North East Pharmacy Procurement Service

Hosted by: North Tees and Hartlepool NHS Foundation Trust

Primary Care Rebate Schemes (PCRS) for Medicines - Assessment Process

1. Introduction

In recent years the existence of Primary Care Rebate Schemes (PCRS) offered by pharmaceutical companies has become increasingly common. Since 2014, CCGs within the North East and North Cumbria region have operated a joint process for assessing and managing such schemes. This is operated on their behalf by The North East Pharmacy Procurement Service (NEPPS). This joint approach allows:

- Co-operation and consistency of approach to rebate schemes across the North East and North Cumbria.
- Prevention of duplication of professional and managerial effort by ensuring joint and collaborative working.
- Facilitates cost effective use of medicines across the North East and North Cumbria by ensuring that rebate schemes meet specific quality control requirements.
- Secures access to specialist procurement advice that can be disseminated across the North East and North Cumbria.

2. Background

The prices of branded medicines are controlled by a UK-wide voluntary scheme called PPRS. Under the terms of the 2014 PPRS agreement, the Department of Health does not support additional or alternative initiatives by health authorities in respect of the pricing of branded medicines in primary care, however there is no specific legislation against them, nor does PPRS preclude initiatives by the pharmaceutical industry.

Although there has been concern that rebate schemes might undermine PPRS, it has been recognised that they are a reality and that they need to be managed in a consistent, transparent and robust process. Concerns were raised that these schemes might be in breach of UK legislation, so in 2012 the London Procurement Programme sought legal advice[1]. This reviewed such issues as the Medicines Act, the Bribery Act and procurement law and concluded that primary care rebate schemes were not unlawful and were within the powers of CCGs to agree to, provided they met requirements related to good governance.

3. Assessment of Primary Care Rebate Schemes

The uptake of rebate schemes should only be undertaken following a thorough assessment process. The objective being to provide robust governance to ensure that any rebate agreements reached with the pharmaceutical industry gain best value for money for NHS organisations.
A number of mechanisms that offer governance to CCGs have been established including that currently undertaken by the PrescQIPP NHS Programme and that formerly undertaken by the London Procurement Partnership (LPP). All of these use good practice principles such as those below, developed by the LPP.

1. Product related

1.1. 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.

1.2. Healthcare 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.

1.3. 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.

1.4. 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.

1.5. Medicines not recommended by NICE might still be the subject of a PCRS, but specific and documented consideration must be given to how such a product can be recommended to prescribers notwithstanding NICE's position. CCGs will need to explain how the scheme meets its duty to use its resources effectively and economically.

2. Rebate scheme related

2.1. Decision making processes should be clinically led and involve all appropriate stakeholders, including patients where appropriate.

2.2. 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.

2.3. 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.

2.4. PCRS should be agreed at a statutory organisational level, they should not be agreed at GP practice level.

2.5. Schemes encouraging exclusive use of a particular drug should be avoided.

2.6. Rebate schemes for medicines in Category M and some medicines in Category C of the Drug Tariff, should be especially carefully considered because of the potential wider impact on community pharmacy reimbursement. Short term local savings are likely to be offset by increased costs to the wider NHS in the longer term. Schemes which promote prescribing of branded generics or original brands in preference to generics, pose the added risk that they undermine the concept of generic prescribing.

2.7. Ideally the PCRS should not be directly linked to requirements to increase market share or volume of prescribing.

2.8. Schemes which link a rebate directly to increase in volume of prescribing above a defined threshold could be judged to be an attempt to influence prescribing inappropriately and should generally be avoided. The administrative burden of monitoring such schemes should be carefully considered.

2.9. 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.

2.10. 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 to six months.
2.11. 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.
2.12. Is the value of the offer quantifiable and proportionate to the administrative burden? Is there an appropriate return on investment?
2.13. Schemes which link a rebate to prescribing of more than one drug should be especially carefully considered to avoid the risk that savings made on one are indirectly offset by costs incurred on another.

3. Information and transparency

3.1. Primary care organisations should make public (for example on their website) the existence of any PCRS they have agreed to.
3.2. Primary care organisations should 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.
3.3. There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.
3.4. PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised.
3.5. Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products' market share.
3.6. 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. As a general principle, information about rebate schemes may be released under FOI requests, but commercially sensitive information is usually withheld. See legal advice for more details.
3.7. 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.
3.8. Is the invoice process transparent as per NHS financial requirements?

4. Assessment process

Assessment of rebate schemes will be carried out by a PCRS Assessment Panel which will meet at regular intervals. This is a sub-group of the North East Pharmacy Procurement Group (NEPPG) and will include the following members or their delegated representative:

- Specialist Procurement Pharmacist (North East and North Cumbria) - NEPPS
- Medicines Optimisation Pharmacist - NECS
- Medicines Optimisation Administrator - NECS
- Medicines Optimisation Pharmacist – North Cumbria CCG
- Medicines Optimisation Pharmacist - Durham Dales, Easington and Sedgefield CCG
- Medicines Optimisation Pharmacist – Newcastle Gateshead CCG
- Medicines Optimisation Pharmacist - North Durham CCG
- Medicines Optimisation Pharmacist - Sunderland CCG

The rebate scheme will be assessed using the following process:

4.1. Companies wishing to have a rebate scheme considered will inform the chair of the assessment panel and submit all relevant paperwork before the meeting.

4.2. Companies may be invited to present to the panel at one of its regular meetings if the members deem this to be necessary.

4.3. Rebate schemes will be assessed, taking into consideration the following factors:

a. The 'Good Practice Principles' listed above.

b. Decisions taken by PrescQIPP

c. National and regional policies and guidance (such as developed by UKMI[2]) related to the prescribing of medicines by brand name – medicines should be prescribed by generic name except where there are clinical and/or safety needs for a product to be prescribed by brand.

d. Any savings should exceed the administrative burden. More consideration will be given to schemes where the savings for the region were over £2000 per year.

4.4. After assessment, rebate schemes will be rated as either ***Appropriate*** or ***Not Appropriate*** and details noted on a checklist (appendix 1) and in the minutes of the North East Pharmacy Procurement Group (NEPPG).

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4.6. Rebate schemes rated ***Appropriate*** by the assessment panel will be referred to the CCGs who will consider whether to accept the scheme, using their relevant governance processes (See key principle 2.2).

4.7. If accepted by a CCG, a rebate scheme will be signed off by the appropriate authorised officer within a CCG and signed paperwork will be returned to the chair of the assessment panel.

4.8. The chair of the assessment panel will inform the manufacturer of the CCG's decision and send on any relevant signed paperwork.

4.9. At agreed intervals, product use, as derived from ePACT data, will be sent to the manufacturer so that rebates can be paid by BACS transfer to the statutory organisation.

4.10. Organisations can appeal against a decision of the panel but only on the grounds that the above process has not been followed. Such appeals should be addressed to the chair of the panel.

5. Roles and responsibilities

Some of the roles and responsibilities surrounding this process are summarised below:

5.1. **Responsibility for assessment**

a. The chair of the assessment panel is responsible for liaising with the company at all stages of the process in order to arrange meetings and arrange collation of appropriate paperwork.

b. The assessment panel is responsible for assessing the rebate scheme against the 'Good Practice Principles' and other factors listed above. This includes assessment of the likely financial benefit of schemes using relevant ePACT data.

c. The assessment panel is responsible for recording their assessment rating and passing the information to the CCGs.

Note: The role of panel members is to ensure that overall good governance is applied to the process rather than necessarily representing their individual organisations and their requirements.

5.2. **Responsibility for approval**

a. The CCG will consider schemes assessed as appropriate and refer them for approval through their local governance processes as suggested in 'key principle' 2.2.

b. A senior officer of the CCG (e.g. Chief Finance or Operating Officer) is responsible for final approval of rebate agreements for each CCG

Note: Should a CCG decide to accept a scheme which has been assessed as 'not appropriate', then it would be doing so at its own risk, and would be responsible for administering the scheme. Such risks could include, but are not limited to, issues around the Bribery Act, general transparency around data handling and the use of public monies, procurement legislation, and NHS policy.

5.3. **Responsibility for communication**

a. The CCG, through its delegated officials, is responsible for communication of the existence of rebate schemes to GPs and the public e.g. via its website.

5.4. **Responsibility for processing claims**

a. The NE Pharmacy Procurement Service will prepare rebate claims using ePACT data. These claims will then be sent to the CCG Medicines Optimisation services and the company for information.

b. The CCG Medicines Optimisation services will arrange for the raising of invoices which will be sent to the company along with the details of the claim.

6. References

[1]Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme. 2012.

[2]Which medicines should be considered for brand-name prescribing in primary care? UKMI. Nov 2017

Appendix 1

Checklist for Primary Care Rebate Schemes

Date:	
Name of Drug:	
Company Name:	
Company Contact:	
Version of contract assessed:	

PresQIPP overall status:

Good practice principles	Principles met: Yes or No	Comments
1. Product related		
1.1 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.		
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.		
1.3 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.		
1.4 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.		
1.5 Medicines not recommended by NICE might still be the subject of a PCRS, 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.		
2. Rebate scheme related		
2.1 Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate.		*For local determination*
2.2 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.		*For local determination*
2.3 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.		
2.4 Primary care rebate schemes should be agreed at a statutory organisational level, they should not be agreed at GP practice level.		
2.5 Schemes encouraging exclusive use of a drug should be avoided.		
2.6 Rebate schemes for medicines in Category M and some medicines in Category C of the Drug Tariff, should be especially carefully considered because of the potential wider impact on community pharmacy reimbursement. Short term local savings are likely to be offset by increased costs to the wider NHS in the longer term. Schemes which promote prescribing of branded generics or original brands in preference to generics pose the added risk that they undermine the concept of generic prescribing.		

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2.13 Schemes which link a rebate to prescribing of more than one drug should be especially carefully considered to avoid the risk that savings made on one are indirectly offset by costs incurred on another.		
3. Information and transparency		
3.1 Primary Care Organisations should make public (for example on their website) the existence of any PCRS they have agreed to.		*Will be done at local level*
3.2 Primary Care Organisations should 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.		
3.3 There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.		
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3.7 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.		
3.8 Is the invoice process transparent as per NHS financial requirements?		

Summary of Assessment:	
Overall Status	**SCHEME CONSIDERED:**