WARRINGTON CLINICAL COMMISSIONING GROUP
Principles for Managing Pharmaceutical Rebates in Primary Care

BACKGROUND

1. Primary care rebate schemes are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded products.

2. A number of rebates have already been agreed with the CCG, and contribute to Quality, Innovation, Productivity and Prevention (QIPP) efficiencies.

3. These principles provide a framework for managing such rebates in a legal and ethical way.

PRINCIPLES FOR MANAGING PHARMACEUTICAL REBATES

SUMMARY

A. Primary care rebate schemes (PCRS) are increasingly being offered by pharmaceutical companies to Clinical Commissioning Groups (CCGs) as a means of introducing new products into the NHS.

B. Concerns have been raised by some CCGs about the lack of clarity as to whether PCRS are allowed under the current regulations. The London Primary Care Medicines Use and Procurement QIPP group (as part of the London Procurement Partnership) previously sought legal advice on this issue and was advised that PCRS are not unlawful. CCGs have the power to agree to PCRS provided the schemes meet certain requirements.

C. This policy provides clarity and guidance for commissioners in Warrington CCG when considering entering into PCRS.
1. PRIMARY CARE REBATE SCHEMES (PCRS)

1.1 PCRS are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded products, enabling refunding of money back to the NHS.

1.2 Use of PCRS allows pharmaceutical companies to reduce the cost of medicines to the primary care sector within the constraints of the Pharmaceutical Price Regulation Scheme (PPRS) rules and the global pricing environment.

1.3 If used correctly, PCRS offer significant opportunities to improve the efficient use of the prescribing budget, improve patients' access to medicines and contribute to Quality, Innovation, Productivity and Prevention (QIPP) efficiencies.

2. RELEVANCE

2.1 PCRS can be adopted in respect of medicines with a EU or UK product licence or to prescribable appliances, dressings, and food supplements. Where a product has multiple indications the scheme should apply in respect of all such indications unless a decision is made otherwise by the CCG.

3. GOVERNANCE & CLINICAL EVALUATION

3.1 All rebate schemes are to be considered at the relevant Pharmacy Management Team Meeting for evaluation as follows:

<table>
<thead>
<tr>
<th>Indicator for Assessment</th>
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<tbody>
<tr>
<td>1. Licensed indications (and those of alternative products)</td>
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<tr>
<td>• All recommendations for use of a medicine within a PCRS must be consistent with the medicine’s UK Marketing Authorisation and in line with its Summary of Product Characteristics (“SPC”).</td>
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<tr>
<td>• CCGs should not consider or promote unlicensed or &quot;off-label&quot; uses of medicines under any PCRS.</td>
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<td>• PCRS must not limit the particular indications for which the medicine in question can be used.</td>
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<td>2. Current formulary / guideline status of the product / existing care pathways</td>
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<tr>
<td>• PCRS should not constrain existing local decision making processes or formulary development</td>
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<td>3. Duration of PCRS</td>
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<tr>
<td>• Term of the PCRS contract must be clearly stated. CCGs must have the right to terminate the contract on notice for convenience (see below “Contractual Requirements”).</td>
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<td>4. Structure of the rebate</td>
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<tr>
<td>• Straight discount on price, volume based scheme, or something more complex?</td>
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<tr>
<td>• Volume based schemes will not be considered.</td>
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<td>• PCRS should not be directly linked to requirements to maintain or increase market share or volume of prescribing.</td>
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<tr>
<td>• PCRS must not specifically advocate the use of one product over another.</td>
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<td>• GPs should not be required to do any more than consider a particular product.</td>
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<td>5. Is the PCRS non-exclusive?</td>
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<tr>
<td>• PCRS should not restrict the CCG from entering into rebate schemes with other manufacturers,</td>
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including manufacturers of competitor products

6. **Recommended by NICE?**
   - Medicines not given recommended status by NICE will not be considered

7. **Administration costs and burden to the NHS**
   - PCRS should only be considered where the administrative burden of monitoring such a scheme does not outweigh financial benefit.
   - Consideration should be given to the administrative cost of audit requirements, financial governance, data collection and any hidden costs

8. **Patent expiries of product or alternatives**
   - Consideration should be made on the potential impact on patent expiry of the drug or an alternative product that would negate any rebate impact.

9. **Viability of scheme based on current usage of product**
   - Low usage may not make a scheme viable

10. **Estimate of potential savings**
    - The value of potential savings should be an initial consideration in order to progress with the scheme

11. **Branded versions of category M generics**
    - CCG will consider the impact of the scheme on other partners including community pharmacy and secondary care

12. **Confidentiality requirements**
    - Clarification should be sought on ability share information on any PCRS across neighbouring CCGs and secondary care.

4. **UNDERPINNING PRINCIPLES**

4.1 Any product 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 and within the local medicines formulary. 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.

4.2 PCRS should be adopted and implemented at an organisational level across the CCG. Schemes should not be agreed at GP practice level.

4.3 Health professionals should always base their prescribing decisions on assessments of their individual patients’ clinical circumstances. PCRS should only be considered for those products where there is a clinical need for such product and its place in a care pathway has already been established through normal CCG governance.

4.4 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 as well all any QIPP priorities to maximise value in the prescribed product.

4.5 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.
4.6 Prescribers should be able to make their choice of products on the basis of clinical suitability, risk assessment and value for money.

4.7 Schemes should be reviewed:

i. whenever relevant NICE or other guidance is updated; and

ii. whenever there is a relevant change in any local or national policies or guidance.

4.8 The detailed content of PCRS offered to primary care organisations will differ between schemes. Any PCRS must be compatible with the effective, efficient and economic use of NHS resources. The CCG will need to be assured that any PCRS does not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the Department of Health’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.

5. CONTRACTUAL REQUIREMENTS

5.1 Commissioners should ensure that a formal written contract is in place, signed on behalf of the CCG and by the pharmaceutical company to ensure that the terms of the scheme are clear and to reduce legal risks.

5.2 All pre-contractual negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by the pharmaceutical company and the CCG. 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.

5.3 Exit criteria and an exit strategy should be agreed before a PCRS is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. Arrangements for the termination of the scheme should be detailed and agreed.

5.4 The requirement for volume thresholds within schemes will rule out the implementation of a rebate.

5.5 The terms of the contract should not prevent the CCG from responding to Freedom of Information (FOI) requests (see below – “Information Governance”).

6. INFORMATION GOVERNANCE

6.1 The PCRS should not place any requirement on the CCGs to collect or provide to the pharmaceutical company any information other than the volume of sales of the product in question. The CCG should not agree to any PCRS which requires the CCG to provide information about the market share of competitor products.
6.2 The CCG should make public the existence of any PCRS they have agreed on its public website page.

6.3 Agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised.

6.4 Information about PCRS schemes is likely to be releasable under an FOI request. This should be discussed with the manufacturer before a CCG enters into any PCRS agreement with them. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract. The CCG should not agree to any PCRS which purports to prevent the CCG from releasing information under an FOI request.

7. **EQUAL ACCESS**

7.1 The CCG must be able to demonstrate that all pharmaceutical companies wishing to offer rebates or similar commercial offers are provided with equal access. When appointments are requested and the reason given is to discuss a PCRS, appointments should always be arranged at the next mutually convenient time.

7.2 The CCG must not offer or expect any favourable positioning of a product with respect to local formulary in return for a rebate. Similarly, suppliers should not make guideline or formulary positioning conditional to any rebate offer.

8. **SIGN-OFF**

8.1 The Senior Prescribing Advisers and the Chief Finance Officer should ensure that a formal written contract is in place, signed on behalf of the CCG and the pharmaceutical company to ensure that the terms of the PCRS are clear and to recue legal risks to the CCG.

9. **UTILISATION OF FUNDS**

9.1 It is important that any funds received by the CCG as part of a PCRS or similar commercial agreement are managed in a transparent, legal and ethical way.

9.2 Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Warrington CCG Finance and Performance Committee.

9.3 No individual should stand to gain a financial (or other) advantage from PCRS. In particular, the PCRS must not confer a financial benefit on a GP or a GP practice.

10. **REVIEW**

10.1 These principles will be reviewed at least every two years, and following any relevant changes in local and/or national policies and guidance.
11. PATHWAY FOR DECISION MAKING

11.1 Appendix 1 shows a pathway for decision making for pharmaceutical rebates in primary care, based on the principles above.
11.2 Appendix 2 shows the Warrington CCG specific in house process flow chart

References and Acknowledgements:

1. West Leicestershire Clinical Commissioning Group, Principles for Managing Pharmaceutical Rebates on Prescribed Products in Primary Care.
2. Review of Primary Care Rebate Schemes, NWCSU Medicines Management Team for Wirral CCG (internal document)
4. Sandwell and Birmingham Clinical Commissioning Group, Policy for managing rebates on prescribed products in primary care, SWBCCG Pol 16
5. Review of Primary Care Rebate Schemes, CSU Medicines Management Team for Wirral CCG
6. HSJ Supplement, For Healthcare Leaders, Drug Savings, November 2013
7. East of England PrescQipp Pharmacy Industry Scheme, Governance Review Board, Operating Model v 2.5

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Appendix 1

Pathway for Decision Making for Pharmaceutical Rebates in Primary Care

1. Initial Considerations
   - Rebate offered by Pharmaceutical Manufacturer
     - Yes
   - Cost advantage (CCG threshold defined)
     - Yes

2. Clinical Considerations
   - Licensed indication
     - Yes
   - No negative assessment by NICE
     - Yes
   - Currently on formulary
     - Yes
   - Patent expiry of product or alternative product does not have an impact
     - Yes

3. Contractual Considerations
   - Term of contract clearly stated with exit clause
     - Yes
   - No exclusivity clause against other formulary products
     - Yes
   - Straight discount on price not associated with volume
     - Yes
   - Administrative burden does not outweigh benefit

Proceed if ALL questions are answered with a ‘Yes’
Appendix 2

Warrington CCG – Rebate Scheme Flow Chart

Any direct Pharmaceutical Representative enquiries to CCG should be redirected to generic Medicines Management email address (medsmanagementbevan@cmcsu.nhs.uk)

Medicines Management Team receive appointment requests regarding potential rebate scheme

Senior Pharmacist/Prescribing Advisor to complete initial review considering clinical and financial aspects e.g. formulary implications / prescribing data / patent expiry / licensed indications

Prepare brief report for Pharmacy Management Team

Discuss at Pharmacy Management Team
  Decide if viable to pursue further

YES
  Reply to email from generic Medicines Management email address advising meeting to be arranged

NO
  Reply to email from generic Medicines Management email address declining meeting with reason

Meet with Pharmaceutical Representative to confirm scheme details including contractual considerations

Prepare briefing note on proposed rebate for Chief Finance Officer.

If rebate approved, and contracts signed by Chief Finance Officer. Add to rebate list on CCG website

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