NHS
Thurrock
Clinical Commissioning Group

Rebate Policy and Procedure

June 2016

Document Control:

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Board Sponsor:	Ade Olarinde
Responsible Committee:	Finance Management and Performance Committee
Ratified By and Date:	
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Target Audience:	Medicines Optimisation Team Finance Team Quality and Patient Safety Team

CONTENTS

1 INTRODUCTION

1.1 Within the NHS, medicines are generally purchased in one of two ways:

- In primary care, medicines are paid for through the Prescription Pricing Division of the NHS Business Services Authority who reimburses pharmacists for the drugs they dispense on the NHS at drug tariff prices.
- In hospitals drugs a purchased direct from the manufacturers (or through purchasing hubs) and as a result are able to tender their business and obtain discounts through therapeutic tendering.

1.2 Over the past few years the pharmaceutical industry has sought to emulate the hospital model through offering retrospective discounts to commissioners based on sales in the community that is on volume of drug prescribed and dispensed on NHS prescriptions.

1.3 In recent years commissioners within primary care have seen the introduction, and significant increase in numbers, of rebates offered within primary care. At present there are tens of schemes offered by companies ranging from the smallest to the largest, with schemes varying in composition and size.

1.4 The Department of Health (DH) 'Strategies to Achieve Cost-Effective Prescribing (2010)'[1] is in line the principle that 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.

1.5 Primary care rebates could provide significant efficiency savings if correctly and transparently governed. Failure to ensure transparency and governance could perversely affect local prescribing. It is therefore paramount to ensure compliance with relevant legislation when partaking in such schemes such as the reimbursement for pharmaceutical services according to the Drug Tariff, the 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.

1.6 To address the issues of transparency and governance NHS Thurrock CCG has developed this policy. The overarching principle of which is that only drugs which are currently on the primary care formulary will be considered.

2 PURPOSE / POLICY STATEMENT

2.1 This policy outlines NHS Thurrock CCG's mechanism and governance arrangements for agreement to participate in any primary care pharmaceutical industry rebate scheme.

2.2 The policy also ensures that the principles in the DH guidance (referred to in paragraph 1.4) are followed:

[1] 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

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 CCG's website*.

2.3 Separate policies exist within the Medicines Management Team to govern clinical practice for prescribing and the use of the formulary. This policy supports other policies by defining the governance framework for obtaining financial rebates in a structured and appropriate way.

3 DEFINITIONS

PrescQIPP NHS Programme's Pharmaceutical Industry Scheme Governance Review Board	A board consisting of pharmacists' representatives from primary and secondary care; East Anglia Medicines Information Service and procurement specialist pharmacist and a PrescQIPP project manager. The board works to a standard operating model and assess the schemes using a standardised assessment tool encompassing a clinical assessment; a contractual assessment and a financial assessment.
Primary Care Formulary	List of agreed cost-effective drugs for use first line in primary care.
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).

4 ROLES AND RESPONSIBILITIES

4.1 Medicines Optimisation Team

4.1.1 The Medicines Optimisation Team is responsible for the operational delivery of this policy as set out within Section 5 (policy detail) below.

4.2 Medicines Management and Safety Committee

4.2.1 The Committee shall seek assurance with regards to transparency, governance and compliance with legislation and good practice in relation to Pharmaceutical Industry Rebate Schemes.

4.2.2 The Committee shall review, and agree rebate schemes proposed by the Medicines Optimisation Team for authorisation by the Chief Finance Officer, ensuring that any approved rebates meet the CCGs prescribing priorities and conform to the CCG's formulary and relevant clinical policies (outside of the rebate process).

4.2.3 The Committee will be responsible for assessing the impact of rebate schemes, both financially and in relation to prescribing patterns, which will be achieved by review of monthly updates on performance (which will also be contained within the monthly finance report).

4.2.4 The Committee will report to the Finance & Performance Committee in relation to any Rebate schemes. Any clinical or quality matters (outside of this policy) will continue to report to the Quality & Patient Safety Committee in accordance with other clinically relevant medicines management policies.

4.3 Finance and Performance Committee

4.3.1 The Finance and Performance Committee shall be the committee responsible for ensuring compliance with this policy and for having oversight of the rebate scheme process. This is because the policy is financial based and does not require any clinical decisions or quality reviews, which is the responsibility of the Quality & Patient Safety Committee.

4.3.2 Reports on the rebate schemes and the savings made will be reported to the Finance and Performance Committee on a monthly basis.

4.3.3 A summary of annual activity will be provided within three months of the year-end so that the committee can assess the effectiveness of the scheme.

4.4 Audit Committee

4.4.1 The Audit Committee is the primary committee responsible for the management of CCG risk and consequently will approve the rebate policy and require assurances from the Medicines Management Safety Committee and the Finance and Performance Committee in relation to systems of internal control to manage any risks associated with the rebate scheme.

4.5 Chief Finance Officer (CFO)

4.5.1 The CFO is the signatory to the rebate schemes.

4.5.2 No rebate scheme may be agreed without prior approval of the CCG CFO, consequently the authority of the CFO provides a segregation of duty for the rebate scheme process, in order to deter fraud.

4.5.3 The CFO is consequently the Board sponsor for the rebate scheme process.

5 POLICY DETAIL

5.1 The CCG will not enter into any rebate schemes where due process (outlined in this

policy) has not been followed.

5.2 The CCG will ensure that there is no undue influence on prescribing patterns as a result of any rebate schemes and that Practices continue to prescribe using the formulary. Consequently there shall be no rebate schemes where drugs are not included within the current formulary.

5.3 GP Practices will not be actively made aware of the rebate schemes that have been agreed so that potential bias can be avoided and prescribing is based on sound clinical judgement.

5.4 Any drugs proposed for approval through the scheme will be assessed by the PrescQIPP NHS Programme's Pharmaceutical Industry Scheme Governance Review Board (Review Board) and given either **GREY** or **AMBER** status. In exceptional circumstances, where the drug is first line on Thurrock CCG formulary and has yet to be evaluated by PrescQIPP (or has been **RED** flagged) the medicines optimisation team will review the scheme using PrescQIPP's assessment tool as detailed in appendix D of the Review Board's Operating Model https://www.prescqipp.info/primary-care-rebates/finish/76-primary-care-rebate-governance/467-primary-care-rebate-board-operating-model and make recommendations for the Medicines Management and Safety Committee based on the outcome of this assessment.

5.5 In 2012, the PrescQIPP NHS Programme established the Pharmaceutical Industry Scheme Governance Review Board, then offering governance on behalf of PCTs, which has now grown to be the largest governance provider on behalf of the majority of CCGs in England, Health and Social Care Board Northern Ireland and the Health Boards of Wales https://www.prescqipp.info/projects/pharmaceutical-industry-scheme-governance-review-board. The CCG will use these governance arrangements in the establishment of any rebate schemes as outlined below.

5.6 Identifying drugs eligible for the rebate scheme

5.6.1 NHS PrescQIPP has established a Pharmaceutical Industry Scheme Governance Review Board ("the Governance Review Board") which provides a central function, to ensure that this is managed with a focus on open, quality-oriented, robust decision-making around rebates. This process also allows greater efficiencies through economies of scale, and reduces challenges from other pharmaceutical companies by providing comprehensive and transparent assessments.

5.6.2 The primary output of the Review Board is an 'Advisory Note' summarising the recommendations for the (assessed) scheme submitted. This is included on a published list on NHS PrescQIPP website which includes an advisory note for each scheme / drug that has been assessed.

5.6.3 The Medicines Optimisation Team regularly review NHS PrescQIPP to identify any primary care formulary drugs for which it would be appropriate to consider a rebate.

5.6.4 In addition, pharmaceutical companies may occasionally contact the CCG directly to introduce a new scheme to the CCG.

5.7 The Governance Review Board Process

5.7.1 The Medicines Optimisation Team will in all cases, check any proposed scheme/drug against each Advisory Note published on the NHS PrescQIPP website that have been assessed by the Governance Review Board.

5.7.2 Any schemes introduced by a pharmaceutical company (or other process i.e.

recommendation by another CCG) that has not yet been assessed on NHS PrescQIPP and are considered an exception to normal process (i.e. are included on the CCG formulary and are generally prescribed) will be assessed by the Medicines Optimisation Team as described in 5.4 above.

5.7.3 Where a scheme / drug has been assessed by NHS PrescQIPP, published Advisory Notes includes a Red, Amber or Grey Status depending on the outcome of the assessment stage. The classification of the three colours is as follows:

Grey	Scheme Considered; No issues identified
Amber	Scheme Considered; Not fully appropriate
Red	Scheme Considered; Inappropriate

5.7.4 Schemes classified **Grey** (and on the CCG formulary) will automatically be recommended for approval. Schemes classified **Amber** or **Red** will be considered further as set out in paragraph 5.8 below and recommended to the Medicines Management and Safety Committee for approval, where appropriate.

5.7.5 The Governance Review Board state that submitted schemes have to demonstrate compliance with the following five principles in order to achieve a Grey/Amber Status:

- The therapeutic initiative has a place in clinical practice
- A long term view of appropriateness is evident
- There is a transparent, sensible plan for payment and tracking
- The governance on what the Scheme is, and is not, going to be used for is robust
- There is a plan for on-going review

5.7.6 The process of reviewing Schemes submitted by pharmaceutical companies consists of 6 stages:

1. Submission (Online)
2. PrescQIPP Assessment
3. Independent Review
4. Board Assessment
5. Response
6. Delivery

5.7.7 Full details can be found at https://www.prescqipp.info/downloads/finish/76/467/0

5.8 Decision to recommend scheme for approval

5.8.1 The Medicines Optimisation Team will check the scheme against the following criteria:

- Is the scheme on the CCG formulary?
- Has the scheme been rated by the Governance Review Board as Grey or Amber?
- If rated Amber, has an assessment using the national tool been carried out and is the team satisfied that the reason for Amber status poses no risk to the CCG*?
- If rated Red, has an assessment using the national tool been carried out, is the team satisfied that there is good reason to consider the scheme regardless of the status and is the team satisfied that the reason for Red status poses no risk to the CCG*?
- Is the team satisfied that the terms and conditions of the scheme are appropriate and are in accordance with the principles of this policy?

- Has the scheme been approved by the Medicines Management and Safety Committee and CFO?

5.8.2 Appendix B charts the scheme consideration and approval process as well as the governance arrangements in place for the on-going monitoring of schemes.

5.8.3 Schemes that meet the criteria above will be approved and entered onto the 'Approved Rebate List'.

** Reasons for accepting Amber or Red rated schemes must be clearly explained and considered under advisement by the Medicines Management and Safety Committee and the Chief Finance Officer.*

5.9 Implementing a Scheme

5.9.1 Once a scheme has been approved by the Medicines Management and Safety Committee, the contract terms and conditions (prepared by the relevant pharmaceutical company) will be reviewed by the Medicines Optimisation Team to ensure that terms and conditions and clauses are appropriate for agreement by the CCG.

5.9.2 The CCG will not agree to any contract terms or clauses that requires them to commit to a course of action contrary to normal business practice such as *(this is not an exhaustive list)*:

- Being tied to an activity
- Being required to achieve a specified level of prescribing before payment is made
- Being required to 'sign up' to a website
- Being required to meet with a 'rep'
- Having to amend or influence the CCG Formulary or product positioning within the Formulary

5.9.3 The CCG Chief Finance Officer is responsible for approving contracts for rebate schemes and will ensure that the contract period is clearly defined and acceptable and there is an exit strategy / clause included.

5.9.4 Approved schemes should be notified to the Finance team and then should be entered onto the 'Approved Rebate List'. The approve rebate list is the control document held within the Medicines Optimisation Team to record the approval of rebate schemes and provide an audit trail that the processes outlined within this policy are followed. The information recorded in the list therefore includes:

- Brand name of drug
- Drug name
- Name of pharmaceutical company
- Key contract terms
- Period of contract
- Date contract approved by Medicines Management and Safety Committee
- Date contract signed by Chief Finance Officer
- Scheme start date
- Frequency of rebate
- Whether the scheme is live
- The PrescQIPP RAG rating
- Reasons for approval of any schemes not RAG rated or rated Amber / Red
- Arrangements for invoicing / receiving income

- Contact details
- Date scheme reviewed

5.10 Managing Rebate Schemes

5.10.1 A named responsible person within the Medicines Optimisation Team will manage the rebate process. This will include horizon scanning to check for new schemes as well as reviewing existing schemes and preparing relevant documents and reports in relation to the processing and approval of schemes as well as regular reporting on income.

5.10.2 The named responsible person within the Medicines Optimisation Team will also be the primary link with the Finance Team and therefore be responsible for ensuring that the Finance Team are notified of when to raise an invoice, for what amount and who to address the invoice to.

5.10.3 The Finance Team will issue invoices and received the income, which will be accounted for within the CCG accounts.

5.10.4 Reports will be provided to the Finance and Performance Committee in relation to the approved schemes and the level of income received and an annual report will be provided to the Audit Committee to confirm that due process (outlined within this policy) has been followed and that adequate controls have operated effectively to ensure that schemes are adequately approved and that there is no adverse impact to or risk to the CCG.

6 MONITORING COMPLIANCE

6.1 Medicines Prescribing and Safety Committee will monitor compliance with this policy on a regular basis, with income monitored at the Finance and Performance Committee. Final oversight remains with the Audit Committee as the committee with devolved responsibility from the CCG Board with regard to systems of internal control and assurance.

6.2 This policy will be disseminated and communicated to all staff via the CCG Intranet and will be discussed at a weekly team meeting to ensure all staff are aware of and follow the policy.

6.2.1 This policy will be available in the Medicines Management section of Thurrock CCGs public website http://www.thurrockccg.nhs.uk/

6.2.2 This policy will be highlighted in the Prescribing Update

7 STAFF TRAINING

7.1 There is no mandatory training associated with the Rebate Scheme, however, the Medicines Optimisation Team will be responsible for ensuring that staff required to adhere to the policy have sufficient knowledge of the rebate scheme process and this policy.

7.2 This will be achieved via team meetings.

8 ARRANGEMENTS FOR REVIEW

8.1 This policy will be reviewed no less frequently than every two years. An earlier review will be carried out in the event of any relevant changes in legislation, national or local policy/guidance.

8.2 If only minor changes are required, the Finance and Performance Committee has authority to make these changes without referral to the CCG Board. If more significant or substantial changes are required, the policy will need to be ratified by the Audit Committee before final approval by the CCG Board.

9 ASSOCIATED DOCUMENTATION

- Appendix D of 8.2 NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board's Operating Model https://www.prescqipp.info/primary-care-rebates/finish/76-primary-care-rebate-governance/467-primary-care-rebate-board-operating-model
- NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board https://www.prescqipp.info/downloads/finish/76/467/0

Associated Policies

- List here the relevant associated CCG policies

10 REFERENCES

- NHS Telford and Wrekin Clinical Commissioning Group Pharmaceutical Industry Rebate Schemes version 2 September 2013 accessed November 2015
- NHS PrescQIPP Pharmaceutical Industry Scheme Governance Review Board https://www.prescqipp.info/downloads/finish/76/467/0 accessed November 2015

11 LIST OF STAKEHOLDERS CONSULTED

Date Policy Circulated	Name of Individual or Group	Were Comments Received?	Were Comments incorporated into Policy?	If no, why not?
19/02/16	Medicines Management and Safety Committee	Yes	Yes	
02/12/15 and 04/04/16	Integrated Governance Group	Yes	Yes	
20/04/16, 09/16/16	Finance & Performance Committee	Yes	Yes	
22/06/16	CCG Board			

12 Results of Equality Impact Assessment

12.1 The EIA has identified no equality issues with this policy.

12.2 The EIA has been included as Appendix A.

13 Change History:

Date	Version	Author	Description
November 2015	Draft v0.1	Françoise Price	Draft for consultation
March 2016	Draft v0.2	Nicola Meeks	Second draft for consultation.
April 2016	Draft v0.3	Françoise Price	Final minor amendments
May 2016	Draft v0.4	Nicola Meeks	Amendments following comments from Finance & Performance Committee.
June	Draft v0.5	Nicola Meeks	Amendments to make committee responsibilities clearer.

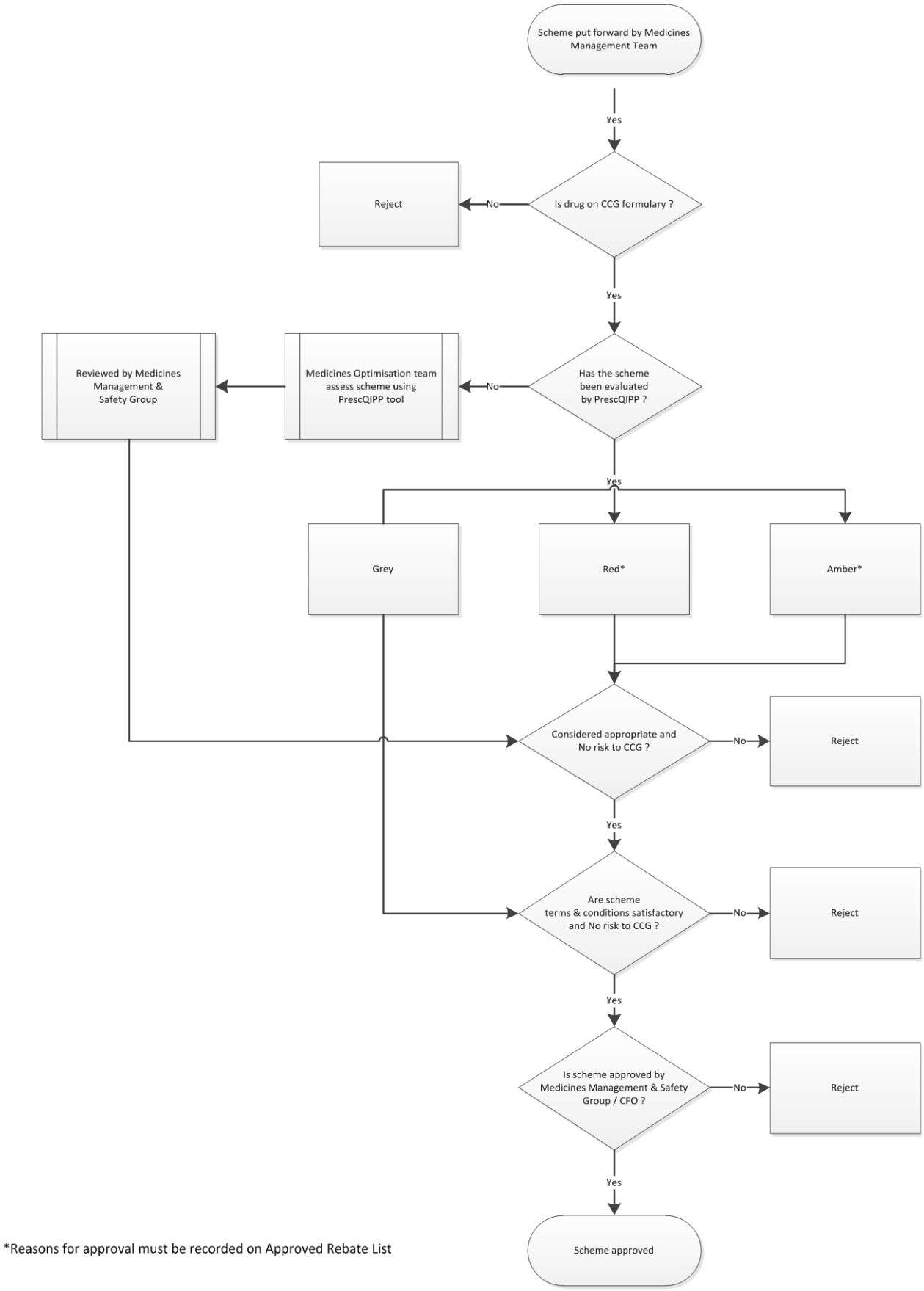
APPENDIX A

Equality Impact Assessment

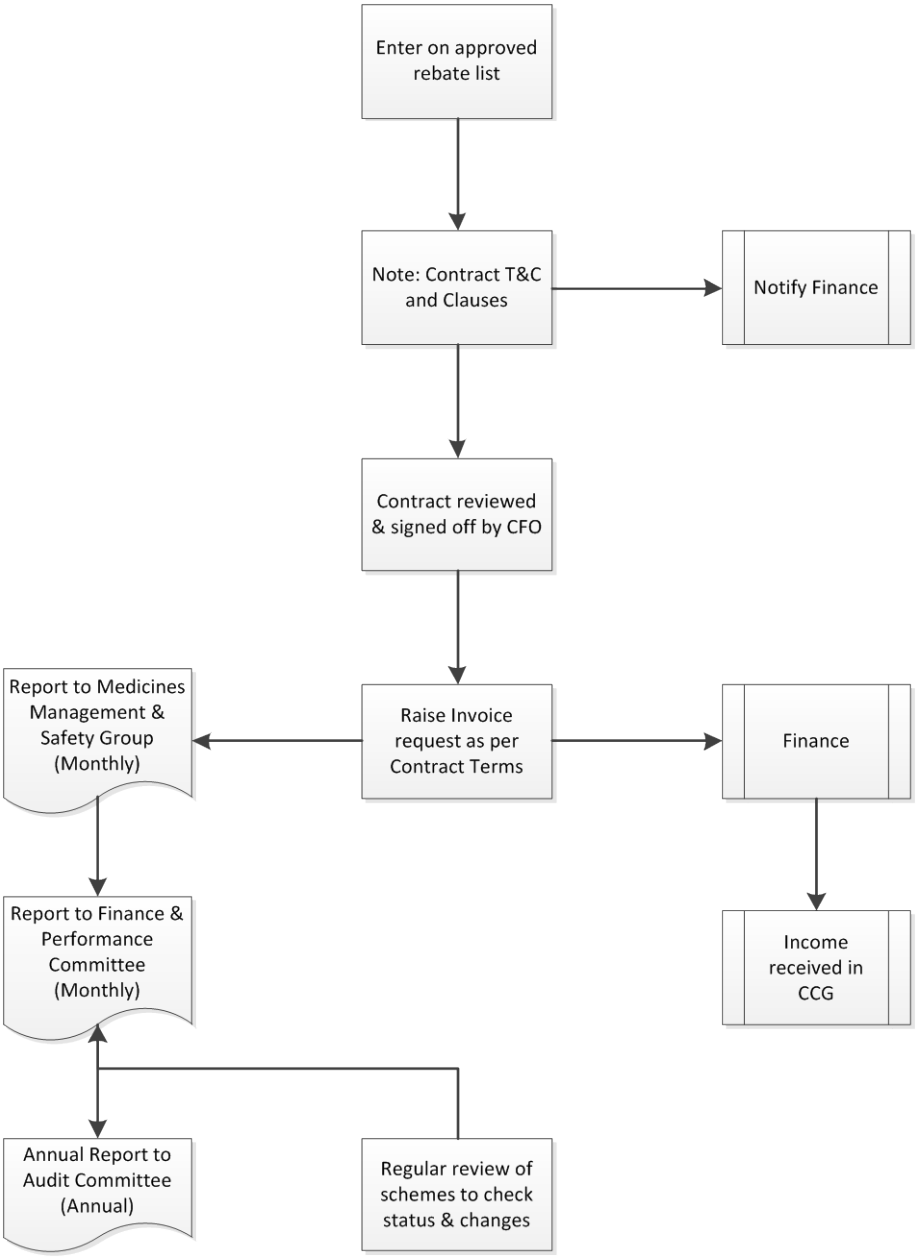
To be completed and attached to any policy/procedural document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	▪ Race	NO	
	▪ Ethnic origins (including gypsies and travellers)	NO	
	▪ Nationality	NO	
	▪ Gender	NO	
	▪ Culture	NO	
	▪ Religion or belief	NO	
	▪ Sexual orientation including lesbian, gay and bisexual people	NO	
	▪ Age	NO	
	▪ Disability - learning disabilities, physical disability, sensory impairment and mental health problems	NO	
2.	Is there any evidence that some groups are affected differently?	NO	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	NO	
4.	Is the impact of the policy/guidance likely to be negative?	NO	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

APPENDIX B - FLOWCHART OF REBATE PROCESS



*Reasons for approval must be recorded on Approved Rebate List


Enter on approved rebate list
Note: Contract T&C and Clauses
Notify Finance
Contract reviewed & signed off by CFO
Report to Medicines Management & Safety Group (Monthly)
Raise Invoice request as per Contract Terms
Finance
Report to Finance & Performance Committee (Monthly)
Income received in CCG
Annual Report to Audit Committee (Annual)
Regular review of schemes to check status & changes