

Primary Care Rebate Scheme Assessment Process

Information for Pharmaceutical Companies

1. Introduction

- 1.1 Primary Care Rebate Schemes (PCRS) are arrangements offered by pharmaceutical companies, or third party companies, which offer retrospective financial rebates on medicines dispensed by Primary Care NHS dispensing contractors (community pharmacies and dispensing doctors).
- 1.2 This document sets out the process for the submission, assessment and implementation of PCRS in NHS Scotland.
- 1.3 There are three routes for agreeing primary care rebates in NHS Scotland:
 - Route 1:** There is an established process for Patient Access Schemes (PAS) in the primary care setting; developed through dialogue between NHS Scotland and the ABPI. Detailed guidance on the arrangements for Patient Access Schemes can be found on the [SMC Website](#) and is out of scope of this document.
 - Route 2:** A stand-alone commercial agreement for medicines supplied via primary care.
 - Route 3:** National Framework agreements typically cover the hospital setting. Companies have the option of offering pricing equivalent to that specified in NP Framework Agreements to Scottish Health Boards for supply by NHS dispensing contractors in primary care with the discount administered as a confidential retrospective rebate to Health Boards.

2. Primary Care Rebate Scheme Review Group

- 2.1 The role of the Primary Care Rebate Scheme Review Group (PCRSRG) is to deliver a national service conducting an objective and independent assessment of primary care rebate schemes submitted by pharmaceutical companies (outside of the PAS arrangements) and advise on their acceptability for implementation by NHS Boards in Scotland.
- 2.2 The group is chaired by a representative of the NHS Scotland Directors of Pharmacy Group and includes a mix of pharmacy and finance representatives from across NHS Scotland. The Secretariat for the group is provided by NHS National Services Scotland (NSS).

3. Submission of proposed Primary Care Rebate Schemes

- 3.1 Where a company is proposing a PCRS (outside of PAS arrangements), they should complete the relevant submission form and email it as a word document to NSS.PCHC@nhs.scot. There are two forms that can be used depending on the nature of the proposed scheme:
 - *Submission form for a stand-alone scheme:* This form is intended to support the agreement of a stand-alone commercial agreement for medicines supplied via primary care.
 - *Submission form where existing National Procurement Framework Agreement in place:* Where the aim is to offer a cost to the NHS equivalent to if the medicine was supplied by a hospital under a Framework Agreement, this form should be used.

4. Assessment of Schemes

- 4.1 General principles that will be considered during the assessment of schemes are set out in Appendix 1.
- 4.2 The PCRSRG will meet every second month. Schemes will be scheduled for review subject to the capacity of the PCRSRG and Secretariat.
- 4.3 A sub-group composed of the Chair of the PCRSRG, the finance representative on the PCRSRG or the Chair of the Scottish Prescribing Advisors Association have the option of approving schemes outside of scheduled meetings; they reserve the right to refer schemes for consideration by the full PCRSRG membership.
- 4.4 The company may be invited to a meeting of the review group to answer question or discuss specific points of concern identified during the assessment process.

- 4.5 National Procurement (NP), a division of NHS National Service Scotland co-ordinates the establishment of pricing agreements on behalf of Scottish Health Boards. The output of the assessment will be a recommendation on whether National Procurement should enter into the agreement on behalf of Scottish Health Boards.
- 4.6 There is not a fixed timescale for assessment of schemes; this will depend on the capacity of the Secretariat and Review Group and the time to resolve any issues identified during the assessment process.
- 4.7 The pharmaceutical company will be informed of the outcome along with any relevant feedback about the scheme identified during the assessment process.

5. Governance of Scheme

- 5.1 The PCRS Agreement will be constituted and governed by the:
- PCRS Submission Form - this can be found in the relevant PCRS application pack and requires completion by the pharmaceutical company.
 - PCRS Approval Letter - which can be found in the relevant PCRS application pack and requires completion by the pharmaceutical company and the NHS National Services Scotland (if the scheme is accepted). National Services Scotland has the authority to approve the establishment of the PCRS agreement on behalf of all Scottish Health Boards.
 - NHS Scotland Standard Terms for Primary Care Rebate Schemes. These Standard Terms are in addition to any conditions of contract for the supply of the medicine and do not cover any issues relating to the supply. Any variation to the Standard Terms must be agreed in writing.

6. Communication

- 6.1 A list of the PCRS in operation with product names and effective dates will be considered public domain information. The discount level (rebate rate) would remain strictly confidential unless indicated otherwise by the company.
- 6.2 The PCRSRG Secretariat will communicate details of the PCRS to NHS Boards in confidence to facilitate implementation. This will primarily be to Chairs of the Area Drug and Therapeutic Committees (ADTCs), Directors of Pharmacy and Directors of Finance and members of The Scottish Practice Pharmacists and Prescribing Advisors Executive who will securely disseminate information to relevant individuals within their NHS Board. Community pharmacies and general medical practitioners, including dispensing doctors, do not have access to the PCRS rebate rate.
- 6.3 A confidential register of schemes will be distributed to Boards periodically. The register will contain the name of the pharmaceutical company, the medicine and preparations included in the scheme, pricing information and scheme start date .

7. Financial Reconciliation Processes

- 7.1 On a quarterly basis, NHS NSS will provide the Supplier with a request for payment for the total value of the rebate due to NHSS and a PRISMS (Prescribing Information System for Scotland) usage report. The information in PRISMS is drawn from reimbursement claims for supply against NHS prescriptions by NHS Dispensing Contractors. Suppliers will rebate the request for payment amount to NSS. NSS will reconcile and transfer payments to each Board on a quarterly basis. Boards will receive a consolidated report with product level details of all rebates due and confirmation they have been received.
- 7.2 Where a supplier has multiple PCRS in place with NHS Health Boards, a separate request for payment will be provided for each scheme.
- 7.3 Boards will need to put local processes in place for recording the PCRS and attributing to the correct cost centre at Board level.
- 7.4 The usage report provided to suppliers details usage as a quantity of tablets/capsules. It is not possible to report at pack level e.g. where there are multiple pack sizes available, the data does

not differentiate the number of packs containing 28 tablets vs. the number of packs containing 56 tablets that were reimbursed.

- 7.5 The data does not differentiate UK marketed packs from parallel imported packs.
- 7.6 Where a medicine is off-patent, there may be limitations in the data that can be provided, for example if a medicine is in Part 7 (basic prices of drugs) of the Scottish Drug Tariff, where a product has been prescribed generically and there are a choice of actual products meeting the generic description, comprehensive information is not available on which supplier's product was dispensed. The information that is available will dependent on the individual circumstances of that medicine.
- 7.7 There is a time lag in the availability of data. This is due to the time for prescriptions to be priced by the NSS Prescription Services Division and constraints around the sharing of data that will form the basis of an Official Publication (official statistics).

8. On-going management of schemes

- 8.1 National Procurement may arrange a periodic review of the rebate scheme with the company to consider benefits realised/benefits optimisation.
- 8.2 The PCRS agreement will subject to earlier termination in Clause 8.4 of the Terms, automatically renew for successive periods of one year. If the Supplier does not wish to extend, notice must be received in writing and shall comply with clause 10.2 of the Terms.
- 8.3 For older schemes that were in place before the addition of automatic renewal, National Procurement may chose to write to the supplier requesting an extension before the scheme end date.

Appendix 1: Principles for PCRS in NHS Scotland

1. It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS. Companies must be able to provide justification for requesting a primary care rebate scheme rather than a transparent list price cut.
2. Any medicines considered under a PCRS must be licensed for use in the UK and considered suitable for routine clinical use.
3. A scheme should not be linked to a particular clinical indication.
4. The acceptance of a scheme should not constrain existing local decision making processes or formulary development. Schemes that require the exclusive use of a particular drug or exclude the NHS from entering into a PCRS offered by manufacturers of competitor drugs will not be agreed.
5. A financial impact assessment will be undertaken as part of the assessment process considering both potential benefits and financial risks to the NHS.
6. Rebate schemes which have a potential wider impact on community pharmacy margins or on the generic medicines market are not appropriate.
7. Volume based schemes will not be considered.
8. No patient-identifiable data should be shared as part of a PCRS.
9. The scheme must be flexible enough to allow the NHS to respond to the emergence of significant new clinical evidence, or significant changes to the market conditions.
10. Compliance must be assured with the NHS Scotland probity, governance and legislative requirements including formal agreements between the NHS and pharmaceutical company regarding respective responsibilities including burden of costs and protection of commercial-in-confidence information.
11. Whilst the level of discount provided through the rebate is commercially sensitive information and considered confidential within the NHS, the existence of the scheme should be public domain information.
12. There should no obligation as part of a scheme for financial rebates to be used for a specific purpose by a Health Board.
13. The experience with PCRS in NHS Scotland will be reviewed on an ongoing basis.