

This policy was approved for use by the Surrey Heartlands CCG Governing Body in April 2020. The policy may still refer to multiple CCGs but the content is accurate and correct.

The policy will be rewritten to reflect the single CCG, as part of the planned policy review cycle, or earlier.



Surrey Heartlands CCG
Surrey Heath CCG
Crawley CCG
Horsham & Mid Sussex CCG

CLIN11

PRIMARY CARE REBATES ETHICAL FRAMEWORK

1. INTRODUCTION

Primary Care Rebate Schemes (PCRS) are regulated by the NHS Standards of Conduct for NHS Staff and the ABPI Code of Practice. Neither prohibits rebates, including volume-based rebates. However, inducements to prescribe are prohibited, so commissioners need to be mindful that any arrangement is not an inducement to prescribe.

The DH has been asked for their view on rebate schemes and the response is attached in Appendix A. Although they raise concerns about the potential impact on the Pharmaceutical Price Regulation Scheme (PPRS) they state that, ultimately, it is for individual NHS organisations to determine whether they should participate in such arrangements.

This document highlights the key principles that need to be established before entering into a rebate agreement. Even if the arrangement does not provide direct personal incentives for GPs to prescribe a particular drug, behaviour patterns of the commissioning organisation that seek to influence or pressure GPs to prescribe the drug could be viewed as inducements to prescribe. A statement within an agreement that a CCG "will recommend" the prescription of the drug could be construed differently to a statement such as *"the parties agree that the execution of this Agreement does not and will not act as any inappropriate or unlawful inducement, directly or indirectly, to the [commissioner] or for individual prescribers to prescribe, supply, administer, recommend, buy or sell any particular [insert Company Name] medicinal product or medical device."*

2. PURPOSE AND SCOPE

This ethical framework covers the principles and processes by which the CCG will consider future Primary care rebate schemes (PCRS) proposals.

Surrey Heartlands CCG, Crawley CCG, Horsham and Mid Sussex CCG, and Surrey Heath CCG have agreed to work collaboratively when considering future PCRS through the Medicines Commissioning Group. This will not preclude individual CCGs from entering into or declining agreements on a unilateral basis.

3. DEFINITION

A primary care rebate scheme is an agreement between a commissioning organisation and a pharmaceutical company that provides an economic benefit to the commissioner and, in theory, provides benefits in relation to the sales of a company's product. Unlike national patient access schemes, which are a way of obtaining new drugs for patients more cheaply, primary care rebate schemes are usually for drugs, nutritional products or devices already on the market where there are competitor products available.

4. BACKGROUND

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism which the Department of Health uses to ensure that the NHS has access to good quality branded medicines at reasonable prices. The scheme seeks to achieve a balance between reasonable prices for the NHS and a fair return for the industry to enable it to research, develop and market new and improved medicines. The PPRS does not apply to devices or nutritional products; nor does it apply to generic medicines whose prices tend to be controlled by their Drug Tariff agreed pricing.

A number of manufacturers have established 'rebate schemes' for drugs used in primary care. 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. The discount schemes are confidential to the NHS enabling manufacturers to maintain a higher price in global markets. The PPRS published in 2014 stated that *"NHS England has agreed to seek to bring to an end initiatives by NHS commissioners (NHS England or clinical commissioning groups) to arrange for rebates to be paid by manufacturers to the commissioning body for the supply of medicines with a positive NICE technology appraisal to providers of NHS services in primary or secondary care."* As such, CCGs must not actively seek rebates from manufacturers, but there is no reason why a CCG cannot consider a rebate offer if initiated by the manufacturer themselves.

A number of CCGs within the MCG subscribe to PrescQIPP. This organisation undertakes assessment of rebate schemes on behalf of its members (see Appendix B) and has confirmed that following assessment by their Primary Care Rebate Board, manufacturers are entering an agreement whereby their rebate offer is valid to all PrescQIPP subscribers. As such, subscriber CCGs are able to approach manufacturers to discuss rebate offers that have been through this process.

The London Primary Care Medicines Use and Procurement QIPP group sought opinion about the legality of these schemes and the advice was that they were not in breach of UK legislation and that they offered genuine benefits to the NHS and to patients. Whilst this legal advice may be shared within the NHS, it should be noted that this legal advice is addressed to the London Procurement Partnership (LPP). If individual organisations identify

any points that require further clarification, then they may need to seek their own further legal advice.

The DH document (gateway reference 14802) on *Strategies to Achieve Cost-Effective Prescribing* (October 2010) was produced to assist CCGs in implementing the QIPP agenda. This states that CCGs should ensure that their strategies to achieve cost-effective prescribing satisfy the following criteria:

- *they are safe for patients;*
- *they meet the clinical needs of patients; and*
- *they secure best value for money from NHS resources*

In addition, the document states that the following principles should underpin local strategies:

- *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;*
- *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;*
- *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;*
- *Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;*
- *Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.*
- *Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the PCT's website.*

5. PRINCIPLES FOR ASSESSING PRIMARY CARE REBATE SCHEMES

Primary care rebate schemes offered to primary care organisations may differ considerably. The following principles provide a framework in which to assess any schemes, but further assurance may be required to ensure 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.

I. PRODUCT RELATED

1. Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by the Prescribing Clinical Network (PCN). The clinical decision should inform the financial/procurement decision and not vice versa.
2. Under therapeutic assessment the medicine/product can demonstrate equivalence or superiority over other medicines / products that may be used at the same point in a care pathway.
3. Prescribing decisions should be made primarily on assessments of individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.
4. The scheme applies only to medicines with an EU or UK product licence. Where a product has multiple indications the scheme should apply to them all.
5. 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.
6. 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.
7. Any agreement must not prevent choice.

II. REBATE SCHEME RELATED

8. Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate.
9. Rebate schemes should be approved through robust governance processes that include Medicines Management Committee approval, and Director level approval.
10. Under financial assessment the agreement should be transparent and represent best value for money for the NHS. The administrative burden to the NHS of setting up and running the scheme must be factored in. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.
11. Schemes will be offered to statutory NHS bodies and not to individual GPs or GP practices.
12. Any scheme offered should not be exclusive. That is there should be no requirement to limit access of other medicines to patients under the scheme
13. Rebate schemes are not appropriate for medicines in Category M and some medicines in other categories of the Drug Tariff, because of the potential wider impact on community pharmacy reimbursement

14. The requirement for volume thresholds within schemes is not actively encouraged.
15. Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure:
 - a. that the terms of the scheme are clear and
 - b. 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.

16. Arrangements for the termination of the scheme are detailed and agreed.
17. PCRS agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a reasonable notice period e.g. three or six months.
18. 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.
19. The agreement must not be construed as an incentive to prescribe.

INFORMATION AND TRANSPARENCY

20. CCG should make public the existence of any PCRS they have agreed to.
21. CCGs 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.
22. There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.
23. PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised. PCRS will not be entered into that requires provision of patient specific data
24. There is no requirement for the NHS to divulge any information other than the volume of sales of the manufacturer's medicine.
25. PCRS will be subject to Freedom of Information (FOI) requests and as general principle information relating to rebate schemes is likely to be releasable. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract.
26. 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.

III. SUPPLY

27. Resilience of supply of relevant products should be confirmed.
28. Accessibility of supply for community pharmacies and in particular whether there are any extra costs to community pharmacy which may not be particularly transparent (for example out of pocket expenses, increased stock holdings, use of a different supplier which amongst other things increases administration burdens.)

6. PROCESS

If a CCG receives an approach from a pharmaceutical company (or third party) offering a rebate and wishes the application to be considered by the MCG, then the requestor should be asked to complete Part 1 of the Primary Care Rebate Scheme (PCRS) Application Form (Appendix C). The receiving CCG should then complete Part 2 of the form for assessment by the MCG.

CCGs may wish to undertake local assessment of PCRS if their governance arrangements support this.

The completed application form will be considered at the MCG against the principles outlined above. Where PrescsQIPP have assessed the scheme independently (see Appendix B), the outcome of their assessment will also be shared with members of the MCG.

The MCG will make a recommendation as to the suitability of each scheme. Individual CCGs may either accept or decline this recommendation; the final decision to enter into a PCRS rests with the CCG.

If entering into a PCRS, the CCG may wish to note this non-personal interest in its conflicts of interest register and to inform the PCN secretary.

REFERENCES

- *Principles and Legal Implications of Primary Care Rebate Schemes*, London Primary Care Medicines Use & Procurement QIPP sub-group, October 2012
- *Strategies to Achieve Cost-Effective Prescribing*, DH (gateway reference 14802), October 2010
- *PrescQIPP Pharmaceutical Industry Scheme Governance Review Board Operating Model v3.0*

APPENDIX A

DH response to an enquiry from NHS Leeds 15th May 2012:

“The PPRS is the UK-wide voluntary scheme agreed between Government and the Association of British Pharmaceutical Industry to control the prices of branded medicines supplied to the NHS. Under the terms of the 2009 PPRS agreement (see paragraph 3.4 of the agreement), it states that 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.

The concern about local schemes is that they may fundamentally undermine the integrity and intent of the PPRS, whose objectives are to deliver value for money, encourage innovation, promote access and uptake for new medicines and provide stability, sustainability and predictability. Alongside increasing administration burdens for local NHS organisations, local pricing arrangements for all medicines would be unlikely to deliver the full objectives of the PPRS.

The pricing arrangements under the 2009 PPRS aim to secure value for money for the NHS whilst providing companies with the right incentives to invest in new and effective medicines for the future. The Department's concern is that local rebate schemes potentially undermine the PPRS pricing arrangements but also, it is possible that companies will seek to make good lost revenues from rebate schemes elsewhere, for example by increasing the wholesale price on other medicines or not offering as much discount to community pharmacies. Both of these scenarios could have implications for the community pharmacy contractual framework funding arrangements or lead to higher growth in the NHS drugs bill.

In view of this, Primary Care Organisations (PCO) should look critically at the wider ramifications of any potential rebate schemes on NHS budgets and future NHS service provision before entering into local agreements.

The PPRS does not extend to non-branded medicines or other items which may be prescribed on the NHS; this includes POM medicines. Depending upon the detail of the rebate scheme, it will be important to consider other relevant issues. If a company is offering an arrangement that is of added value to a PCO, for example, it supports implementation of one of the PCO's prescribing policies, or optimises patient's use of their medicines, there may be a benefit.

Before entering into any such arrangement a PCO may want to consider:

- 1. PCO/Practitioner administration burdens*
- 2. Longevity of any such arrangements*
- 3. Resilience of supply of relevant products*

4. *Accessibility of supply for community pharmacies and in particular whether there are any extra costs to community pharmacy which may not be particularly transparent (for example out of pocket expenses, increased stock holdings, use of a different supplier which amongst other things increases administration burdens.)*
5. *The need to obtain adequate independent legal advice to ensure there are no specific difficulties for example the Bribery Act, competition law and/or rules around procurement.*
6. *Access to robust data about product use and costs, taking into account administration burdens, needing to combine data sources when any historic or product comparison are needed and patient confidentiality requirements.*

In respect of 5, the Department issued guidance to PCTs and clinical commissioning groups on the operation of cost effective prescribing policies, including prescribing incentive schemes. This guidance reflects the decision of the European Court of Justice (ECJ) on the legality of prescribing incentive schemes. The guidance is clear about the policies which must be in place to ensure any schemes do not inappropriately influence prescribers. I attach a copy below for your information.

<http://www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Prescriptions/Costeffectiveprescribing/index.htm>

The ABPI code of practice is a matter for the ABPI and not for the Department to comment on.

Ultimately, it is for individual NHS organisations to determine whether they should participate in such arrangements. “

Summary of PrescQIPP Operating Framework

PrescQIPP have developed an operating model to independently assess PCRS, which classifies potential schemes as follows:

- Grey – Scheme Considered; No significant reservations
- Amber – Scheme Considered; Not fully appropriate
- Red – Scheme Considered; Inappropriate

Under this model, submitted schemes are required to demonstrate compliance with the following five principles in order to achieve a Grey/Amber Status:

1. The therapeutic initiative has a place in clinical practice
2. The arrangements for the scheme are simple and easy for the NHS to implement.
3. There is a transparent, sensible plan for payment and tracking
4. The governance on what the Scheme is, and is not, going to be used for is robust
5. There is a plan for ongoing review

PrescQIPP also strongly recommend adherence to a number of other principles that are in line with those developed by the London Primary Care Medicines Use & Procurement QIPP sub-group.

Primary Care Rebate Scheme (PCRS) Application Form**To be completed by proposer:**

Product(s):		Supplier:	
Submitted by:		Role:	
Contact number(s):		Email:	
Address:		Date:	

Please confirm that:	Yes	No
Is the rebate value linked to an increase in market share or volume of prescribing?		
Does the agreement preclude CCGs from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so?		
Is there a requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data?		
The supply chain for this product(s) is resilient		
Products are accessible to community pharmacies through usual wholesale routes and will not incur additional cost, e.g. out of pocket expenses, increased stock holdings, use of a different supplier		
Does the rebate offer relate to all licensed indications for the medicine?		

Please provide brief details of the Rebate Scheme.

Include what your data requirements will be, whether there is a volume threshold or thresholds, percentage/value discount, duration of contract/agreement and any other relevant information required to assess viability.

Attach any additional documents which you might consider relevant to your submission.

Note: The supplier should be aware that any contracts entered into will require the following clauses:

- The CCG is required to make public the existence of this and any other PCRS they have agreed to.
- The CCG reserve the right to consider any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These PCRS will all be considered using the same criteria.
- The CCG will only collect or submit to the manufacturer any data relating to the volume of use of the products subject to the PCRS as derived from ePACT data.
- No patient specific data will be made available to the manufacturer.
- The CCGs will not provide information to the manufacturer about competitor products market share.
- The PCRS will be subject to Freedom of Information (FOI) requests and as a general principle information relating to rebate schemes is likely to be releasable, subject to non-disclosure exceptions such as commercially sensitive information
- The CCG reserve the right to share discounts and details of the PCRS offered within the NHS.

Please submit this form electronically to Rachel.Claridge@nhs.net

To be completed by the CCG Medicines Management Team

	Yes	No
Has the clinical need for the medicine and its place in care pathways been agreed by PCN?		
Under therapeutic assessment the medicine/product can demonstrate equivalence or superiority over other medicines / products that may be used at the same point in a care pathway?		
If the product is a medicine, is it licensed in the UK?		
The product does not have a negative decision from NICE?		
There is no directive for health professionals to prescribe a specific product, i.e. the PCRS does not prevent choice?		
The product is not contained in Category A or M of the Drug Tariff?		
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?		
The PCRS meet the requirements of the Data Protection Act?		
Is the administrative burden arising from the agreement manageable?		
Does the scheme offer value for money?		

Summary and issues for consideration

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Advisory notes for commissioners

29. Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure:

- a. that the terms of the scheme are clear and
- b. 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.

30. A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered.

31. PCRS agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a reasonable notice period e.g. three or six months.

32. 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.

33. The agreement must not be construed as an incentive to prescribe

34. Under financial assessment the agreement should be transparent and represent best value for money for the NHS. The administrative burden to the NHS of setting up and running the scheme must be factored in. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.