

## **Policy for approving Primary Care Rebate Schemes**

### **1. Introduction**

A number of manufacturers have established 'rebate schemes' for drugs used in primary care to help the NHS QIPP agenda. Under the terms of such a scheme, the NHS is charged the Drug Tariff price for primary care prescriptions dispensed, the manufacturer then provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data. Such schemes are being offered to Clinical Commissioning Groups (CCGs) by the pharmaceutical industry in relation to named products.

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. Scope of the policy**

This policy applies to North Hampshire CCG and all of its employees, members of the CCG, co-opted members and members of the Governing Body and its committees who must comply with the arrangements outlined in this policy.

### **3. Aims and Objectives**

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that North Hampshire CCG has 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 scheme's terms are in line with organisation vision, values, policies and procedures and to ensure that the CCG is transparent in its process for considering these schemes.

The principles outlined in this policy document allow for the objective evaluation of schemes submitted to the CCG and a clear process for approving and scrutinising agreements.

### **4. Legal Advice**

There have been concerns raised by some CCGs on the lack of clarity on whether such schemes are allowed under the current regulations. The London Primary Care Medicines Use and Procurement QIPP group as part of the London Procurement Partnership agreed that it was unclear whether these schemes were allowed within the current regulations and sought legal opinion from DAC Beechcroft LLP.

In conclusion, legal opinion states that primary care rebate schemes are not unlawful and are within the powers of CCGs to agree to, provided they meet certain requirements. The detailed legal advice obtained by the London Procurement Partnership has been shared within the NHS. It is accepted that NEH&F CCG may wish to take further legal advice on any point identified and on the content of any particular scheme prior to entering into any agreement. 4

### **5. Principles for Assessing Primary Care Rebate Schemes (PCRS)**

Any pharmaceutical companies wishing to enter into a rebate scheme with North Hampshire CCG will need to undertake the PrescQIPP Governance Review Board documentation

(<http://www.prescqipp.info/projects/pi>). PrescQIPP will undertake a financial and clinical review of the offer and assist CCGs in managing the legal implications of entering into the presented schemes.

A positive recommendation by PrescQIPP will be followed by a further North Hampshire CCG review for a decision to be made locally. The chart in Appendix A outlines the overall process.

The following principles will be used to determine the suitability of a rebate scheme for consideration and ratification:

### **5.1 Product Related**

- There should be a demonstrable clinical need for the product.
- All products should normally be recommended for prescribing in North Hampshire CCG and be listed on the CCG Preferred Drugs List and local Acute Trust formularies where appropriate.
- Products should not have a negative decision by NICE
- 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.
- PCRS 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.
- Consistent savings must be achievable across all pack sizes where applicable.

### **5.2 Rebate Scheme Related**

- The administrative burden to the CCG of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. 5
- Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.
- PCRS 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, and choice where appropriate, must be the driver.
- PCRS 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 PCRS 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 PCRS. 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.
- Short term rebate schemes (less than 2 years) will not normally be considered. It is expected that the reduced price should be available to the CCG over an extended period of time.

### **5.3 Information and Transparency**

- The PCRS will not preclude the CCG 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.
- PCRS will not be entered into that require provision of patient specific data.
- PCRS 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.
- North Hampshire CCG will publish a list of the schemes it participates in on the CCG intranet. The full terms of the scheme may not be published depending on the nature of the rebate scheme contract.

## **6. Information Governance**

North Hampshire CCG supports the principles of transparency enshrined in the Freedom of Information Act. PCRS often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information.

Section 43 of the Freedom of Information Act sets out an exemption from the right to know if: 6

- 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. North Hampshire CCG benefits from many of these schemes through the prices charged to it for tariff-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.

North Hampshire CCG 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.

### **7. Accountability**

The Medicines Optimisation Group will be responsible for assessing schemes against the principles outlined in section 5 above. The "Primary Care Rebate Scheme Decision Form" in Appendix B will be used to record the assessment against the principles and to provide a recommendation to the Clinical Executive Committee.

The Clinical Executive Committee is responsible for final approval of rebate agreements on behalf of North Hampshire CCG.

The Clinical Executive Committee is responsible for the formal approval of this policy and ratification of the process for each rebate scheme.

### **8. Equality Impact Assessment (EIA)**

The Medicines Management team do 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

### **References**

The following were used as the basis for this policy:

Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012. <http://www.lpp.nhs.uk/media/43744/Primary-Care-Rebate-Schemes-Principles-NHS-London-Procurement-Partnership.pdf>

PrescQIPP Pharmaceutical Industry Scheme Governance Review Board, 2014. <https://www.prescqipp.info/primary-care-rebates/finish/76-primary-care-rebate-governance/467-primary-care-rebate-board-operating-model> 8