NHS
Staffordshire and Stoke-on-Trent
Integrated Care Board

Approving and Managing Primary Care Pharmaceutical Rebate Schemes Policy

Job Title of Policy Author	Medicines Optimisation Governance and Service Improvement Lead
Review/Development Body	Medicines Optimisation/ Chief Medical Officer
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CONSULTATION SCHEDULE		
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Claire Dearden Medicines Optimisation	Pharmaceutical Rebate Task and Finish group	V1.1 28/09/2021
Samantha Bostock	RSM UK Risk Assurance Services LLP	V2 21/07/2022
Claire Dearden Medicines Optimisation	ICB Policy Review Group	V3 28/04/2025
Claire Dearden Medicines Optimisation	Integrated Medicines Optimisation Group	V3 04/06/2025

IMPACT ASSESSMENTS		
	Date Completed	**Comments**
Equality Impact Assessment (EIA)	12/05/2025	Reviewed inline with the review interval.
Quality Impact Assessment (QIA)	N/A	*(for no impact insert: No impact identified)* *(If non-applicable insert N/A)*
Data Protection Impact Assessment (DPIA)	N/A	*(for no impact insert: No impact identified)* *(If non-applicable insert N/A)*

VERSION CONTROL				
Version	**Job Title of Lead/Policy Author**	**Ratification Date**	**Ratification Body**	**Summary of Amendments**
1.1	Medicines Optimisation Governance and Service Improvement Lead	28/10/2021	Staffordshire & Stoke-on-Trent CCGs Governing Body in Common	CFO- changed to Deputy Director of Finance – Commissioning and Financial Management JMOG changed to Pharmaceutical Rebate Task and Finish group Appendix A updated with RAG rating on administration time involved and outcome log
2	Medicines Optimisation Governance and Service Improvement Lead	05/07/2022	Staffordshire & Stoke-on-Trent Integrated care Board	Adapted for use of the ICB
3	Medicines Optimisation Governance and Service Improvement Lead	02/09/2025	Finance & Performance Committee V3	Full Review- due to document reaching the three-year review period. Document check for accuracy Updated roles to reflect current job titles within the ICB Updated meetings as per current ICB approval mechanisms and restructure Legal advice updated- added Abbott vs Amyes case References updated Inserted into the new ICB policy format Equality Impact Assessment review stage 1 undertaken Updated section 6 to reflect current practice
4	Medicines Optimisation Governance and Service Improvement Lead	18/09/2025	Staffordshire & Stoke-on-Trent Integrated care Board V3	Version 3 approved.

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1. Introduction

Primary care pharmaceutical rebate schemes (PCPRS) are contractual arrangements offered by pharmaceutical companies or third-party companies, which offer financial rebates on primary care prescribing expenditure for branded medicine(s) and other products. Such schemes are offered as a matter of course to the Integrated Care Board by the pharmaceutical industry to introduce new drugs into the NHS, or more simply as a tool to increase/ establish market share of existing/new medicine(s).

2. Purpose

This policy provides a framework for managing PCPRS in a legal and ethical way. It forms the basis of the process that Staffordshire and Stoke-on-Trent (SSOT) Integrated Care Board (ICB) use to evaluate rebate schemes so that they are only signed off where they provide good value for money and the scheme's terms are in line with organisation vision, values, policies, and procedures. The policy also provides assurance that the ICB is transparent in its process for considering these schemes.

3. Scope

This policy applies to commissioners of Medicines Optimisation services in Staffordshire and Stoke on Trent ICB when considering a PCPRS on offer to NHS organisations. It should be used in conjunction with the following policies which have been adopted by the ICB until a formal review and adoption has taken place:

- Gifts and hospitality policy
- Commercial sponsorship
- Anti- fraud and Anti- bribery policy
- Business Ethics Policy.
- Prime Financial Policies and Scheme of Delegation (Policy No 4.27).

4. Definitions

- Primary care pharmaceutical rebate schemes (PCPRS)
- Staffordshire and Stoke-on-Trent (SSOT)
- Integrated Care Board (ICB)
- National Institute for Health and Clinical Excellence (NICE)
- PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PRISGB)
- Freedom of Information (FOI)
- Integrated Medicines Optimisation group (IMOG)

5. Duties and Responsibilities

Director of Operational Finance

- Provides oversight of all aspects of this policy to ensure organisational compliance.
- Is authorised to sign rebate agreements of behalf of the ICB

Associate Director of Corporate Governance

- Provides governance and corporate oversight for this policy
- Contract advise from a ICB governance perspective

Head of Medicines Optimisation

- Ensures that due process is followed for assessment of new schemes and renewal of any existing schemes
- Ensures this policy is adhered to in all decisions relating to acceptance or refusal of PCPRS
- Provides pharmaceutical oversight for this policy

Medicines Optimisation Governance and Service Improvement Lead

- Authoring of this policy, ensuring maintenance and review
- Key contact for all PCPRS agreements
- Monitoring
- Preparation of PCPRS application papers
- The Medicines Optimisation Governance and Service Improvement Lead will be accountable for operational management of the process for approving PCPRS, from identification through to implementation and review of PCPRS agreements

Medicines Optimisation Pharmacy Technician Project Manager

Ensures rebates are claimed in a timely fashion

ICB Finance Team

Ensures rebates are claimed and invoiced in a timely fashion

Pharmaceutical Rebate Task and Finish group

Assesses rebate schemes against the policy principles and makes recommendations

Attendance (or nominated deputes for Medicine Head of Medicines Optimisation, Director of Operational Finance and Deputy Director of Corporate Services & Associate Director of Corporate Governance)

- Director of Operational Finance
- Associate Director of Corporate Governance
- Head of Medicines Optimisation
- Medicines Optimisation Governance and Service Improvement Lead
- Lay Member
- Clinical Primary Care Representative

6. Principles for Assessing Rebate Schemes

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. However, within the NHS there is general acceptance by commissioners and providers alike that on occasions there are commercial barriers for manufacturers to change the published price, and so instead they prefer to use the rebate scheme as a way of reducing the effective price of a medicine available for use in the NHS.

The acceptance of a scheme should not constrain existing local decision-making processes or formulary development. The ICB follows the principles below from Department of Health guidance on Strategies to Achieve Cost-Effective Prescribing [1].

- 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.
- 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.

Good Practice Principles

In addition to ensuring that particulars of a PCPRS do not contravene the overarching principles mentioned above, SSOT ICB will adopt the following good practice principles when deciding whether it participates in a PCPRS or not.

Product Related

- PCPRS will only be considered for those medicines which are already commissioned and included in the local formulary and its place in a care pathway has already been established through normal SSOT ICB Governance.
- SSOT ICB will consider PCPRS for products that are not medicines but used in medical conditions such as devices and nutritional products provided these products meet requirements of relevant national and local clinical guidelines. These products should be available for prescribing as per the Drug Tariff.
- The price of a medicine or product will be considered but this consideration will be secondary to the clinical need for the medicine/product and its place in established pathways.
- SSOT ICB will not consider or promote unlicensed, or 'off-label' uses of medicines as part of a PCPRS. Furthermore, a PCPRS must be linked with a drug and not limited to indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.

- PCPRS for medicines or products not recommended by NICE and not approved by the local formularies will not be entered into.

- PCPRS are not appropriate for medicines in Category M and some medicines in Category A of the Drug tariff, because of the potential wider impact on community pharmacy reimbursement. Advice should be sought from the Head of Medicines Optimisation for any Category A medicines.

- Products should be available through normal supply channels and not require special procurement or place extra financial burden on community pharmacies when trying to acquire the necessary stock.

Rebate Scheme Related

- PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PRISGB) [2] regularly assesses pharmaceutical schemes on financial and contractual basis, and regarding any clinical implications. SSOT ICB will consider any PRISGB assessments in its decision-making process.

- PCPRS should not be linked directly to requirements to increase market share or volume of prescribing.

- 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. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.

- 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.

- SSOT ICB will not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs/products, should they wish to do so. These PCRS should all be considered using the same criteria.

- All PCRS agreements must meet the requirements of the Data Protection Act, General Data Protection Regulation and patient confidentiality must never be compromised.

- Individual contracts will contain details of any confidentiality agreements, but such agreements must not preclude the sharing of information, including discounts and scheme details, within the wider NHS.

- PCPRS 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 Governance

- Contracts will be held in accordance with the ICB records management policy.
- There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.
- SSOT ICB supports the principles of transparency enshrined in the Freedom of Information Act. PCRS often contain confidentiality clauses which may restrict what information may be disclosed under Freedom of Information (FOI). The ICB will publish its policy for accepting rebate agreements along with the list of products for which rebate agreements exist on its public facing website.
- As part of the FOI process any decision from the Information Commissioners Officer to disclose information will be adhered to.
- SSOT ICB will ensure that all PCRS agreements meet the requirements of the Data Protection Act and the General Data Protection Regulation.

Legal Advice

- The London Procurement Partnership (LPP) commissioned two sets of legal advice in 2012 and 2015 which they made available to the NHS for interest. The advice is specific to LPP and whilst others might find it of general interest, they should not rely on it in a dispute or case but seek their own independent legal advice. This advice was produced prior to there being any case law in this area.
- Since 2019 there has been case law on this subject. A summary of the Abbott vs. Aymes and an NHS CCG case held in the High Court of Justice Queens Bench Division Administrative Court on Wednesday 17th July 2019 [CO/506/2019] [3]

7. Training and Implementation

Process for the Assessment, Approval and Management of Rebate Schemes

Assessment and Approval

- The Head of Medicines Optimisation and the Medicines Optimisation Governance and Service Improvement Lead will ensure that contractual papers and briefing summaries on PCPRS are tabled at Pharmaceutical Rebate Task and Finish group meetings in timely manner.
- Pharmaceutical Rebate Task and Finish group will assess any PCPRS on offer in line with principles stated above (An assessment form for this purpose is attached in Appendix A).
- Director of Operational Finance will be responsible for approving and signing the contracts based on recommendation from the Pharmaceutical Rebate Task and Finish group.

Use of Rebate Income

- Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Chief Finance Officer. Generally, the rebate income is used to offset any financial deficit in the primary care prescribing budget.

8. Monitoring

- The Head of Medicines Optimisation and the Medicines Optimisation Governance and Service Improvement Lead will ensure adherence to the policy.

- The Medicines Optimisation Governance and Service Improvement Lead will ensure that pharmaceutical rebates are being processed at agreed intervals.

- The Head of Medicines Optimisation and the Medicines Optimisation Governance and Service Improvement Lead will conduct annual review of the schemes considering factors such as any recent relevant clinical guidance, entry of a new product or any other relevant clinical developments.

- The Medicines Optimisation Governance and Service Improvement Lead will liaise with the pharmaceutical companies on review of schemes which are due to expire within 3 months.

9. Review, Ratification and Archiving

Pharmaceutical Rebate Task and Finish group is a multidisciplinary group) has considered, amended, and endorsed this policy.

Approval and Ratification process for the Policy

- Pharmaceutical Rebate Task and Finish group
- Integrated Medicines Optimisation group
- Finance and Performance Committee
- Ratified by the Staffordshire & Stoke-on-Trent Integrated Care Board

The policy will be reviewed every 3 years, or earlier if national policy or guidance, organisational changes are required to be considered. The review will then be subject to review and re-ratification.

10. Dissemination and Publication

Dissemination of the final policy is the responsibility of the author. They must ensure the policy is uploaded on the intranet via the Communications Team. The Communications team is responsible to issue an organisation-wide notification of the existence of the Policy.

Heads of Departments/Managers are responsible for ensuring that all staff (including bank, agency, contracted and volunteers) have access to and are made aware of policies that apply to them.

All staff and members of the public will be able to access copy of this policy via the policy section of the ICB internet and Staffordshire and Stoke-on-Trent ICS Formulary

Staffordshire and Stoke-on-Trent Integrated Care Board

11. References and Associated Documents

1 STRATEGIES TO ACHIEVE COST-EFFECTIVE PRESCRIBING: GUIDANCE FOR PRIMARY CARE TRUSTS AND CLINICAL COMMISSIONING GROUPS. (n.d.). Available at:https://assets.publishing.service.gov.uk/media/5a7c50f2ed915d3d0e87b8f5/dh_120213.pdf

2 Prescqipp.info. Principles of Governance of Primary Care Rebates for Commissioners (2025). Available at https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2fhhsj0ito%2fprinciples-of-governance-of-primary-care-rebates-for-icbs-hbs.pdf [Accessed 11 Apr. 2025].

3 Prescqipp.info. PrescQIPP Summary of Abbott vs Aymes and an NHS CCG held in the High Court of Justice Queens Bench Division Administrative Courton Wednesday 17th July 2019 [CO/506/2019] (2025). Available at: https://www.prescqipp.info/login/?returnUrl=%252fmedia%252f5666%252fkevans_summary_of_court_proceedings_sept_2019docx.doc [Accessed 11 Apr. 2025].

12. Impact Assessments

This proposal has been through an Initial Assessment process and no identifiable or potential adverse impact against any protected characteristics or inclusion health group have been identified or mitigating actions/reasonable adjustments have been taken. In the event of any new data, information or reporting, identifying any adverse or potential adverse impact, this assessment will be reviewed, and a full impact assessment will be carried out where it is deemed necessary to do so. Accessible and inclusive Information and equality monitoring (where it is practical to do so) have been considered or implemented.

13 Appendices

Appendix A: Primary Care Pharmaceutical Rebate Scheme Assessment Template

Date assessed by Pharmaceutical Rebate Task and Finish Group	
Potential value of the rebate	

1. Is the product in the local formularies? What is the status of the product in the formulary?
2. For non-formulary products: (a) is the product commonly used? (b) is the product backed by any national and professional clinical guidelines?
3. What is the Drug Tariff status for the product?
4. Is the product available through normal wholesaler and pharmacy channels?
5. Has the product been assessed by the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board? If so, what was the recommendation?
6. Does the scheme require increase in volume of prescribing or market share?
7. Does the scheme prohibit in any way use of competitor products or require affording any special status to the scheme product? Consider any contract clauses that impose restrictions on the ICB entering any future schemes?
8. What data must be submitted as part of the scheme to claim the rebate?
9. What are the contractual exit arrangements for both parties? Are these arrangements acceptable?
10. Are there sufficient details to support Freedom of Information enquiries?
11. Does the contract allow for communication to all relevant stakeholders?
12. Does the scheme meet requirements of the General Data Protection Regulation?
13. How much administration is required to manage the scheme?

RAG rating	Detail	Cost/hours

Green	Third party company or pharma company generates prescribing data and pays straight into ICB bank account.	4hrs per quarter - £80 = £320 per year
Amber 1	Third party company or pharma company generates prescribing data – ICB inform Finance to invoice	6hrs per quarter - £120= £480 per year
Amber 2	ICB generates prescribing data, checks with company and company pays straight into ICB bank account	8hrs per quarter - £160= £640 per year
Red	ICB generates prescribing data, checks with company, and then informs Finance to invoice	15hrs per quarter - £300= £1200 per year Plus, finance ICB time

Financial threshold vs time	Financial threshold £3,000	RAG rating for this agreement	*To be completed*

Copy of the contracts: *PDF or word documents to be embedded here*

Date of meeting	xxx/xx/xxxx
Overall decision and comments	
Corporate and Governance approval	
Finance approval	
Medicines Optimisation approval	