NHS SCOTLAND

STANDARD TERMS

FOR

PRIMARY CARE REBATE SCHEMES

VERSION 5.0 / JULY 2023

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1. DEFINITIONS AND INTERPRETATIONS

1.1 In these Terms the following expressions shall, unless otherwise specified or the context otherwise requires, have the following meanings:-

"1978 Act"	means the National Health Service (Scotland) Act 1978;
"Affiliate"	means any company which (directly or indirectly) controls, is controlled by and/or is under common control with the Supplier;
"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 the PCRS Agreement;
"Board"	means an NHS Scotland Health Board, or other statutory body constituted in terms of the 1978 Act;
"Confidential Information"	means (a) all Patient Identifiable Information; and (b) all information the disclosure of which would or would be likely to prejudice substantially the commercial interests of any person;
"Device"	means the medical device supplied by the Supplier for the use by a Patient or Patients for a medical purpose and that is the subject of a Primary Care Rebate Scheme and is identified in the PCRS Submission and Approval Letter;
"Drug"	means the pharmaceutical or medicinal product supplied by the Supplier for the treatment of a Patient or Patients that is the subject of a Primary Care Rebate Scheme and is identified in the PCRS Submission and Approval Letter;
"Gross Ingredient Cost"	means the total value charged to the Health Boards prescribing budget for each strength and formulation of the Drug or Device within the scope of the PCRS Agreement. This value is calculated in the Prescribing Information System for Scotland from the reimbursements to NHS Dispensing Contractors i.e. the quantity supplied multiplied by NHS List Price for the Drug or Device.
"Force Majeure"	means any circumstances beyond the reasonable control of the affected Party (including, without limitation, any strike, lock-out or other industrial action which is not confined to the workforce of the affected Party) and which could not have been avoided or mitigated by the exercise of all reasonable care by that Party and further provided that such event materially affects the ability of the Party seeking to rely upon it to perform its obligations under the PCRS Agreement;
"**Indirect Taxes**"	means value added taxes, sales taxes, consumption taxes and other similar taxes;

"NSS"	means the Common Services Agency, a statutory body constituted by section 10 of the 1978 Act;
"NHS Dispensing Contractors"	means a community pharmacy business, a dispensing doctor, an appliance supplier or stoma provider with a contract to provide a NHS dispensing service;
"Party or Parties"	means the Board and the Supplier identified in the PCRS Approval Letter that enter into a PCRS Agreement;
"Patient"	means a person who receives treatment or care from the Board and/or paid for by the Board or where the Board reimburses the cost of treatment of drugs or devices prescribed;
"Patient Identifiable Information"	means information relating to the identity, medical condition or history of a Patient, or the patient or prospective patient of any Board and any and all data generated and/or derived therefrom;
"Primary Care Rebate Scheme"	means the scheme proposed by pharmaceutical companies and operated by Boards to improve the cost effectiveness of drugs or devices dispensed in primary care;
"PCRS Agreement"	means an agreement between a Supplier and a Board in respect of a Primary Care Rebate Scheme for the Drug or Device established by the PCRS Approval Letter and constituted and governed by the PCRS Submission, PCRS Approval Letter and these Terms;
"PCRS Approval Letter"	means the letter issued by or on behalf of the Board approving the Supplier's PCRS Submission for its Drug or Device to be accepted further to a Primary Care Rebate Scheme, which approval may be subject to such conditions or qualifications of the PCRS Submission as the Board and the Supplier may have agreed in advance;
"PCRS Submission"	means a proposal from the Supplier to facilitate the use of its Drug or Device in the treatment of Patients by reducing the cost of treatment;
"Rebate"	means the rebate provided by the Supplier in accordance with clause 5 of the PCRS Submission;
"Representative"	means the representative of a Party, as notified to the other Party pursuant to Clause 3.1 of these Terms;
"Supplier"	means the pharmaceutical company that receives the PCRS Approval Letter for the Drug or Device that may be purchased or paid for by the Board for use in the treatment of a Patient in accordance with a particular PCRS Agreement;
"Supplier Confidential Information"	means such information as is identified by the Supplier in the PCRS Submission as confidential because of its commercial sensitivity and having the necessary quality of confidence;

"Supply"	Means the supply of the Drug or Device for the treatment of Patients within the Board's geographical area of responsibility;
"Terms"	means these standard terms for the operation of Primary Care Rebate Schemes in Scotland ;
"Writing"	means any communication in writing including by electronic mail and "**Written**" shall be construed accordingly.

1.2 In these Terms unless otherwise specified or the context otherwise requires:-

1.2.1 words importing the singular only shall include the plural and vice versa;

1.2.2 reference in these Terms 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;

1.2.3 reference to a Clause means a Clause of these Terms;

1.2.4 the headings in these terms are for convenience only and shall not affect their interpretation; and

1.2.5 in the event of any inconsistency or ambiguity between the terms of the PCRS Submission and the PCRS Approval Letter and/or these Terms, the operation of the PCRS Agreement shall be governed by the PCRS Approval Letter, the PCRS Submission and these Terms in that order.

2. COST REDUCTION MECHANISMS

2.1 All Rebates shall be made in accordance with the claim procedures set out in the PCRS Submission and the PCRS Approval Letter.

2.2 The Supplier undertakes that any usage data received pursuant to the PCRS Agreement is for the sole purpose of assisting the calculation of any Rebate due to the Boards for the relevant financial quarter.

3. REPRESENTATIVES

3.1 The Representatives of the Parties for the purposes of administering the PCRS Agreement shall be as notified in Writing by one Party to the other from time to time.

3.2 All queries and day to day communications regarding the operation of the PCRS Agreement shall be dealt with by the Parties' Representatives in the first instance and the Board's Representative and the Supplier's Representative shall directly liaise for the purposes of monitoring and reviewing the operation and performance of the PCRS Agreement.

4. LIMITATION OF LIABILITY

4.1 Nothing in the PCRS 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.

4.2 Subject to Clause 4.1 of these Terms, neither Party nor any of its Affiliates shall be liable to the other Party or its Affiliates in contract, delict (including negligence), or otherwise, for any indirect, special, exemplary or consequential loss of any kind.

5. CONFIDENTIALITY AND FREEDOM OF INFORMATION

5.1 Both Parties agree and confirm that no Patient Identifiable Information will be provided to the Supplier further to the PCRS Agreement.

5.2 The Board shall treat as confidential all Supplier Confidential Information and shall not disclose to any third party without the prior Written consent of the Supplier any Supplier Confidential Information; provided that such undertaking will not apply where the information:

5.2.1 is or becomes public knowledge other than by breach of this Clause 5;

5.2.2 is in the possession of the Board without restriction in relation to disclosure before the date of receipt;

5.2.3 is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;

5.2.4 is independently developed without access to the Supplier Confidential Information;

5.2.5 to the extent that the Board is required to disclose such Supplier Confidential Information by law or any regulatory or government authority (but only to that extent) and provided that to the extent the Board is legally able to do so it shall (i) advise the Supplier as soon as reasonably practicable of any such legal requirement made of it by a regulatory or governmental authority to disclose Confidential Information, (ii) seek an opportunity for the Supplier to make representations to the regulatory or governmental authority, and (iii) advise the regulatory or governmental authority of the confidential nature of the Supplier Confidential Information.

5.3 Nothing contained in this Clause 5 shall prevent the Board from disclosing any Supplier Confidential Information wherever disclosure is required by virtue of the Board's status as an NHS entity to a department, office or agency of the Scottish Government or to any other NHS entity or to any consultant, contractor or other person engaged by the Board in connection with the PCRS Agreement; Provided that the Board shall require the recipient of such Supplier Confidential Information to accept an obligation of confidentiality in relation to such Supplier Confidential Information in terms no less onerous than contained in these Terms.

5.4 Nothing whether expressly provided in the PCRS Agreement, or otherwise implied, shall preclude the 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 the PCRS Agreement unless (i) such information constitutes a trade secret; (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 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 the Board. The Board will take all reasonable steps to provide the Supplier with notice of any intended disclosures under FOI prior to making such information public.

5.5 The Supplier shall:

5.5.1 transfer any request for information relating to the PCRS Agreement to the Board as soon as practicable after receipt and in any event within five (5) Days of receiving such request for information;

5.5.2 provide all such assistance as may be required by the Board, and to enable the Board to comply with its obligations under FOI.

6. ASSIGNATION AND AFFILIATES

6.1 The Board, acting reasonably, shall consider any application for assignation of the PCRS 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 Drug or Device to such third party.

6.2 The PCRS Agreement shall automatically devolve to the statutory successors of the Board and the Board shall give reasonable notice to the Supplier of such changes.

6.3 For the avoidance of doubt, the Board acknowledges that the Supplier is entering into the PCRS 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 the PCRS Agreement shall only be enforceable by the Supplier on their behalf.

7. FORCE MAJEURE

7.1 If either Party is affected by Force Majeure it shall promptly notify the other Party of the nature and extent of the circumstances in question.

7.2 Neither Party shall be deemed to be in breach of these Terms, or otherwise be liable to the other, for any delay in performance or the non-performance of any of its obligations under the PCRS 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.

8. TERMINATION

8.1 The PCRS Agreement may be terminated immediately at any time by either Party ("the Terminating Party") giving Written notice to the other in the event that:

8.1.1 the Drug or Device is withdrawn by the Supplier or by order of any regulatory authority; or

8.1.2 there is any publicly announced investigation of the affairs of the other Party by a regulatory authority relating to any suspected or actual breach of any Applicable Law by that other Party such that the continued operation of the PCRS Agreement would, in the reasonable opinion of the Terminating Party, have a material adverse effect on the reputation of the Terminating Party; or

8.1.3 the Supplier chooses to make a List Price reduction for the Drug or Device (other than a temporary List Price reduction) which reduces the List Price of the Drug or Device below the effective price after Rebate.

8.2 The Board may terminate the PCRS Agreement immediately if the Board determines that the PCRS Agreement cannot be lawfully continued.

8.3 The Board may terminate the PCRS Agreement at any time on giving at least thirty (30) days notice.

8.4 The Supplier may terminate the PCRS Agreement at the end of the agreement period (as identified in the PCRS Submission); on giving at least ninety (90) days notice of termination.

If no notice is received by this date, the PCRS Agreement shall automatically renew for successive periods of one year (1) thereafter.

8.5 Termination shall not affect the pre-existing rights and obligations of the Parties under the PCRS Agreement or the continuing rights and obligations which are expressly or by implication intended to survive termination including the right to Rebate in respect of the period up to the date of termination or expiry and provisions relating to Confidentiality.

9. UNRESOLVED MATTERS

9.1 It is the intention of the Board and the Supplier to resolve any dispute or difference between them by mutual dialogue consistent with the overall aims and objectives of the PCRS Agreement. Any matter under the PCRS Agreement, either in relation to its interpretation or application or otherwise relating to the rights and obligations of the Board and the Supplier shall be referred to their respective Chief Executives or to the duly authorised persons designated by the Chief Executives if the matter cannot be resolved by the Board Representative and the Supplier Representative in the first instance. The matter shall be referred within two months of the date that the Board or the Supplier first identify the matter as unresolved. Dialogue in the form of discussions, correspondence and minutes of meetings shall be confidential.

9.2 The Board and the Supplier and where relevant their Chief Executives or representatives shall meet to consider the possible avenues for resolution of any dispute or difference. Prior to such meetings the Board and the Supplier may take expert advice on matters in dispute as appropriate.

9.3 If agreed between the Board and the Supplier and where relevant their Chief Executives or representatives, they shall be free at any time to refer an unresolved matter to an independent review panel composed of expert or experts who have appropriate management, technical, professional and/or business skills to independently report on the dispute. Any conflicts such experts may have must be declared. The remit of such expert or experts and the reliance to be placed on any such report, the deadlines that apply to hearings of the panel and to the production of its report, the sharing of costs of the panel and the action to be taken in light of any such report shall be determined by the Board and the Supplier and where relevant their Chief Executives or representatives.

10. GENERAL

10.1 No variation of these Terms shall be binding unless agreed in Writing between the Board's Representative and the Supplier's Representative.

10.2 A notice required or permitted to be given by either Party to the other under these Terms or the PCRS Agreement shall be in Writing delivered personally, sent by first class recorded delivery post or sent by email. Notices shall be addressed to that other Party at its registered office or principal place of business or such other address for receipt of notices (including email address) as either Party may previously have notified the other party in Writing. A notice shall be deemed to have been served:

10.1.1 if personally delivered, at the time of delivery;

10.1.2 if posted, at the expiration of forty-eight (48) hours after the envelope letter was delivered into the custody of the postal authorities; or

10.1.3 if sent by email, on receipt of notification of delivery.

10.2 No waiver by either party of any breach of the PCRS Agreement by the other shall be considered as a waiver of any subsequent breach of the same or any other provision.

10.3 If any provision of the PCRS 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 these Terms and the remainder of the provision in question shall not be affected.

10.4 The Board is under no direct or indirect obligation to utilise the Rebate for a specific purpose.

10.5 The Board acknowledge that prescribing decisions made by individual clinicians will be determined by the clinical needs of the Patients. The Board will remain free at all times to use and promote the use within the Board of any treatment. The Board is not under any obligation to endorse or increase the usage of the Drug, Device or any other product of the Supplier. The Parties are not agreeing that the Drug or Device either is or is not medically superior to any other product.

10.6 The Supplier and the Board agree that this PCRS 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 Drug, Device or any other product sold or provided by the Supplier or as an incentive to grant an interview for sales or marketing purposes.

10.7 Both parties confirm that they will comply with all Applicable Laws, statues, regulations and codes relating to anti-bribery and anti-corruption including, but not limited to the Bribery Act 2010.

10.8 Nothing is intended to, or shall be deemed to, establish any partnership or joint venture between the Parties, constitute any Party the agent of the other Party, nor authorise a Party to make or enter into any commitments for or on behalf of the other party.

10.9 The Rebate payment is inclusive of all Indirect Taxes. If any Indirect Taxes are applicable, the Supplier shall pay such Indirect Taxes at the applicable rate.

11. GOVERNING LAW

11.1 These Terms and any PCRS 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.