

Primary Care Rebate Scheme Assessment Process: Guidance for Companies

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Primary Care Rebate Scheme Assessment Process Overview

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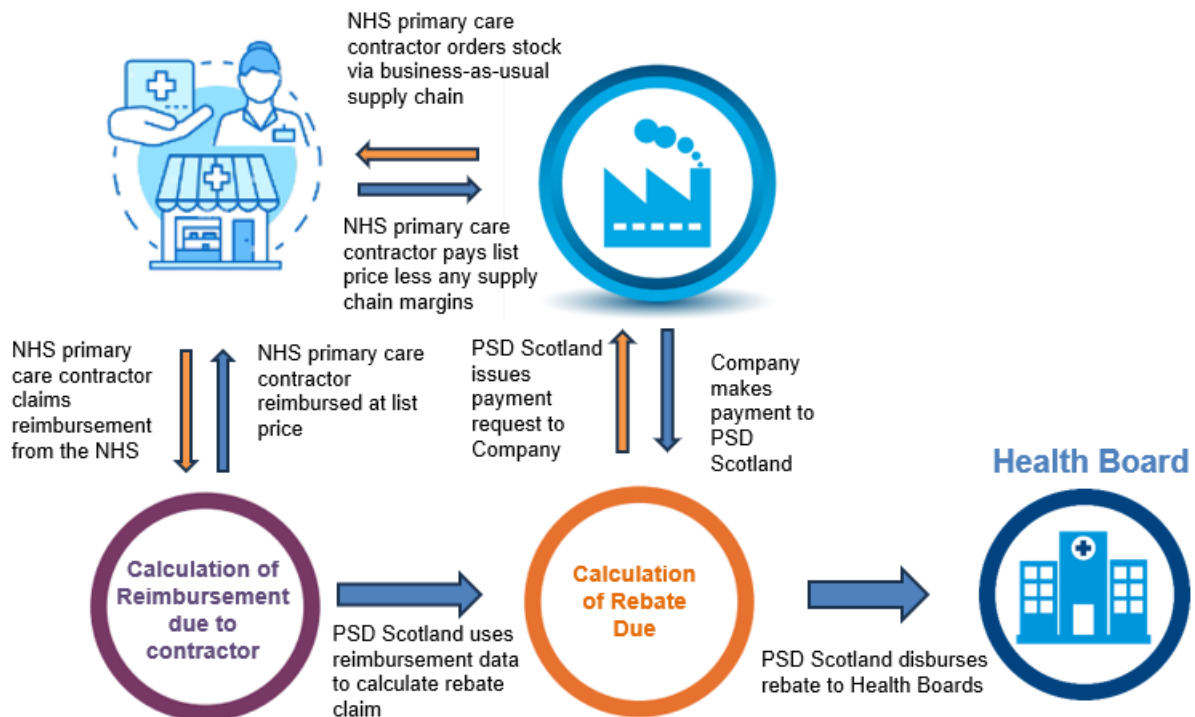
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1. Introduction

Primary Care Rebate Schemes (PCRS) are arrangements offered by companies which offer retrospective financial rebates on products dispensed in primary care.

The schematic below provides a high-level summary of the operational arrangements. Under PCRS, primary care contractors purchase products at list price (less any supply chain margins). On a quarterly basis, Public Services Delivery Scotland (PSD Scotland) on behalf of boards provides the company with a supply report and a request for payment. This information is used by the company to pay a confidential rebate to PSD Scotland via BACS payment. PSD Scotland then disburses funds to each board in proportion to usage of the product in each board area.

Chart 1: PCRS Process Overview



Given the administrative burden and the financial risk for the NHS inherent in primary care rebate arrangements, the strong NHS Scotland preference is a reduction of the transparent NHS List Price rather than a rebate scheme. However, rebate schemes will be considered where there is sufficient justification and a clear benefit for the NHS.

This document sets out the process for the submission, assessment, implementation and ongoing management of PCRS in NHS Scotland.

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2. Scope of Schemes

Primary care rebates can cover a medicine, device or other such product that is supplied to NHS Patients via primary care contractors. This includes:

- Supply via NHS Dispensing Contractors (i.e. a community pharmacy, a dispensing doctor or a dispensing appliance contractor with a contract to provide a NHS dispensing service).
- Supply via a provider holding a contract with an entity within NHS Scotland to provide pharmaceutical goods and services to prisons and young offenders institutions that are directly managed or contracted by the Scottish Prison Service. The current prison pharmacy contractor is MD Green Ltd in partnership with Phoenix Healthcare Distribution.

All presentations of products within scope of a PCRS must be listed with a list price on the dictionary of medicines and devices (dm+d). This is essential to enable reconciliation of the scheme as pricing information held in dm+d is used to calculate reimbursement due to contractors for the supply of products to NHS patients. To add a product to dm+d or to notify the dm+d team of changes including new presentations, contact the NHSBSA at pippa@nhsbsa.nhs.uk or alternatively use the EMC [Market Access](#) facility.

Reimbursement data does not contain any information on the supply chain used by contractors to source a product, including whether a parallel import was used. PCRS agreements cover the total quantity of a product supplied by NHS dispensing contractors and prison pharmacy contractors to NHS patients, regardless of purchasing channel, including use of parallel imports.

Where a medicine is in Part 7 of the [Scottish Drug Tariff](#), with a fixed reimbursement price, reimbursement data would only contain the name of the brand used where the product was prescribed using the brand name. Where a medicine is not in Part 7 of the Scottish Drug Tariff, the pharmacy must endorse generically written prescriptions with the name of the brand dispensed to ensure correct payment therefore in this scenario, information is available on the specific brand dispensed. Rebates will be reconciled on the basis of any usage of the product recorded in reimbursement data, including where prescriptions have been written using the generic name for the medicine and information has been captured during the reimbursement process on the brand dispensed by the contractor.

Prescription reimbursement data is collected on a monthly cycle; it is not possible to differentiate usage on particular days of the month. Therefore, schemes should start with effect the 1st of a month. As rebates are retrospectively reconciled, it is feasible for schemes to be backdated.

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It is important that the NHS has confidence in the longevity of schemes when pricing is being considered in product selection decisions. For this reason, the minimum term of a scheme is two years; longer minimum terms are regularly offered. As the expectation is that these are long term agreements, after the initial fixed term, there is provision for schemes to automatically renew for successive periods of one year unless notice is provided at least ninety days in advance of the annual renewal date.

3. Routes for Agreeing a PCRS

There are two routes for agreeing primary care rebates in NHS Scotland:

Route 1: A stand-alone commercial agreement for products supplied to NHS patients via primary care. This includes:

- Medicines and other products predominantly prescribed in primary care; and
- Medicines that are predominantly prescribed in secondary care that are on an NHS Scotland Framework Agreement and the company wishes to offer price parity across primary and secondary care with pricing in primary care managed via a confidential retrospective rebate.

This document provides guidance on this approach.

Route 2: 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.

4. Review Group

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 companies (outside of the PAS arrangements) and advise on their acceptability for implementation by boards.

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 PSD Scotland.

5. Assessment and Reconciliation Process

5.1. Submission of Proposed Primary Care Rebate Schemes

Where a company is proposing a PCRS (outside of the PAS arrangements), they should complete the PCRS Application Pack, arrange for the submission form included in the pack to be signed and email this as a word document to the PCRSRG Secretariat (nss.pchc@nhs.scot).

5.2. Assessment

In assessing schemes, the PCRSRG will consider:

- The potential financial benefits of the scheme to NHS Scotland and whether this will significantly outweigh the administrative costs and financial risks for the NHS in entering into the proposed PCRS. Where benefits are only likely to be realised if there is a change in prescribing practice, consideration will be given to how likely prescribing practice will change over the proposed minimum term.
- Any potential risks. For example, PCRS are rarely accepted for branded generics where there is no clinical requirement to prescribe by brand name. This is due to the potential for increased branded prescribing to reduce supply chain resilience and create regional distortions in community pharmacy access to the guaranteed levels of purchase profits that forms part of the community pharmacy funding arrangements in Scotland.
- Whether the scheme is transactable. For example, if a medicine is listed in Part 7 of the Drug Tariff, it will only be possible to identify the brand of the product if the medicine has been prescribed by brand name.

General principles that are considered during the assessment of schemes are set out in Appendix 1.

The company may be invited to a meeting of the review group to answer questions or discuss specific points of concern identified during the assessment process.

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.

The PCRSRG meet every second month. Where there are no significant issues identified in the Secretariat's assessment of the proposed scheme, the Chair of the PCRSRG has the option of approving schemes outside of scheduled meetings; the Chair reserves the right to refer schemes for consideration by the full PCRSRG membership.

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PSD 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 PSD Scotland should enter into the agreement on behalf of all boards.

The company will be informed of the outcome along with any relevant feedback about the scheme identified during the assessment process.

5.3. Governance of Scheme

PSD Scotland has the authority to approve the establishment of the PCRS agreement on behalf of all health boards.

The PCRS Agreement will be constituted and governed by the:

- PCRS Submission Form - this can be found in the PCRS application pack and must be completed and signed by the company.
- PCRS Approval Letter - this can be found in the PCRS application pack and is signed by PSD Scotland (if the scheme is accepted by the PCRSRG). PSD Scotland has the authority to approve the establishment of the PCRS agreement on behalf of all boards.
- NHS Scotland Standard Terms for Primary Care Rebate Schemes. The Standard Terms are in addition to any conditions of contract for the supply of the product and do not cover any issues relating to supply.

In the event of any inconsistency or ambiguity between the PCRS Approval Letter, PCRS Submission and the NHS Scotland Standard Terms, the operation of the PCRS Agreement shall be governed by the PCRS Approval Letter, the PCRS Submission and the Standard Terms in that order.

5.4. Implementation and Communication

The PCRSRG Secretariat will share a copy of the signed PCRS Agreement with boards in confidence to facilitate implementation. This is shared along with a guidance document which outlines the value of the rebate per board and highlights any medicines efficiency opportunities. Circulation is to Directors of Finance, Directors of Pharmacy, Chairs of Area Drug and Therapeutic Committees (ADTCs), the Executive of the Scottish Practice Pharmacist and Prescribing Advisers Association (SP3A) and the formulary pharmacists' network. These contacts then securely disseminate the information to relevant individuals within their board. Community pharmacies and general medical practitioners, including dispensing doctors, do **not** have access to the PCRS pricing information.

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A confidential register of schemes is distributed by PSD Scotland to boards periodically. The register contains the name of the company, the product and preparations included in the scheme, pricing information, scheme start and earliest termination date.

A register of schemes, excluding confidential pricing information, is published by PSD Scotland in the public domain periodically. This includes the name of the company, the products included within the scheme, scheme start date and earliest termination date.

5.5. Calculation of Rebate Due

The total value of the rebate due to boards is calculated as the volume of product supplied to patients multiplied by the difference in the list price and the PCRS price (i.e. the agreed effective price after rebate).

For products dispensed by NHS dispensing contractors, the NHS Scotland Prescribing Information System is the reporting platform used as the basis of the volume of product supplied. For prison pharmacy contractors, it is reimbursement claims to boards from prison pharmacy contractors.

As set out in detail in Section 2, the volume used to calculate the value of the rebate due includes consideration of all instances that the product has been supplied by an NHS dispensing contractor or prison pharmacy contractor to an NHS Scotland patient, regardless of the supply chain used, including parallel imports and regardless of whether the prescription was written generically or using the product's brand name.

5.6. Financial Reconciliation

On a quarterly basis, PSD Scotland will provide the company with a supply report which is drawn from reimbursement data and a request for payment for the total value of the rebate due to NHS Scotland.

Chart 2: Example Supply Report Layout

Health Board	Product Name	Form Type	Paid Quantity	Cost	Rebate: 10%
Fife	Product Tabs 5mg	GP10	2184	£77,970	
	Product Tabs 10mg	GP10	4200	£149,940	
	Product Tabs 5mg	Prison	112	£3,998	
	Product Tabs 10mg	Prison	168	£5,998	
Fife			Sum:	£237,906	£23,791

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Where a company has multiple PCRS in place, a separate request for payment and usage report will be provided for each scheme.

There is a time lag in the availability of data. This is due to the timescales for contractor reimbursement to be calculated and constraints around the sharing of data that will form the basis of official statistics. Requests for payment are issued quarterly to the named contact within the company following the schedule below.

Dispensing Quarter	Estimated Month that usage data is available	Estimate for request for payment to be issued
1 January to 31 March	July	End August
1 April to 30 June	October	End November
1 July to 30 September	January	End February
1 October to 31 December	April	End May

The company must raise any queries relating to the value of the rebate claim with PSD Scotland within 15 days of receiving the request for payment.

The company then rebates the requested amount(s) to the bank account of PSD Scotland by BACS (Banker's Automated Clearing Services) transfer within 30 days of receiving the report and sends a remittance advice note; if companies require completion of an account form, forward to nss.pchc@nhs.scot for completion.

Upon receipt, PSD Scotland will disburse funds to each board. Boards will receive a consolidated report with product level details of all rebates due and confirmation they have been received.

5.7. On-going Management of Schemes

The standard NHS Scotland PCRS agreement includes a requirement on the company to notify PSD Scotland as soon as practicable of any change to the NHS List Price; any change in the name used to market the product; if there has been a change in the company holding marketing rights for the product; or if a new strength, formulation, specification or pack size of the product is to be made available.

On receipt of a notification of change, PSD Scotland will work with the company to confirm that the scheme continues to be transactable and agree any changes required. The PCRS can be terminated immediately if the list price is reduced to or below the level of the

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effective price after rebate. Additional presentations can be added to the scheme by agreement.

6. Further Information

For support, please contact the Primary Care Rebate Scheme Review Group Secretariat (nss.pchc@nhs.scot).

Appendix 1: Principles of PCRS in Scotland

1. It is preferable for companies to supply products to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden. Companies must be able to provide justification for requesting a PCRS 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 medicine 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 purchase 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 market conditions.
10. Compliance must be assured with the NHS Scotland probity, governance and legislative requirements including formal agreements between the NHS and the 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 board.
13. Schemes where only some but not all pack sizes of the product are included will not normally be considered.
14. The experience with PCRS in NHS Scotland will be reviewed on an ongoing basis.