and (except as expressly permitted by this Agreement) will not use or (without the prior written consent of the other Party) disclose to any third party any information received from the other Party concerning the Product that is marked confidential or would otherwise be reasonable considered confidential, including (a) technical information, proprietary data, formulae, techniques, specifications, research and development data and non-public information provided by or on behalf of the Manufacturer, (b) any technical, stability or safety information or data or (c) this Agreement and its contents (all being "**Product Information**"). Each Party undertakes to the other Party to take all steps as shall from time to time be necessary to ensure compliance with the provisions of this Clause 10 by its Representatives.

10.2 The obligations in Clause 10.1 shall not apply in relation to:

10.2.1 Product Information which is or becomes public knowledge other than as a result of a breach of Clause 10.1;

10.2.2 Product Information which the Party using or disclosing the Product Information can demonstrate by written records either knew prior to the other

Party's first disclosure to it or received from a third party entitled to disclose the same;

10.2.3 Product Information which any Party is required to disclose by law, any Court of competent jurisdiction, any Government agency or regulatory body lawfully requesting the same or by the regulations of any stock exchange provided that (to the extent not prohibited by law or order of court, government agency or regulatory body or stock exchange regulation) the disclosing Party promptly notifies and consults with the other Party in advance in relation to the timing and content of such disclosure.

10.3 The provisions of Clause 10.2.3 shall apply to any disclosure a Party is required to make to the relevant authorities and responsible ethics committees in accordance with applicable law. The Parties acknowledge that there is a general understanding that any relevant authority or responsible ethics committee will keep Product Information submitted to it confidential, and the Party making such disclosure will mark any such Product Information disclosed as "confidential", but each Party accepts that the Party making such disclosure in accordance with applicable law would be unable to impose any specific obligations upon such bodies.

10.4 A Party shall ensure that any of its Representatives who have access to any of the other Party's Product Information shall ensure its Representatives have a need to access the Product Information for the purposes of the Services and ensure its Representatives have entered into written undertakings of confidentiality at least as restrictive as in this Agreement and which apply to the Product Information. The Party shall be responsible for any breach of this Clause 10 by any of its Representatives, whether or not such Representatives have entered into written undertakings of confidentiality in accordance with this Agreement.

10.5 If the Supplier receives a request under the FOI Legislation to disclose any Product Information, it will immediately notify the Authority and comply with its obligations with respect to such request under FOI Legislation.

10.6 If the Authority receives a request for Confidential Information of the Supplier pursuant to the FOIA it shall inform the Supplier, as applicable in writing of such request as soon as practicable after receipt but in any event shall take reasonable steps to inform the supplier within two (2) working days. Such notification shall include the name and address given by the applicant and a description of the information requested.

10.7 The Authority will notify the Supplier of any decision to disclose the Supplier's Confidential Information pursuant to a request under the FOIA prior to any disclosure being made. Such notification shall be made in writing as soon as practicable but in any event at least ten (10) working days prior to the date of disclosure.

10.8 The Authority will allow the Supplier to comment on any information that it proposes to disclose and to request that it redacts or withholds information that the Supplier reasonably considers to be exempted from the obligation to disclose under the FOIA.

10.9 The obligations contained in this Clause 10 shall survive the expiration or termination of this Agreement for a period of ten (10) years.

11. INTELLECTUAL PROPERTY

11.1 Nothing in this Agreement shall affect or prejudice the ownership of any Intellectual Property in the Product, which shall be exclusively governed by the Supply Agreement.

12. PRICING AND PAYMENTS

12.1 In exchange for the Services, the Supplier must invoice the Authority for the Charges.

12.2 All Charges:

12.2.1 exclude VAT, which is payable on provision of a valid VAT invoice; and

12.2.2 include all costs and expenses connected with the supply of Services.

12.3 The Authority must pay the Supplier the Charges within 30 days of receipt by the Authority of a valid, undisputed invoice, in cleared funds to the Supplier's account stated in the invoice or in the Order Form.

12.4 A Supplier invoice is only valid if it:

12.4.1 includes all appropriate references including the Purchase Order Number and other details reasonably requested by the Authority; and

12.4.2 includes a detailed breakdown of Services which have been delivered.

12.5 If there is a dispute between the Parties as to the amount invoiced, the Authority shall pay the undisputed amount. The Supplier shall not suspend the provision of the Services unless the Supplier is entitled to terminate the Agreement for a failure to pay undisputed sums in accordance with clause 15.

12.6 The Authority may retain or set-off payment of any amount owed to it by the Supplier under this Agreement or any other agreement between the Supplier and the Authority if notice and reasons are provided.

13. RIGHTS AND PROTECTION

13.1 The Supplier warrants and represents that:

13.1.1 it has full capacity and authority to enter into and to perform the Agreement;

13.1.2 the Agreement is executed by its authorised representative;

13.1.3 it is a legally valid and existing organisation incorporated in the place it was formed;

13.1.4 there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against it or its affiliates that might affect its ability to perform the Agreement;

13.1.5 all necessary rights, authorisations, licences and consents (including in relation to Intellectual Property rights) are in place to enable the Supplier to perform its obligations under the Agreement and the Authority to receive the Services;

13.1.6 it doesn't have any contractual obligations which are likely to have a material adverse effect on its ability to perform the Agreement; and

13.1.7 it is not impacted by an Insolvency Event.

13.2 The warranties and representations in clause 2.5 and clause 13.1 are repeated each time the Supplier provides Services under the Agreement.

13.3 The Supplier indemnifies the Authority against each of the following:

13.3.1 breach of the terms of this Agreement arising from the wilful misconduct of the Supplier, any of its Subcontractors and/or Representatives; and

13.3.2 non-payment by the Supplier of any tax or National Insurance.

13.4 If the Supplier becomes aware of a representation or warranty made in relation to the Agreement that becomes untrue or misleading, it must immediately notify the Authority.

13.5 All third party warranties and indemnities covering the Services must be assigned for the Authority's benefit by the Supplier.

14. RECTIFYING ISSUES

14.1 If there is a material Default, the Supplier must notify the Authority within 3 Working Days of the Supplier becoming aware of the material Default and the Authority may request that the Supplier provide a Rectification Plan within 10 Working Days of the Authority's request alongside any additional documentation that the Authority requires.

14.2 When the Authority receives a requested Rectification Plan it can either:

14.2.1 reject the Rectification Plan or revised Rectification Plan giving reasons; or

14.2.2 accept the Rectification Plan or revised Rectification Plan (without limiting its rights) in which case the Supplier must immediately start work on the actions in the Rectification Plan at its own cost.

14.3 Where the Rectification Plan or revised Rectification Plan is rejected, the Authority:

14.3.1 will give reasonable grounds for its decision; and

14.3.2 may request that the Supplier provides a revised Rectification Plan within 5 Working Days.

15. TERMINATION

15.1 A Party shall be entitled to terminate this Agreement with immediate effect by giving notice in writing to the other Party if:

15.1.1 the other Party commits a material breach of its obligations under this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after receipt of notice in writing requiring it to do so;

15.1.2 the other Party commits a series of persistent minor breaches which, when taken together, amount to a material breach; or

15.1.3 the other Party suffers an Insolvency Event.

15.2 The Authority may suspend or terminate this Agreement, at its sole discretion, with immediate effect by giving notice in writing to the Supplier at any time.

15.3 The termination or expiry of this Agreement (however caused) will not affect any rights and/or liabilities of either Party which have accrued before termination or expiry, or any provision of this Agreement which expressly or by implication is intended to come into or continue in effect on or after termination or expiry.

15.4 Upon suspension, expiry or termination of this Agreement for any reason:

15.4.1 the Parties shall work together to facilitate an orderly cessation of the Services, as applicable; and

15.4.2 the Supplier shall ensure all Patient Courses of Product are continued to be stored, handled and transported by and on behalf of the Supplier in accordance with this Agreement and all applicable Laws in the Territory, including cGDP;

15.4.3 at the Authority's option, the Supplier shall deliver all Patient Courses of Product stored by the Supplier to a Replacement Supplier or the Authority (as instructed by the Authority).

16. FORCE MAJEURE

16.1 Subject to compliance with Clause 16.2 a Party (or any person acting on its behalf) shall have no liability or responsibility for failure to fulfil any obligation under this Agreement so long as, and to the extent to which, the fulfilment of such obligation is prevented, frustrated, hindered or delayed as a consequence of a Force Majeure Event.

16.2 It shall be a condition of Clause 16.1 that, as soon as reasonably practicable after the occurrence of a Force Majeure Event, the Party claiming the benefit of Clause 16.1:

16.2.1 notifies the other Party of the nature and extent of such Force Majeure Event; and

16.2.2 uses all reasonable endeavours to remove any such causes and resume performance under this Agreement as soon as feasible.

17. FURTHER ASSURANCE

Each Party shall (at its own expense) promptly execute and deliver all such documents, and do all such things, or procure the execution and delivery of all documents and doing of all such things as are required to give full effect to this Agreement and the transactions contemplated by it.

18. AUDITS

18.1 The Authority shall use its CRE to procure:

18.1.1 the Manufacturer shall maintain all records relating to the manufacture, testing, packaging, transport and release of the Product for no less than five years from the effective date of the Supply Agreement, or such longer period as may be required by applicable Laws;

18.1.2 the Manufacturer shall grant to the Authority or its authorised agents such access to those records as they may reasonably require to confirm the Product was manufactured, labelled, handled, stored, transported and sold to the Authority and packaged in accordance with the Authorisation and all applicable laws in the Territory, including cGMP and cGDP.

18.2 The Authority shall have the right during the Term of this Agreement, to enter the Supplier's UK Repack Facility to inspect the facility and Products. Where the Authority carries any out any inspection under this Clause 18.2 it shall ensure that Authority personnel (and any third party personnel appointed by the Authority for such inspection) shall comply with all Supplier policies and procedures relating to the Supplier's UK Repack Facility.

18.3 Inspections carried out pursuant to clause 18.2 shall be carried out during business hours on reasonable notice to the Supplier, provided that in the event of an emergency, the Supplier shall grant the Authority immediate access to its UK Repack Facility.

19. VARIATION AND WAIVER

19.1 Any variation of this Agreement shall be in writing and signed by or on behalf of the Parties.

19.2 In the event that any changes to this Agreement are required in order to comply with changes to applicable law, the Parties shall not unreasonably withhold or delay agreement to such change or its implementation; nor shall a Party impose unreasonable conditions (having regard to the other terms of this Agreement) in implementing the change.

19.3 Any waiver of any right under this Agreement is only effective if it is in writing and it applies only to the Party to whom the waiver is addressed and to the circumstances for which it is given.

19.4 No failure to exercise or delay in exercising any right or remedy provided under this Agreement or by law constitutes a waiver of such right or remedy, nor shall it prevent or restrict any future exercise or enforcement of such right or remedy.

19.5 No single or partial exercise of any right or remedy under this Agreement shall prevent or restrict the further exercise of that or any other right or remedy.

20. PREVENTING FRAUD, BRIBERY AND CORRUPTION

20.1 The Supplier shall not offer, give, or agree to give anything, to any person (whether working for or engaged by the Authority or any other public body) an inducement or reward for doing, refraining from doing, or for having done or refrained from doing, any act in relation to the obtaining or execution of the Agreement or any other public function or for showing or refraining from showing favour or disfavour to any person in relation to the Agreement or any other public function.

20.2 The Supplier shall take all reasonable endeavours (including creating, maintaining and enforcing adequate policies, procedures and records), in accordance with Good Industry Practice, to prevent any matters referred to in clause 20.1 and any fraud by the Supplier's Representatives and the Supplier (including its shareholders, members and directors) in connection with the Agreement and shall notify the Authority immediately if it has reason to suspect that any such matters have occurred or is occurring or is likely to occur.

20.3 If the Supplier notifies the Authority as required by clause 20.2, the Supplier must respond promptly to their further enquiries, co-operate with any investigation and allow the audit of any books, records and relevant documentation.

20.4 If the Supplier or the Supplier's Representatives engage in conduct prohibited by clause 20.1 or commits fraud in relation to the Agreement or any other agreement with a Crown Body (including the Authority) the Authority may:

20.4.1 require the Supplier to remove any of the Supplier's Representatives from providing the Services if their acts or omissions have caused the default; and

20.4.2 immediately terminate the Agreement.

21. EQUALITY, DIVERSITY AND HUMAN RIGHTS

21.1 The Supplier must follow all applicable employment and equality Law when they perform their obligations under the Agreement, including:

21.1.1 protections against discrimination on the grounds of race, sex, gender reassignment, religion or belief, disability, sexual orientation, pregnancy, maternity, age or otherwise; and

21.1.2 any other requirements and instructions which the Authority reasonably imposes related to equality Law.

21.2 The Supplier must use all reasonable endeavours, and inform the Authority of the steps taken, to prevent anything that is considered to be unlawful discrimination by any court or tribunal, or the Equality and Human Rights Commission (or any successor organisation) when working on the Agreement.

22. HEALTH AND SAFETY

22.1 The Supplier must perform its obligations meeting the requirements of:

22.1.1 all applicable Law regarding health and safety; and

22.1.2 the Authority's current health and safety policy while at the Authority's premises, as provided to the Supplier.

22.2 The Supplier and the Authority must as soon as possible notify the other of any health and safety incidents or material hazards they're aware of at the Authority premises that relate to the performance of the Agreement.

23. ENVIRONMENT AND SUSTAINABILITY

23.1 In performing its obligations under the Agreement, the Supplier shall, to the reasonable satisfaction of the Authority:

23.1.1 meet, in all material respects, the requirements of all applicable Laws regarding the environment; and

23.1.2 comply with its obligations under the Authority's current environmental policy, which the Authority must provide.

23.2 The Supplier must ensure that the Supplier's Representatives are aware of the Authority's environmental policy.

24. OBEYING THE LAW

24.1 the Supplier shall comply with the provisions of:

24.1.1 the Official Secrets Acts 1911 to 1989; and

24.1.2 section 182 of the Finance Act 1989.

24.2 the Supplier indemnifies the Authority against any costs resulting from any Default by the Supplier relating to any applicable Law.

24.3 the Supplier must appoint a Compliance Officer who must be responsible for ensuring that the Supplier complies with Law, clause 24.1 and clauses 20 to 23, 26, and 27.

25. DEALING WITH CLAIMS

25.1 if a Beneficiary is notified of a Claim then it must notify the Indemnifier as soon as reasonably practical and no later than 10 Working Days.

25.2 at the Indemnifier's cost the Beneficiary must both:

25.2.1 allow the Indemnifier to conduct all negotiations and proceedings to do with a Claim; and

25.2.2 give the Indemnifier reasonable assistance with the claim if requested.

25.3 the Beneficiary must not make admissions about the Claim without the prior written consent of the Indemnifier which cannot be unreasonably withheld or delayed.

25.4 the Indemnifier must consider and defend the Claim diligently using competent legal advisors and in a way that doesn't damage the Beneficiary's reputation.

25.5 the Indemnifier must not settle or compromise any Claim without the Beneficiary's prior written consent which it must not unreasonably withhold or delay.

25.6 each Beneficiary must use all reasonable endeavours to minimise and mitigate any losses that it suffers because of the Claim.

25.7 if the Indemnifier pays the Beneficiary money under an indemnity and the Beneficiary later recovers money which is directly related to the Claim, the Beneficiary must immediately repay the Indemnifier the lesser of either:

25.7.1 the sum recovered minus any legitimate amount spent by the Beneficiary when recovering this money; and

25.7.2 the amount the indemnifier paid the Beneficiary for the Claim.

26. TAX

26.1 The Supplier must not breach any tax or social security obligations and must enter into a binding agreement to pay any late contributions due, including where applicable, any interest or any fines.

26.2 Where the Supplier or any Supplier Staff are liable to be taxed or to pay National Insurance contributions in the UK relating to payment received under the Contract, the Supplier must both:

26.2.1 comply with the Income Tax (Earnings and Pensions) Act 2003 and all other statutes and regulations relating to income tax, the Social Security Contributions and Benefits Act 1992 (including IR35) and National Insurance contributions; and

26.2.2 indemnify the Authority against any Income Tax, National Insurance and social security contributions and any other liability, deduction, contribution, assessment or claim arising from or made during or after the Contract Period in connection with the provision of the Services by the Supplier or any of the Supplier Staff.

26.3 If any of the Supplier Staff are Workers who receive payment relating to the Services, then the Supplier must ensure that its contract with the Worker contains the following requirements:

26.3.1 the Authority may, at any time during the Contract Period, request that the Worker provides information which demonstrates they comply with Clause 26.2.1, or why those requirements do not apply, the Authority can specify the information the Worker must provide and the deadline for responding;

26.3.2 the Worker's contract may be terminated at the Authority's request if the Worker fails to provide the information requested by the Authority within the time specified by the Authority;

26.3.3 the Worker's contract may be terminated at the Authority's request if the Worker provides information which the Authority considers isn't good enough to demonstrate how it complies with Clause 26.2.1 or confirms that the Worker is not complying with those requirements; and

26.3.4 the Authority may supply any information they receive from the Worker to HMRC for revenue collection and management.

27. CONFLICT OF INTEREST

27.1 The Supplier must take action to ensure that neither the Supplier nor the Supplier Staff are placed in the position of an actual, potential or perceived Conflict of Interest.

27.2 The Supplier must promptly notify and provide details to the Authority if an actual, potential or perceived Conflict of Interest happens or is expected to happen.

27.3 The Authority will consider whether there are any appropriate measures that can be put in place to remedy an actual, perceived or potential Conflict of Interest. If, in the reasonable opinion of the Authority, such measures do not or will not resolve an actual or potential Conflict of Interest, the Authority may terminate its Agreement immediately by giving notice in writing to the Supplier where there is or may be an actual or potential Conflict of Interest.

28. NOTICES

28.1 A notice served under this Agreement:

28.1.1 shall be in writing in the English language;

28.1.2 shall be signed by or on behalf of the Party giving it;

28.1.3 shall be sent for the attention of the relevant persons identified in Section 14 of the Order Form.

29. ENTIRE AGREEMENT

29.1 This Agreement and the documents referred to in it constitute the whole agreement and understanding of the Parties and supersede any previous arrangement, understanding or agreement between them relating to the subject matter of this Agreement.

29.2 Each Party acknowledges that, in entering into this Agreement, it has not relied on any statement, representation, assurance or warranty (whether made negligently or innocently) other than those expressly set out in this Agreement or the documents referred to in it.

29.3 Each Party agrees that all liability for and remedies in respect of any representations are excluded except as expressly provided in this Agreement.

30. **SEVERABILITY**

30.1 If any court of competent authority finds that any provision of this Agreement is invalid, illegal or unenforceable, that provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected.

30.2 If any invalid, illegal or unenforceable provision of this Agreement would be valid, legal and enforceable if some part of it were modified or amended, the Parties shall negotiate in good faith to amend such provision such that, as amended, it is valid, legal and enforceable, and, to the greatest extent possible, achieves the Parties' original commercial intention.

31. **NO PARTNERSHIP OR AGENCY**

Nothing in this Agreement shall create, evidence or imply any agency, partnership or joint venture between the Parties. No Party shall act or describe itself as the agent of the other Party nor shall it represent that it has any authority to make commitments on behalf of the other Party.

32. **RIGHTS OF THIRD PARTIES**

No term of this Agreement shall be enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a Party to this Agreement, but this does not affect any right or remedy of a third party which exists or is available apart from under that Act.

33. **ASSIGNMENT**

33.1 The Authority may at any time transfer, assign, novate or otherwise dispose of its rights and obligations under this Agreement or any part of this Agreement to any Contracting Authority, and the Supplier warrants that it will carry out all such reasonable further acts required to effect such transfer, assignment, novation or disposal.

33.2 Other than to Subcontract or delegate some of its obligations under this Agreement with the prior written consent of the Authority (such consent to be at the Authority's discretion), the Supplier may not assign, transfer, mortgage, charge, or grant any interest in, the whole or any part of the benefit of, or any of its rights or obligations or interests under, this Agreement.

34. **COUNTERPARTS**

This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same Agreement.

35. **GOVERNING LAW AND JURISDICTION**

35.1 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with English law.

35.2 The Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter or formation (including non-contractual disputes or claims).

ANNEX 1

SERVICES SPECIFICATION

Specification for Product (Lagevrio) Co-packaging

Activity

- Associate individual product packages (single packs) with the relevant Batch Specific Variation letter (Patient Letter) and ensure packaging is robust enough to withstand light handling to maintain the association between Product and letter, ideally using a clear plastic bag.
- Place co-packaged Product in the original external packaging or provide suitable alternative external packaging.
- Associate the Product with a unique Product identifier to differentiate from unprocessed Product on relevant IT stock management systems.
- The above activity to be undertaken in accordance with Good Manufacturing Practices principles, with defined process steps and record keeping.
- Above process steps to be undertaken in an environment which maintains manufacturer specified storage temperatures (as specified in relevant Summary of medical Product Characteristics (SmPC) issued by the Marketing Authorisation holder (Merck Sharp & Dohme)
- Final Product to be released by the Supplier Qualified Person as compliant with the above specification.
- Final Product to be held at storage temperature as specified in SmPC until issued to customer or disposed of.

Quantity

- Total quantity of [redacted]
- To be packaged in instalments as detailed in the relevant Order to represent economically sensible processing volumes but no greater than [redacted] Patient Courses in a single batch.
- Each batch shall be processed, released by the Supplier Qualified Person and available for distribution to end-users within 10 working days from receiving a request from the Authority.

Messaging Activity

- Print the DHCP Letter (2 sheets of A4, double sided) and distribute this to the pharmacies automatically in the Tote box each time a pharmacy orders Lagevrio (one DHCP Letter per order bundle as opposed to 1 DHCP Letter per Patient Course).
- This would be limited to no more than 2 DHCP Letters per pharmacy

Quantity

- (Note: as at the date of this Agreement it is estimated that the Authority would need to prepare up to [redacted] DHCP Letters based on the last 12 months of orders, there have been 2316 unique pharmacies who have placed orders of Lagevrio (comprising [redacted] Patient Courses) so with a maximum of 2 DHCP Letters per pharmacy (1 for the first order, plus an additional letter as a contingency), [redacted] has been calculated on this basis but may be varied by the Parties in writing in accordance with the Agreement).

ANNEX 2

CHARGES

Co-packing: [redacted]

DHCP Letter: [redacted]