Quality care, best value, better outcomes

North Staffordshire Clinical Commissioning Group

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Policy on Primary Care Rebate Schemes within North Staffordshire

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CONSULTATION AND RATIFICATION SCHEDULE

Name and Title of Individual	Date Consulted
Alex Palethorpe Head of Governance	April 2013
Legal Advisers Mills and Reeves	May 13

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Contents

1.0 Introduction

Primary care rebate schemes (PCRS) are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s). Such schemes are increasingly being offered to Clinical Commissioning Groups (CCGs) by the pharmaceutical industry as a means to introduce new drugs into the NHS, or more simply as a tool to increase/ establish market share of existing/new medicine(s).

This policy provides the clarity and guidance for commissioners in North Staffordshire CCG when considering entering in a primary care rebate scheme.

2.0 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[1] 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 and it is acknowledged that North Staffordshire CCG will seek further legal advice on any point identified. (Detailed legal advice from DAC Beechcroft is available from North Staffordshire CCG Medicines Management).

3.0 Scope

This policy applies to commissioners of medicines management services in North Staffordshire CCG and should be used in conjunction with the following NHS North Staffordshire policies which have been adopted by the CCG until a formal review and adoption has taken place:

- Commercial sponsorship within NHS North Staffordshire;
- Business Ethics Policy;
- Prime Financial Policies and Scheme of Delegation *(Policy No 4.27)*.

4.0 Overarching Principles

4.1 It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS.

4.2 Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development. This is in line with DH document (gateway reference 14802) on *Strategies to Achieve Cost-Effective Prescribing (2010)*[2]. This states that the following principles should underpin local strategies:

i. The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, e.g. from the National Institute for Health and Clinical Excellence (NICE) or other authoritative sources;

ii. Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, e.g. patients whose clinical history suggests they need a particular treatment should continue to receive it;

iii. The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;

iv. Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;

v. Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.

vi. Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the PCT's website.

5.0 Good Practice Principles for Primary Care Rebate Schemes

The detailed content of primary care rebate schemes offered to primary care organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. Although these Good Practice Principles can help CCGs assess these schemes, the CCG will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing made under the 2006 Act, the

Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness (see legal advice for more details).

The CCG will adopt the following principles when deciding whether it participates in a PCRS or not:

5.1 Product Related

5.1.1 PCRS will only be considered for those medicines where there is a clinical need for a medicine and its place in a care pathway has already been established through normal CCG Governance, i.e. Medicines Management Committee (MMC), Area Prescribing Committee (APC). The price of a medicine will be considered but this consideration will be secondary to the clinical need of the medicine and its place in established pathways.

5.1.2 Health professionals should always base their prescribing decisions primarily on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.

5.1.3 The CCG will not consider or promote unlicensed or 'off-label' uses of medicines as part of a PCRS. Furthermore, a PCRS must be linked with a drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.

5.1.4 All recommendations for use of a medicine within a PCRS must be consistent with the UK Marketing Authorisation of the medicine in question, i.e. the PCRS should only advocate the use of the drug in line with the data sheet/Specific Product Characteristics (SPC) for the drug in question.

5.1.5 Medicines not recommended by NICE will not be considered under a PCRS unless there is clear evidence that the scheme helps the CCG meets its duty to use its resources effectively, efficiently and economically.

5.2 Rebate Scheme Related

5.2.1 Any and all decision making processes will be clinically-led and involve all appropriate stakeholders, including patients where appropriate.

5.2.2 The clinical decision should inform the financial/procurement decision and not vice versa.

5.2.3 Rebate schemes will only be approved through robust governance processes by the Medicines Management Committee.

5.2.4 Any administrative burden to the CCG of setting up and running a PCRS must be factored into the assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements financial governance, data collection and any hidden costs.

5.2.5 The term of agreement must clearly be stated.

5.2.6 GPs at practice level cannot negotiate or agree to any PCRS and none negotiated at the GP level will be approved by the CCG

5.2.7 The CCG will not approve any PCRS that gives exclusivity to a particular drug.

5.2.8 The CCG will not approve any PCRS that involve Category M and some medicines in Category C in the Drug Tariff, which can impact on community pharmacy reimbursement.

5.2.9 Where possible the CCG will avoid rebate schemes directly linked to increase market share or volume of prescribing unless the volume based scheme is clinically appropriate.

5.2.10 A volume based scheme will only be considered providing the administrative burden of monitoring such a scheme does not outweigh financial benefit.

5.2.11 Commissioners will ensure that a formal written contract is in place, signed by both parties to ensure:

I. That the terms of the scheme are clear.
II. To maximise the legal protection.

All negotiations around a scheme should be expressed as 'subject to contract' i.e. not binding until a formal contract has been signed by both parties.

5.2.12 The CCG will ensure that all PCRS agreements include a right to terminate on notice (i.e. without having to have any reason for doing so) with a sensible notice period e.g. three months.

5.2.13 The CCG should agree exit criteria and an exit strategy before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. The CCG will agree a shorter notice period in these circumstances.

5.3 Information and Strategy

5.3.1 The CCG will make public the existence of any PCRS they have agreed on the public website page.

5.3.2 The CCG will not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These PCRS should all be considered using the same criteria.

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

5.3.4 The CCG will ensure that all PCRS agreements meet the requirements of the Data Protection Act, and patient confidentiality must never be compromised.

5.3.5 No scheme will be entered into that requires CCG Commissioners to provide information about competitor products market share.

5.3.6 Freedom of Information (FOI) requests: as a general principle, information relating to rebate schemes is likely to be releasable. These should be discussed before entering into any PCRS agreement. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract. (See legal advice from DAC Beechcroft for further details).

5.3.7 Where appropriate the CCG will allow discounts and details of any PCRS offered, to be shared within the NHS and will be agreed as part of the PCRS contract.

6.0 Policy Review

This policy will be reviewed by a period of no longer than 2 years as stated or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

7.0 Acknowledgements

North Staffordshire CCG acknowledges the work done by the London Procurement Partnership and the legal advice obtained by them from DAC Beechcroft in producing this policy.

8.0 References

1. Principles and Legal Implications of Primary Care Rebate Schemes 2012. London Procurement Partnership. http://www.lhttp://www.lpp.nhs.uk/page.asp?fldArea=2&fldMenu=6&fldSubMenu=7&fldKey=271pp.nhs.uk/page.asp?fldArea=2&fldMenu=6&fldSubMenu=10&fldKey=252 . [Accessed 07.01.2013].

2. Strategies to Achieve Cost-effective Prescribing. DH Gateway Reference 14802. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120213.pdf