NHS
Nottingham and Nottinghamshire

Nottingham & Nottinghamshire ICB Principles and Process for Approving Primary Care Prescribing Rebate Schemes

April 2025

Version 3.0

Contents

1. Introduction

Nottingham & Nottinghamshire ICB has approved the implementation of prescribing rebate schemes as a means of achieving efficiency savings targets. This includes helping to prioritise the resources of the medicines optimisation team. This document outlines the principles and processes for decision making which will ensure that rebate schemes adhere to the ICB values and do not influence clinical decision making.

The 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (2024 Voluntary Scheme) came into force on 1 January 2024, following the expiry of the 2019 Voluntary Scheme and shall remain in force for five years. The Voluntary Schemes replaced the Pharmaceutical Price Regulation Scheme (PPRS) as the mechanism by which the Department of Health and Social Care (DHSC) ensures that the NHS has access to branded medicines at a reasonable price. The 2024 Voluntary Scheme balances setting reasonable prices for the NHS against delivering a fair return for the pharmaceutical industry so that investment and innovation in pharmaceuticals is incentivised.

The 2024 Voluntary Scheme does not apply to devices or nutritional products; nor does it apply to unbranded generic medicines whose prices tend to be controlled by their Drug Tariff agreed pricing. The scheme is complex, and the full text of the 2024 voluntary scheme is available on the DHSC website: https://www.gov.uk/government/publications/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth

Several manufacturers have established ‘rebate schemes’ for drugs used in primary care to support the NHS cost efficiencies agenda. The NHS is charged the Drug Tariff price for primary care prescriptions dispensed, and then the manufacturer provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data.

Some schemes are straight discounts and are not volume based, whilst others have varying discount rates available dependent upon the volume of drug prescribed. The discount schemes are confidential to the NHS enabling manufacturers to maintain a higher price in global markets.

2. Purpose

Rebate agreements usually take the form of legal agreements between the manufacturer and ICB. It is important that Nottingham & Nottinghamshire ICB has principles and a process to support evaluation and sign-off of rebate schemes to ensure that schemes are only signed off where they provide good value for money to the public purse and the schemes terms are in line with organisation vision, values, policies and procedures and also to ensure that the ICB is transparent in its process for considering these schemes.

The principles outlined in this document allow for the objective evaluation of schemes submitted to Nottingham & Nottinghamshire ICB and for a clear process for approving and scrutinising agreements.

3. Principles for Assessing Rebate Schemes

The following will be used to determine the suitability of taking a Rebate Scheme to the Nottingham & Nottinghamshire Medicines Optimisation Steering Group (NNMOSG) for consideration and ratification:

3.1. Product Related

a) There should be a demonstrable clinical need for the product.

b) Products should not have a negative decision by NICE or hold any MHRA safety concerns.

c) There shall be no directive for health professionals to prescribe a specific product, solely because a Primary Care Rebate Scheme (PCRS) is in place. Prescribing decisions should be made on assessments of an individual patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.

d) Any medicine considered under a Primary Care Rebate Scheme (PCRS) must be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be linked to a particular indication for use.

e) Any device or nutritional supplement considered under a PCRS should be included within the relevant chapter of the Drug Tariff.

f) Rebate schemes promoting unlicensed or off label uses will not be entered into. All recommendations for use of a medicine within a PCRS must be consistent with the Marketing Authorisation of the medicine in question.

g) Rebate schemes should ideally have been subjected to PrescQIPP scrutiny and be part of their live schemes. PrescQIPP is an independent, not for profit social enterprise which aims to support quality prescribing in the NHS and helps to ensure that treatments prescribed to patients are safe, effective and good value for money. PrescQIPP does this by providing information, guidance and support on prescribing to a large community of NHS professionals. PrescQIPP has experience of assessing rebate schemes and has produced background information, aimed both at the NHS and for industry. The Pharmaceutical Industry Scheme Governance Review board (PISGRB) has been created by PrescQIPP in response to requests by commissioners to provide guidance as to the acceptability of Primary Care Rebate Schemes being offered to the NHS by the pharmaceutical industry. The role of the PISGRB is only to provide an independent assessment of rebate schemes. PrescQIPP does not approve or reject schemes but assists commissioners in the process of decision making regarding the acceptance or rejection of a scheme.

h) The assessment process is designed to identify potential issues that commissioners may wish to consider when deciding whether to use any rebate schemes submitted to PrescQIPP. The assessment is split into three sections clinical, contractual and financial.

i) PrescQIPP have developed a sample standard terms contract that is available on their website. Ideally, any contracts entered into will utilise this standard contract. If a drug company elects to use a different contract for a scheme scrutinised by PrescQIPP, the contract will need to be checked carefully as regards clinical and financial criteria.

j) Rebate schemes that have **not** been subjected to PrescQIPP processes will also need to be scrutinised carefully as regards clinical and financial criteria.

3.2. Rebate Scheme Related

a) The administrative burden to Nottingham & Nottinghamshire ICB of setting up and running the scheme must be factored into assessment of the likely financial benefit of the scheme.

b) Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.

c) Primary care rebate schemes encouraging exclusive use of a particular brand of product will not be entered into. Where specific brand prescribing is required due to the nature of the product e.g. Glucose Testing strips or some specific drugs (e.g. modified release products), then an increase in that particular product usage may be seen but individual patient need must be the driver.

d) Primary care rebate schemes are not appropriate for medicines in Category M and some medicines in Category A of the Drug Tariff. This is due to the potential wider impact on community pharmacy reimbursement.

e) The primary care rebate scheme will not be directly linked to requirements to increase market share or volume of prescribing. It is recognised that an increase in market share may be a consequence of the primary care rebate scheme. This principle may be waived if the scheme is available as a result of a formal open tender.

f) A volume-based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.

3.3. Information and Transparency

a) The primary care rebate scheme will not preclude Nottingham & Nottinghamshire ICB from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so.

b) There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.

c) Primary care rebate schemes that require provision of patient specific data will not be entered into.

d) Primary care rebate schemes will be subject to Freedom of Information (FOI) requests. Advice will be sought from the ICB FOI lead as to what information should be shared.

e) Nottingham & Nottinghamshire ICB will publish a list of the schemes in which they participate on their website, along with the start and end dates of each contract. The full terms of the scheme may not be published depending on the nature of the rebate scheme contract.

4. Freedom of Information

Nottingham & Nottinghamshire ICB will support the principles of transparency enshrined in the Freedom of Information Act. Rebate agreements often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information. Nottingham & Nottinghamshire ICB will publish the principles and process

for accepting rebate agreements along with the list of products for which rebate agreements exist on its publicly available website.

Section 43 of the Freedom of Information Act sets out an exemption from the right to know if:

- the information requested is a trade secret, or
- release of the information is likely to prejudice the commercial interests of any person. (A person may be an individual, a company, the public authority itself or any other legal entity.)

The UK is a reference pricing country for pharmaceutical and medical device products and any change to publicly available UK prices can impact on the international profitability of pharmaceutical and medical device companies. Pharmaceutical and medical device companies often consider their pricing structures to be trade secrets and there are precedents within the NHS in restricting access to pricing information for these products.

NICE negotiates several patient access schemes as part of the NICE Technology Appraisal programme. The details of the products that are available to the NHS under a patient access scheme (or discount scheme) are published on the NICE website. The commercial and operational details of the individual schemes are not made publicly available and are the subject of confidentiality clauses. Nottingham & Nottinghamshire ICB benefit from many of these schemes through the prices charged to it for PbR excluded drugs.

Section 43 is a qualified exemption. That is, it is subject to the public interest test which is set out in section 2 of the Act. Where a public authority is satisfied that the information requested is a trade secret or that its release would prejudice someone's commercial interests, it can only refuse to provide the information if it is satisfied that the public interest in withholding the information outweighs the public interest in disclosing it.

Nottingham & Nottinghamshire ICB will consider all Freedom of Information requests on rebate agreements on their individual merits taking into account the public interest and whether the release of information will prejudice other parties to the agreements.

5. Duties/Accountabilities and Responsibilities

5.1. Duties within organisation

The Nottingham and Nottinghamshire ICB Senior Medicines Optimisation Pharmacist, with the responsibility for the rebate schemes process, will ensure that rebate schemes are assessed against the principles outlined in section 3 above. The “Rebate Scheme Decision Form” in Appendix 1 will be used to record the assessment against the principles and to provide a recommendation to the NNMOSG. Schemes will be discussed and ratified at NNMOSG.

5.2. Responsibilities for approval

NNMOSG will approve new and revised rebate schemes.

Copies of the “Rebate Scheme Decision Forms” will be presented to the appropriate committees for scrutiny when appropriate.

6. Public Sector Equality Duty

Nottingham & Nottinghamshire ICB aim to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

Nottingham & Nottinghamshire ICB have considered the general legal duty required by the Equality Act 2010 and does not consider it necessary to carry out an equality impact assessment (EIA) on these principles and process as it does not have an impact on patients, carers, staff or the wider community.

7. Scope of the Principles and Process

These principles and this process applies to the Nottingham & Nottinghamshire ICB and applies to all employees, members of the ICB, co-opted members and members of the Governing Bodies and committees who comply with the arrangements outlined in this document.

8. Monitoring Compliance with the Document

Compliance with the principles and process will be monitored. A list of any rebate schemes considered will be presented to the appropriate committees when requested along with any decision to sign up to the scheme or not.

The NNMOSG will monitor rebate schemes on the basis that they relate to cost efficiencies.

Copies of Appendix 1 will be maintained for all schemes formally considered by the ICB and will be available for audit if necessary.

9. Arrangements for Review

This document will be reviewed two years after the date of authorisation and may be reviewed sooner if there is a change in legislation or new national guidance. NNMOSG will be responsible for approving changes to this document.

10. References

The following policies were used to review and update this document:

- DHSC: 2024 Voluntary Scheme for Branded Medicines, Pricing, Access and Growth
- PrescQIPP: Principles of Governance of Primary Care Rebates for Integrated Care Boards / Health Boards, October 2018
- Information Commissioner's Office: The Guide to Freedom of information, August 2017

11. Version Control

Version control - **Nottingham & Nottinghamshire ICB Principles and Process for Approving Primary Care Prescribing Rebate Schemes**			
Version	**Date**	**Author**	**Changes**
2.0	02/09/2022	Lyneth Hicks & Jill Theobald	• CCG changed to ICB throughout and added new logo. • NMOC changed to NNMOSG throughout • Addition of Bassetlaw • Ratification process changed - future policy updates will be ratified by NNMOSG, and new rebates will be approved by NNMOSG rather than via CPMT. • Removed need to for sign-off of new schemes by chief finance officer. • No longer have statement that not being on formulary precludes us having a rebate. • Added detail of action to take if contract is not a standard PrescQIPP version – scrutiny required. Amendment to appendix 1: • Addition of line to consider if PrescQIPP contract is being used and when to obtain scrutiny of contract. • All criteria are now statements rather than a mixture of questions and statements.
3.0	March 2025	Jill Theobald, NNICB Senior Medicines Optimisation Pharmacist	• Changed from Policy to Principles and Process • Removed reference to the old CCGs. • Added information about the Voluntary Scheme for Branded Medicines Pricing 2024. • Clarified that PrescQIPP do not approve rebate schemes, they assess them and highlight concerns. • Added that the start and end date of each contract is included in the list of current schemes on the ICB website. • Changed reference to QIPP to cost efficiencies. • Adopted standard footer for ICB medicines optimisation team.

Appendix 1: Rebate Scheme Decision Form

Product	
Company	
Recommendation	
Estimated Potential Savings	
Length of term of scheme	
Evaluation Carried Out By	
Date Completed	
NNMOSG Date of Approval	

Criteria	**✓ / X / NA**
The scheme does not contravene APBI, MHRA guidelines/code of practice.	
Scheme does not encourage prescribing contrary to ICB policy.	
The product does not have a negative decision from NICE.	
There is no requirement for a directive or guideline to be given to health care professionals to prescribe the specific product.	
If the product is a medicine, is it licensed in the UK.	
The rebate scheme is not designed to increase off label use of the drug.	
If the product is a device or nutritional supplement, is it contained in the current drug tariff.	
The rebate scheme aligns with ICB prescribing policies and guidelines.	
No change in current practice required by the scheme.	
The rebate scheme does not require exclusive use of a specific brand.	
The product is not contained in Category A or M of the drug tariff.	
The rebate scheme is not linked directly to a requirement for an increase in market share or volume of prescribing.	
The rebate scheme does not prevent consideration of other schemes.	
There is no requirement to submit additional information beyond the volume of prescribing of the product.	
There is no requirement to collect patient specific data.	
No other contractual or legal issues identified during the evaluation (add detail below if issues have been identified)	

The scheme has been to the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PISGRB) for approval, and the contract is as per the PrescQIPP website.	
If PrescQIPP have raised a concern or if not a PrescQIPP contract, appropriate scrutiny has been sought.	

Any Further Information:

Estimated administrative burden

Any legal or contractual issues uncovered

Governance issues

Freedom of Information issues

Any other pertinent issues