



NHS SCOTLAND

STANDARD TERMS FOR PATIENT ACCESS SCHEMES

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NHS Scotland Central Legal Office © 2020

Anderson House, Breadalbane Street, Bonnington Road, Edinburgh, EH6 5JR
(Tel: 0131 275 7838 / Fax: 0131 275 7994)
Website: <http://www.show.scot.nhs.uk/clo>

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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, as amended;
“Affiliate”	means any company which (directly or indirectly) controls, is controlled by and/or is under common control with the Supplier;
“Board”	means an NHS Scotland Health Board, a statutory body constituted in terms of the 1978 Act;
“Board’s Representative”	means the party appointed by the Board and notified to the Supplier pursuant to Clause 5 below;
“Confidential Information”	means: (i) all information relating to the identity, condition or medical history of any NHS patients (including Patients); (ii) Supplier Confidential Information ; and (iii) information, the disclosure of which is otherwise subject to exemption from disclosure under the Freedom of Information (Scotland) 2002 or is prohibited in terms of the Data Protection Legislation;
“Data Protection Legislation”	means the General Data Protection Regulation (Regulation (EU) 2016/679), the Data Protection Act 2018 and any other law in force from time to time with regards to the processing of personal data and privacy;
“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 Patient Access Scheme and is identified in the PAS Submission and Approval Letter;
“Force Majeure”	means any circumstances beyond the reasonable control of either party (including, without limitation, any strike, lock-out or other industrial action);
“NHSS”	means the National Health Service Scotland;

“HIS”	means Healthcare Improvement Scotland, a statutory body established by section 10A of the 1978 Act;
“NSS”	means the Common Services Agency, a statutory body constituted by section 10 of the 1978 Act;
“Parties”	means the Board and the Supplier identified in the PAS Approval Letter that enter into a PAS 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 or drugs prescribed;
“Patient Access Scheme”	means the scheme proposed by pharmaceutical companies and operated by NHSS Health Boards with the support of HIS and NSS to improve the cost effectiveness of new drugs;
“PAS Agreement”	means an agreement between a Supplier and a Board in respect of a Patient Access Scheme for the Drug established by the PAS Approval Letter and constituted and governed by the PAS Submission, PAS Approval Letter and these Terms;
“PAS Approval Letter”	means the letter issued by or on behalf of the Board approving the Supplier’s Submission for a Patient Access Scheme, which approval may be subject to such conditions or qualifications of the PAS Submission as the Board and the Supplier may have agreed in advance;
“PAS Submission”	means a proposal from the Supplier to facilitate the use of its pharmaceutical product in the treatment of Patients by reducing the cost of treatment;
“Supplier”	means the pharmaceutical company that receives the PAS Approval Letter for the Drug that may be purchased or paid for by the Board for use in the treatment of a Patient in accordance with a particular PAS Agreement;
“Supplier Confidential Information”	means such information as is identified by the Supplier in the PAS Submission as confidential because of its commercial sensitivity;
“Supplier’s Representative”	means the party appointed by the Supplier and notified to the Board pursuant to Clause 5;
“Supply”	means the supply of the Drug for the treatment of Patients;

“Terms”	means the standard terms for the operation of Patient Access Schemes in Scotland set out in this document;
“Verification Record”	means the Board’s record keeping requirements to verify the application of the PAS Agreement identified in the PAS Submission;
“Writing”	means any communication in writing including 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; and

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

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

2. SUPPLY

2.1 The Supply of the Drug by the Supplier or an Affiliate for the treatment of Patients of the Board whether procured directly by the Board or where the cost is reimbursed by the Board shall be subject to the PAS

Agreement (the PAS Approval Letter, the PAS Submission and these Terms) in addition to the conditions of contract governing the sale and purchase of the Drug.

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

3. PAS APPROVAL LETTER

- 3.1 The PAS Approval Letter issued by or on behalf of the Board together with the PAS Submission shall detail the Drug and the approved cost reduction measures in accordance with the following principles:

- 3.2 The Drug and all relevant dosages and formulations shall be clearly identified in the PAS Submission;

- 3.3 The cost reduction mechanism proposed in the PAS Submission shall detail the rebate or other method of reducing the cost of treatment;

- 3.4 The Board shall maintain any Verification Record specified in the PAS Submission.

4. COST REDUCTION MECHANISMS

- 4.1 All refunds or rebates or additional Supply shall be made in accordance with the procedures set out in the PAS Submission and the PAS Approval Letter.

- 4.2 Where the Board is required to maintain a Verification Record, the Board shall provide the Supplier with the Verification Record on reasonable request and shall, at the cost of the Supplier, provide such additional information and substantiating evidence as is held by the Board to

confirm the claims made by the Board hereunder, provided that the Board shall use all reasonable endeavours to minimise the cost of providing such information and substantiating evidence in so far as reasonably practicable and subject always to the Board's overriding obligations in respect of patient confidentiality.

In the case of additional supply provided following a claim, the terms and conditions of contract that applied to the original purchase of the Drug shall apply to any additional supply, save as to price, delivery date and ordering procedure.

5. REPRESENTATIVES

5.1 The Representatives of the Parties for the purposes of administering the PAS Agreement shall be as notified in Writing by one party to the other from time to time.

5.2 All queries and day to day communications regarding the operation of a PAS 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 PAS Agreement.

6. FREEDOM OF INFORMATION AND CONFIDENTIALITY

6.1 No term of this Agreement, whether express or implied, shall preclude the Board from making public under the Freedom of Information (Scotland) Act 2002 and/or any codes applicable from time to time relating to access to public authorities' information, details of all matters relating to these Terms or the PAS Agreement unless such information constitutes Confidential Information.

- 6.2 Both 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 a PAS Agreement.
- 6.3 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:
- 6.3.1 is or becomes public knowledge other than by breach of this Clause 6;
- 6.3.2 is in the possession of the Board without restriction in relation to disclosure before the date of receipt;
- 6.3.3 is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;
- 6.3.4 is independently developed without access to the Supplier Confidential Information;
- 6.3.5 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.

- 6.4 Nothing contained in this Clause 6 shall prevent the Board from disclosing any Supplier Confidential Information wherever disclosure is required by virtue of the Board's status as an NHSS entity to a department, office or agency of the Scottish Government or to any other NHSS entity or to any consultant, contractor or other person engaged by the Board in connection with the PAS 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
- 6.5 Nothing contained in this provision shall prevent NSS from disclosing Supplier Confidential Information to NHS purchasing authorities in any part of the UK, provided that NSS 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.

7. ASSIGNATION AND AFFILIATES

- 7.1 The PAS Agreement applies to the Drug Supplied to the Patients of the Board while the Drug is approved by NHSS Health Boards and the Board for prescribing to NHSS Patients. The Board, acting reasonably, shall consider any application for assignation of the PAS 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 to such third party.
- 7.2 The PAS Agreement shall automatically devolve to the statutory successors of the Board and the Board shall give reasonable notice to the Supplier of such changes.

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

8. FORCE MAJEURE

8.1 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.

8.2 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 PAS 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.

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 PAS Agreement. Any matter under a PAS 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 A notice required or permitted to be given by either party to the other under these Terms or the PAS Agreement shall be in Writing addressed to that other party at its registered office or principal place of business or such other address (including electronic) as may at the relevant time have been notified pursuant to this provision to the party giving the

notice.

- 10.2 No waiver by either party of any breach of the PAS 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 PAS 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.

11. GOVERNING LAW

These Terms and any PAS 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.