Nottinghamshire Policy for Approving Primary Care Prescribing Rebate Schemes

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Clinical Lead:	
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1. Introduction

Nottinghamshire CCGs have approved the implementation of prescribing rebate schemes as a means of QIPP savings. This includes helping to prioritise the resources of the medicines management team under the pressures of QIPP and financial turnaround. The policy outlines the principles and processes for decision making which will ensure that rebate schemes adhere to the values of the CCGs (Nottingham City CCG, Rushcliffe CCG, Nottingham North and East CCG, Nottingham West CCG Newark and Sherwood CCG and Mansfield and Ashfield CCG)) within Nottinghamshire and correspondingly, do not influence clinical decision making.

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism by which the Department of Health ensures that the NHS has access to branded medicines at a reasonable price. The PPRS 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 PPRS does not apply to devices or nutritional products; nor does it apply to generic medicines whose prices tend to be controlled by their Drug Tariff agreed pricing. The view of the Department of Health expressed in the consultation document on value based pricing is that the existing PPRS does not promote innovation or access to medicines, as the freedom of companies to set the price of new drugs results in the NHS often paying high prices which are not justified by the benefits of the drug and/or of having to restrict access to the drug.

A number of manufacturer's have established 'rebate schemes' for drugs used in primary care to support the NHS QIPP 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 CCG. It is important that the Nottinghamshire CCGs have a policy 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 CCGs within Nottinghamshire are transparent in their process for considering these schemes.

The principles outlined in this policy document allow for the objective evaluation of schemes submitted to Nottinghamshire CCGs 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 Chief Finance Officer and the Nottinghamshire Medicines Optimisation Committee (NMOC) for consideration and ratification:

Product Related

There should be a demonstrable clinical need for the product.

All products should normally be recommended for prescribing within Nottinghamshire CCGs and be listed on local formularies as appropriate.

Products should not:

- be included in the Area Prescribing Committee Grey List
- have a negative decision by NICE
- hold any MHRA safety concerns

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.

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.

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

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.

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 assessing of 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 any particular scheme. PrescQIPP does not approve or reject schemes, but assists commissioners in the process of decision making regarding the acceptance or rejection of a scheme.

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.

Rebate schemes that have not been subjected to PrescQipp processes will need to be scrutinised carefully as regards clinical and financial criteria and they will also need to be subject to appropriate legal scrutiny.

Rebate Scheme Related

The administrative burden to Nottinghamshire CCGs of setting up and running the scheme must be factored into assessment of the likely financial benefit of the scheme.

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

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.

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.

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.

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

Information and Transparency

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

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

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

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

The CCGs within Nottinghamshire will publish a list of the schemes in which they participate on the CCG website. The full terms of the scheme may not be published depending on the nature of the rebate scheme contract.

4. Freedom of Information

Nottinghamshire CCGs 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. Nottinghamshire CCGs will publish the policy for accepting rebate agreements along with the list of products for which rebate agreements exist on its publically 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 publically 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 a number of 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 publically available and are the subject of confidentiality clauses. Nottinghamshire CCGs 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.

Nottinghamshire CCGs 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 Nottinghamshire Chief Pharmacist with the lead on rebate schemes will be responsible for assessing schemes against the principles outlined in section 3 above. Schemes will be discussed in the CCG Pharmacist Management Team Meeting. The "Rebate Scheme Decision Form" in Appendix C will be used to record the assessment against the principles and to provide a recommendation to the NMOC.

5.2. Responsibilities for approval

The Chief Finance Officer will approve schemes with ratification from the NMOC.

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

6. Public Sector Equality Duty

Nottinghamshire CCGs 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.

Nottinghamshire CCGs have considered the general legal duty required by the Equality Act 2010 and does not consider it necessary to carry out an EIA on this policy as it does not have an impact on patients, carers, staff or the wider community.

7. Scope of the Policy

This policy applies to the CCGs within Nottinghamshire and applies to all employees, members of the CCG, co-opted members and members of the Governing Bodies and committees who must comply with the arrangements outlined in this policy.

8. Monitoring Compliance with the Document

Compliance with the policy 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 NMOC will monitor rebate schemes on the basis that they relate to CCG QIPP.

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

9. Arrangements for Review

This policy will be reviewed two years after the date of authorisation. The policy may be reviewed sooner if there is a change in legislation or new national guidance.

10. References

The following policies were used as the basis of this policy:

- Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit. 2013.
- Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012.

- Primary Care Rebate Schemes. Health Service Journal. 2013
- Freedom of Information Act Awareness Guidance No. 5. Information Commissioner's Office. 2008. http://www.ico.org.uk/for_organisations/guidance_index/~/media/documents/library/Freedom_of_Information/Detailed_specialist_guides/AWARENESS_GUIDANCE_5_V3_07_03_08.ashx
- NHS Greater Huddersfield CCG Policy

11. Appendix 1: Rebate Scheme Decision Form

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

Question	**√/x**
The scheme does not contravene APBI, MHRA guidelines/code of practice?	
Scheme does not encourage prescribing contrary to CCG policy	
Is the product listed on CCG/Joint/Acute Trust Formulary	
The product is not listed on the APC grey or red list	
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	
Does the rebate scheme align with CCG 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	
Have any other contractual or legal issues been identified during the evaluation (add detail below)	
Has the scheme been to the PrescQipp Pharmaceutical Industry Scheme Governance Review Board (PISGRB) for approval	

Any Further Information: Estimated administrative burden Any legal or contractual issues uncovered Governance issues Freedom of Information issues Any other pertinent issues