Policy and Principles of Primary Care Rebate Schemes

Introduction

A number of manufacturers 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, 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.

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that Milton Keynes 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 schemes terms are in line with organisation vision, values, policies and procedures and also 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 for a clear process for approving and scrutinising agreements.

Principles for Assessing Rebate Schemes

The following will be used to determine the suitability of taking a Rebate Scheme to MKCCG for consideration and ratification:

1. Product Related

- There should be a demonstrable clinical need for the product.
- Decision making should be clinically led
- All products should be recommended for prescribing on local formulary
- 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 and will only be used where products are considered clinically interchangeable.
- 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.

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.

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

- Rebates should be at organisation level not GP practice level.

- 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.

- The CCG must ensure that a formal written contract is in place, signed by both parties to ensure that the terms of the scheme are clear and to maximise legal protection.

- 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.

- The need for exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to significant clinical evidence or changes to market conditions. A shorter notice period should be agreed in these circumstances.

Information and Transparency

- The primary care rebate scheme 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 ePACT2 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.

- Discounts and details of any PCRS should be allowed to be shared within the NHS. This should be agreed as part of the contract.

Freedom of Information

MK CCG supports 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. The CCG will publish its 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. MK CCG benefits 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.

MK 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.

Duties / Accountabilities and Responsibilities
The CCG Head of Medicines Management will be responsible for assessing schemes against the principles outlined above. Decisions will be endorsed by the CCG Prescribing Group.

The CCG Senior Medicines Management Technician will be responsible for administering the rebate schemes in conjunction with the Primary Care Finance Manager.

The financial benefit for rebate schemes will be reported as part of QIPP to the CCG Finance Team and CDG.

Assessment framework

Product	**Company Contact Details**
	Question Yes/No
Is product listed on MK Joint Trusts Formulary?	
The product is not listed on the Double Red or 'Do Not Prescribe 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?	
If the product is a vitamin and classed as a food supplement, is it recommended for use in MK CCG?	
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?	
Confirm that 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. of years scheme is available? (Is it >2 years?)	
Estimated potential savings (per annum)?	
Have any other contractual or legal issues been identified during the evaluation?	
Outline: Estimated administrative burden Any potential legal or contractual issues Any Governance issues Any Freedom of Information issues Any other pertinent issues	
Recommendation	
Rationale	
Evaluation carried out by (Name, Title & Date)	
Checked by (Name, Title & Date)	

CCG Decision I do/do not support the decision to agree to this primary care rebate scheme

Signed: Date:

Head of Medicines Management

I do/do not support the decision to agree to this primary care rebate scheme

Signed: Date

Primary Care Financial Officer

Policy developed by CCG Pharmaceutical Advisers. Next review due September 2021