Principles and Legal Implications of Primary Care Rebate Schemes

1. Background

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). The London Primary Care Medicines Use and Procurement QIPP group agreed that it was unclear if these schemes were allowed within current regulations, and were concerned that proliferation of primary care rebate schemes may cause an unacceptable administrative burden to the NHS. It was agreed that these schemes should only be implemented if legal opinion advised that they were not in breach of UK legislation and that they offered genuine benefits to the NHS and to patients.

Following legal advice and consultation with stakeholders, a set of principles of good practice for primary care organisations to use to facilitate robust scrutiny and identification, adoption and implementation of primary care rebate schemes have been developed, and are outlined below.

The group agreed the following overarching principles:

- 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.

- 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 the DH document (gateway reference 14802) on *Strategies to Achieve Cost-Effective Prescribing (October 2010)*. 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, eg, 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, eg, 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;

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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.

2. Legal Advice

Legal advice sought by the London Procurement Partnership (LPP) concluded that primary care rebate schemes are not unlawful and are within the powers of PCTs and will be within the powers of CCGs to agree to, provided they meet certain requirements. Commissioners should refer to the detailed legal advice from DAC Beachcroft for further information (available from Jas Khambh at LPP, jasbinder.khambh@lpp.nhs.uk). Whilst this legal advice may be shared within the NHS, it should be noted that this legal advice is addressed to the LPP. If individual Trusts identify any points that require further clarification, then they may need to seek their own further legal advice.

3. 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 PCOs assess these schemes, the PCO 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).

Issue	Good practice principles
Product related	• Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by established local decision-making processes. The clinical decision should inform the financial/procurement decision and not vice versa. • 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. • Any medicine considered under a 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. • Rebate schemes promoting unlicensed or off label uses must 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 i.e. the PCRS should only advocate the use of the drug in line with the data sheet for the drug in question. • Medicines not recommended by NICE might still be the subject of a PCRS,

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	but specific and documented consideration must be given to how such a product can properly be recommended to prescribers notwithstanding NICE's position. CCGs will need to explain how the scheme helps it meet its duty to use its resources effectively, efficiently and economically.
Rebate scheme related	• Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate. • Rebate schemes should be approved through robust local governance processes that include Medicines Management Committee/Area Prescribing Committee (or equivalent) approval, involving both primary and secondary care and Director level approval. • The administrative burden to the NHS 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. • Primary care rebate schemes should be agreed at a statutory organisational level, they should not be agreed at GP practice level. • Schemes encouraging exclusive use of a particular drug should be avoided. • Rebate schemes are not appropriate for medicines in Category M and some medicines in Category C of the Drug Tariff, because of the potential wider impact on community pharmacy reimbursement • Ideally the PCRS should not be directly linked to requirements to increase market share or volume of prescribing. • A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered. • Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure (i) that the terms of the scheme are clear and (ii) to maximise the legal protection. All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties. • PCRS agreements should 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 or six months. • 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 emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances.
Information and Transparency	• Primary care Organisations (PCTs and in the future CCGs) should make public (for example on their website) the existence of any PCRS they have agreed to. • Primary care organisations should not enter into any PCRS which

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	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. • There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data. • PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised. • Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share. • Freedom of Information –As a general principle information relating to rebate schemes is likely to be releasable, these issues should be discussed with the manufacturer before a commissioner enters into any agreement with them. Ideally, provisions about FOIA requests and commercially sensitive information should be contained in the contract. See legal advice for more details. • Discounts and details of any PCRS offered should be allowed to be shared within the NHS. This should be agreed as part of the PCRS contract.

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