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| **Agreement**  **between**  **The Common Services Agency**  **and**  ***Company Name***  **Pre-HTA FOC Scheme Agreement** |
| **File Ref: XPFC/GEN/1 JMS/LW** |

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**AGREEMENT**

between

**THE COMMON SERVICES AGENCY**

more commonly known as National Services Scotland, constituted pursuant to the National Health Service (Scotland) Act 1978 and having its headquarters at Gyle Square, 1 South Gyle Crescent, EDINBURGH EH12 9EB

(“**NSS**”), acting for itself and on behalf of NHS Scotland Health Boards

and

**Company Name**

**Company designation (to include Registration Number and Registered Address)**

(the “**Supplier**”)

# DEFINITIONS AND INTERPRETATIONS

* 1. In this Agreement the following expressions shall, unless otherwise specified or the context otherwise requires, have the following meanings:

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| **“1978 Act”** | means the National Health Service (Scotland) Act 1978, as amended; |
| **“Affiliate”** | means any company which (directly or indirectly) controls, is controlled by and/or is under common control with the Supplier; |
| **“Agreement”** | means this Pre-HTA FOC Scheme agreement; |
| **“Applicable Laws”** | means all applicable laws, rules, regulations, including case law, as well as any guidance, guidelines and requirements of any regulatory authorities and any industry codes of practice in effect from time to time applicable to the activities performed under this Agreement; |
| **“Approved Indications”** | Means **Enter approved indication(s)**, being Indication(s) that are within the scope of this Agreement; |
| **“Board”** | means an NHS Scotland Health Board, a statutory body constituted in terms of the 1978 Act; |
| **“Commencement Date”** | means the last date of execution of this Agreement; |
| **“Confidential Information”** | means: (i) all information relating to the identity, condition or medical history of any NHS patients (including Patients); (ii) information, the disclosure of which is otherwise subject to exemption from disclosure under the Freedom of Information (Scotland) Act 2002 or disclosure of which is prohibited in terms of the Data Protection Legislation; |
| **“Data Protection Legislation”** | means (i) the GDPR and any applicable national implementing Laws as amended from time to time; (ii) the DPA 2018 to the extent that it relates to the Processing of Personal Data and privacy; and (iii) any other Law in force from time to time with regards to the Processing of personal data and privacy, which may apply to either Party in respect of its activities under the Agreement; |
| **“DPA 2018”** | means the Data Protection Act 2018; |
| **“Price”** | means Enter Price per Pack, being the price of the Product; |
| **“Product”** | Means the following presentations of **Enter Generic Name (Enter Brand Name)**®;   |  |  |  | | --- | --- | --- | | **Strength** | **Form** | **Pack Size** | | **strength** | **Form** | **Size** | | **strength** | **Form** | **Size** | | **strength** | **Form** | **Size** | | **strength** | **Form** | **Size** | |
| **“Force Majeure”** | means any circumstances beyond the reasonable control of either party (including, without limitation, any strike, lock-out or other industrial action); |
| **“GDPR”** | means the General Data Protection Regulation​ (Regulation (EU) 2016/679); |
| **“NHSS”** | means the National Health Service Scotland; |
| **“Party or Parties”** | means the Supplier, NSS and each of the Boards; |
| **“Patient”** | means a person who is enrolled on the Pre-HTA FOC Scheme established by this Agreement during the Patient Enrolment Period and receives treatment or care from a Board; |
| **“Patient Enrolment Period”** | means the period during which patients may be enrolled on the Pre-HTA FOC Scheme established by this Agreement by a Board, being the period from the Commencement Date until the date of publication by SMC of a Detailed Advice Document to Boards in relation to the Product following submission to SMC by the Supplier or Affiliate in relation to the Product for the Approved Indications, or until the date the Product is made available through the NHSS ultra-orphan pathway for the Approved Indications; |
| **“Pre Health Technology Assessment Free of Charge Pricing Scheme (Pre-HTA FOC Scheme)”** | means a scheme proposed by pharmaceutical companies prior to a health technology assessment recommendation from the Scottish Medicines Consortium that enables provision of a drug to Boards at either no charge or at a cost of £1.00 per pack or less; |
| **“SMC”** | means the Scottish Medicines Consortium; |
| **“Supplier’s Representative”** | means the party appointed by the Supplier as its representative and notified to NSS in Writing; |
| **“Supply”** | means the supply of the Product for the treatment of Patients; |
| **“Term”** | means the term of this Agreement, being the period from the Commencement Date until either (i) the date occurring ninety (90) days after the publication by SMC of a Detailed Advice Document to Boards recommending the use of the Product by NHSS for the Approved Indications or (ii) the date occurring ninety (90) days after the Product is made available for prescribing in NHSS under the ultra‑orphan pathway for the Approved Indications or (iii) an individual Patient enrolled on the Pre-HTA FOC Scheme no longer requires the medicine on clinical grounds if either the Detailed Advice Document to Boards published following a submission by the Supplier or Affiliate does not recommend the use of the Product by NHSS or where the Patient is within a sub-group that falls outside of an SMC prescribing restriction; |
| **“Writing”** | means any communication in writing including electronic mail and written shall be construed accordingly. |

* 1. In this Agreement unless otherwise specified or the context otherwise requires:
     1. words importing the singular only shall include the plural and vice versa;
     2. reference in this Agreement to a provision of a statute shall be construed as a reference to that provision as amended, re-enacted or extended at the relevant time;
     3. reference to a Clause means a Clause of this Agreement; and
     4. the headings in this Agreement are for convenience only and shall not affect its interpretation.

# PATIENT REGISTRATION AND SUPPLY

* 1. Each of the Boards shall be entitled to enrol Patients on the Pre-HTA FOC Scheme established by this Agreement during the Patient Enrolment Period.
  2. The Supplier shall supply, and the Board shall be entitled to purchase, the Product for the Approved Indications for Patients at the Price in accordance with this Agreement during the Term.
  3. The Product will be supplied to Patients through hospital pharmacies and the following medicines homecare providers: **Enter Homecare Provider(s)**
  4. The Supplier shall provide NSS with a report of Board activity under this Agreement on a monthly basis, such report to include on a Board basis: the volume of Product supplied to Patients.

# REPRESENTATIVES

All queries and day to day communications regarding the operation of this Agreement shall be dealt with by NSS and the Supplier’s Representatives in the first instance and NSS and the Supplier’s Representative shall directly liaise for the purposes of monitoring and reviewing the operation and performance of this Agreement.

# LIMITATION OF LIABILITY

* 1. Nothing in this Agreement limits or excludes a Party’s liability for death or personal injury arising out of negligence, for fraud, fraudulent misrepresentation, criminal acts, or where such a limitation or exclusion would be contrary to law.
  2. Subject to Clause 4.1 of this Agreement, neither Party, nor any of its Affiliates, shall be liable to the other Party or its Affiliates for any indirect, special, exemplary or consequential loss of any kind.

# FREEDOM OF INFORMATION AND DATA PROTECTION

* 1. All Parties warrant that all necessary steps will be taken to maintain full compliance with Data Protection Legislation. No Confidential Information relating to the identity, condition, medical treatment or history of a Patient will be provided to a Supplier further to this Agreement.
  2. NSS shall provide information about the Pre-HTA FOC Scheme to Boards and the Supplier shall not promote or market the Pre-HTA FOC Scheme directly to clinicians or patients.
  3. Nothing whether expressly provided in this Agreement, or otherwise implied, shall preclude NSS or a Board from making public under the Freedom of Information (Scotland) Act 2002 and the Environmental Information (Scotland) Regulations 2004 and/or any codes or regulations applicable from time to time relating to access to public authorities’ information (“FOI”), details of all matters relating to this Agreement unless (i) such information constitutes Confidential Information; (ii) the disclosure of such details would or would be likely to prejudice substantially the commercial interests of any person (including but not limited to the Supplier, NSS or any Board); or (iii) such details fall within any other exemption under FOI provided always that application of any such exemption referred to at (i), (ii), (iii) above shall be at the sole discretion of NSS or the Board as the case may be. NSS and each Board will take all reasonable steps to provide the Supplier with notice of any intended disclosures under FOI prior to making such information public.
  4. The Supplier shall:
     1. transfer any request for information relating to this Agreement to NSS as soon as practicable after receipt and in any event within five (5) Days of receiving such request for information;
     2. provide all such assistance as may be required by NSS to enable the Board to comply with its obligations under FOI and Data Protection Legislation.

# ASSIGNATION AND AFFILIATES

* 1. NSS, acting reasonably, shall consider any application for assignation of this Agreement to a third party by the Supplier where the Supplier intends to assign or sell its rights in relation to the supply of the Product to such third party.
  2. This Agreement shall automatically devolve to the statutory successors of NSS and the Boards and NSS shall give reasonable notice to the Supplier of any such changes.
  3. For the avoidance of doubt, NSS and the Boards acknowledge that the Supplier is entering into this Agreement on behalf and for the benefit of all of the Supplier’s Affiliates. The Agreement is intended to confer a benefit on such Affiliates provided that the rights of such Affiliates under this Agreement shall only be enforceable by the Supplier on their behalf.
  4. The Supplier acknowledges that NSS is entering into this Agreement for and on behalf of itself and each Board and this Agreement is for the benefit of NSS and each Board.

# FORCE MAJEURE

* 1. If any Party is affected by Force Majeure it shall promptly notify the other Party of the nature and extent of the circumstances in question.
  2. No Party shall be deemed to be in breach of this Agreement, or otherwise be liable to any other, for any delay in performance or non-performance of any of its obligations under this Agreement to the extent that the delay or non-performance is due to any Force Majeure and the time for performance of that obligation shall be extended accordingly.

# TERMINATION

* 1. This Agreement may be terminated immediately at any time by NSS or the Supplier giving Written notice to the other for that purpose in the event that:
     1. the Product is withdrawn from the global market by the Supplier or by order of any regulatory authority due to concern regarding the safety of the Product; or
     2. there is any publicly announced investigation of the affairs of a Party by a regulatory authority relating to any suspected or actual breach of any Applicable Law by that Party such that the continued operation of this Agreement would, in the reasonable opinion of the other Party, have a material adverse effect on the reputation of that other Party.
  2. NSS may terminate this Agreement immediately if NSS determines that this Agreement cannot be lawfully continued.
  3. Termination shall not affect the pre-existing rights and obligations of the Parties under this Agreement or the continuing rights and obligations which are expressly or by implication intended to survive termination.

# GENERAL

* 1. No variation of this Agreement shall be binding unless agreed in Writing between NSS and the Supplier’s Representative.
  2. A notice required or permitted to be given to a Party under this Agreement shall be in Writing delivered personally, sent by first class recorded delivery post or sent by e-mail. Notices shall be addressed to NSS at its principal place of business or to the Supplier at its registered office or such other address for receipt of notices (including e-mail address) as may previously have been notified to the other party in Writing. A notice shall be deemed to have been served:
     1. if personally delivered, at the time of delivery;
     2. if posted, at the expiration of forty-eight (48) hours after the envelope letter was delivered into the custody of the postal authorities; or
     3. if sent by e-mail, on receipt of notification of delivery.
  3. No waiver by a Party of any breach of this Agreement by another shall be considered as a waiver of any subsequent breach of the same or any other provision.
  4. If any provision of this Agreement is held by a court or other competent authority to be invalid or unenforceable in whole or in part the validity of the other provisions of this Agreement and the remainder of the provision in question shall not be affected.
  5. The Supplier acknowledges that prescribing decisions made by individual clinicians and approved by a Board will be determined by the clinical needs of the Patients and the Boards by entering into this Agreement make no commitment to purchase the Product.
  6. The Parties agree that this Agreement does not effect as a reward or incentive for an individual’s past, present or future willingness to prescribe, supply, administer, recommend, buy or sell the Product or any other product sold or provided by the Supplier or as an incentive to grant an interview for sales or marketing purposes.
  7. The Parties confirm that they will comply with all Applicable Laws, statutes, regulations and codes relating to anti-bribery and anti-corruption including, but not limited to the Bribery Act 2010.
  8. Nothing is intended to, nor shall be deemed to establish any partnership or joint venture or agency between the Boards and the Supplier or between NSS and the Supplier.

# GOVERNING LAW

This Agreement shall be governed and construed in accordance with the laws of Scotland and the Parties hereby submit to the non-exclusive jurisdiction of the Scottish Courts.

**IN WITNESS WHEREOF** these presents typewritten on this and the preceding pages are executed as follows:-

|  |  |
| --- | --- |
| For and on behalf of **The Common Services Agency** | |
| Place | Date |
| Signed by | Witnessed by |
| Print Name | Print Name |
| Designation | Designation |
|  | Address |
| For and on behalf of **Company Name** | |
| Place Click here to enter text. | Date Click here to enter text. |
| Signed by | Witnessed by |
| Print Name Click here to enter text. | Print Name Click here to enter text. |
| Designation Click here to enter text. | Designation Click here to enter text. |
|  | Address Click here to enter text. |