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**Primary Care Rebate Schemes**

**Policy**

**April 2023**

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**The on-line version on the ICB website is the only version that is maintained. Any printed copies should, therefore, be viewed as ‘uncontrolled’ and as such may not necessarily contain the latest updates and amendments.**

**AMENDMENTS**

Amendments to the policy may be issued from time to time. A new amendment history will be issued with each change.

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# Introduction

The NHS operates a single 'Drug Tariff' pricing mechanism that accounts for an overwhelming majority of its prescriptions dispensed in primary care. This prevents local pricing arrangements affecting list prices. The list prices of medicines in the NHS Drug Tariff are regularly adjusted in response to the market, allowing the prices of generic medicines to go up or down.

The Pharmaceutical Price Regulation Scheme (PPRS) is the mechanism by which the Department of Health ensures that the NHS has access to branded medicines at a reasonable price. The PPRS balances setting reasonable prices for the NHS against delivering a fair return for the pharmaceutical industry so that investment and innovation in pharmaceuticals is incentivised.

Pharmaceutical companies can offer Primary Care Rebate Schemes (PCRS) to Integrated Care Boards (ICBs) nationwide, but sometimes these can be more targeted to specific localities. A rebate scheme is a confidential contractual agreement between the manufacturer and the ICB. Under the agreement the ICB receives funding from the manufacturer when its member GP practices prescribe a specific drug. Some schemes offer a straight-forward rebate pricing mechanism, such as a set price per packet or dose. However, some schemes are much more complex in nature involving 'stepped pricing' and 'ceiling and floor limits'.

# Purpose

The aims and objectives of this policy are to protect the ICB along with its member GP practices, service users, staff, and other stakeholders, as well as the assets of the ICB, whilst ensuring delivery of its strategic and corporate objectives.

Rebate agreements usually take the form of legal agreements between the manufacturer and the ICB. The aim of this policy is to provide a framework for managing rebates in a legal and ethical way to ensure that each scheme is only signed off if it provides good value for money to the public purse and its terms are in line with organisational vision, values, policies, and procedures and to ensure the ICB is transparent in its process for considering these schemes. The principles outlined in this policy document allow for the objective evaluation of schemes submitted to the ICB and a clear process for scrutinising and approving agreements.

# Definition/ Explanation of Terms

|  |  |
| --- | --- |
| Primary Care rebate scheme | Contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for a particular branded medicine. |
| QIPP | Quality, Innovation, Productivity and Prevention and is a large scale programme introduced across the NHS to ensure the NHS delivers more for the same funding |
| Formulary | A list of medicines and medical devices approved for use by healthcare professionals |
| DHSC | Department of Health and Social Care |
| Drug tariff | The amount that the NHS repays pharmacies for generic prescription medications |
| Summary of product characteristics | Information about medicines outlining the form, clinical parameters and pharmacological properties, written and updated by pharmaceutical companies based on their product research and knowledge. |
| Data sheet | A publication containing detailed prescribing information on a specific medicine |
| ePACT | Digital tool which gives authorised users access to prescription data which can then be analysed |
| Pharmaceutical Price Regulation Scheme (PPRS) | The mechanism used by the UK Department of Health to ensure that the NHS has access to good quality branded medicines at reasonable prices. |

# Scope of the Policy

This policy applies to NHS Humber and North Yorkshire (HNY) Integrated Care Board (ICB) and all of its employees, members of the Place, co-opted members, members of the Board and its committees and employees of North of England Commissioning Support (NECS) providing services to any part or Place within the ICB. All must comply with the arrangements outlined in this policy.

The policy relates only to 'primary care rebates', based on NHS prescribing in primary care. It should be used in conjunction with the following policies or procedures in place or in development:

* Operational Scheme of Delegation
* Commercial Sponsorship Policy

Failure to comply with this policy would be considered a breach of the terms and conditions of employment and may result in the matter being treated as a disciplinary offence under the individual's employer's disciplinary procedure.

# Duties/ Accountabilities and Responsibilities

## Duties within the organisation

The following gives an overview of the duties of individuals, departments and committees, including levels of responsibility.

## Chief Executive / Accountable Officer

Ensures the ICB has an appropriate policy in place.

## Executive Director of Finance and Investment

* Provides oversight of all aspects of this policy to ensure organisational compliance.
* Ensures agreed governance arrangements are in place for decision making.
* Provides regular reports to the Finance, Performance & Delivery Board.
* Is authorised to sign rebate agreements of behalf of the ICB.
* Ensures rebates are claimed in a timely fashion.
* Must ensure that members of staff are aware of this policy and the processes to be followed.

## ICB Executive Director of Clinical & Professional Services

* Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates.

## Medicines Management/Optimisation Teams (MMT /MOT)

* To establish and maintain an ICB Rebates Sub-group.
* To identify potential PCRSs and channel those to the ICB Rebates Sub-group for consideration with accompanying relevant information.
* Support Finance and Accounting colleagues in claiming rebate income each quarter.

## ICB Rebates Sub-group

* Review rebate schemes in line with criteria detailed within section 7.6 of this policy, including consideration of external reviews, for example those carried out by PrescQIPP.
* Provide an appraisal and recommendation to the representative Place Based Director of Finance and the Executive Director of Finance and Investment.
* Ensures the policy is followed to support in all decisions relating to acceptance or refusal of rebates.
* Regularly review the rebate scheme register, held on the ICB’s website, for accuracy.
* Ensures rebates are claimed in a timely fashion.

## ICB's Integrated Pharmacy and Medicines Optimisation Committee (IPMOC)

IPMOC will discuss the rebate 'decision form' and endorse if appropriate.

## Heads of Medicines Management and Senior Strategic Lead Pharmacist

Both will review and approve the rebate offer on behalf of the six Places (as delegated) prior to sign-off by the Executive Director of Finance and Investment.

## A Place based director of Finance (Lead for Prescribing)

Review and approve the rebate offer prior to sign-off by the Executive Director of Finance and Investment.

## Head of Service – Financial Accounting & Reporting

Reclaim rebate funding from the administrator of the scheme.

## ICB's Quality Committee

The Quality Committee is responsible for the approval of this policy and its updates.

# Legal Advice

Concerns were previously raised by some NHS commissioners regarding the lack of clarity in relation to such schemes and whether they are allowed under the current regulations. The London Primary Care Medicines Use and Procurement QIPP group, as part of the London Procurement Partnership (LPP), agreed that it was unclear whether these schemes were allowed within the regulations in 2015 and sought legal opinion from DAC Beechcroft.

The detailed legal advice obtained by the LPP from DAC Beechcroft1 in January 2016 has been shared within the NHS and is available from the MMT/MOT. Its stated conclusion was that primary care rebate schemes were not unlawful. It was therefore accepted to be within the powers of CCGs (Clinical Commissioning Groups) to agree to PCRSs, provided they meet certain requirements. It is understood that current regulations have not altered this position, though NHS Humber and North Yorkshire ICB can seek further legal advice as appropriate.

The ICB may wish to take legal advice on the content of any particular scheme prior to entering into any agreement.

# Rebate Scheme Policy Requirements

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. 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. This is in line with Department of Health document (gateway reference 14802) on Strategies to Achieve Cost-Effective Prescribing (2010)2. This states that the following principles should underpin local strategies:

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.*
2. *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.*
3. *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.*
4. *Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money.*
5. *Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.*
6. *Limited scheme terms will be published on the ICB's website.*

## Good Practice Principles for Rebate Schemes

The detailed content of rebates offered to the ICB will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. These Good Practice Principles can help the ICB in assessing these schemes. The ICB will need to be assured 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 DHSC’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.

The ICB will also adopt the following principles when deciding whether to participate in a rebate scheme or not.

**Product related:**

* The ICB will only consider rebate schemes for a medicine / prescribable device that is already commissioned and included in both (North Yorkshire and York (NYY) and Humber) of the ICB joint formularies. Ideally its place in a care pathway should already be established through an HNY Area Prescribing Committee or equivalent. Existing or historical rebates may be continued.
* When selecting treatment for a patient, the price of a medicine / prescribable device will be considered but this consideration will be secondary to the clinical need for the medicine / device and its place in established pathways.
* Health professionals should always base their prescribing decisions primarily on assessments of the individual patient’s clinical circumstances. The impact of a rebate scheme is a secondary consideration.
* The ICB will not consider or promote unlicensed or ‘off-label’ uses of medicines as part of a rebate scheme. Furthermore, a rebate scheme for a drug or product must be linked to total use of that drug or product and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.
* All recommendations for use of a medicine within a rebate scheme must be consistent with the UK Marketing Authorisation of the medicine / device in question, i.e. the rebate scheme should only advocate the use of the product in line with the data sheet / Specific Product Characteristics (SPC) for the product in question.
* Medicines / devices with a current negative recommendation by NICE will not be considered unless they also have a positive recommendation for another indication.
* Any product rejected by the ICB's Integrated Pharmacy and Medicines Optimisation Committee or the ICB's Area Prescribing Committees (or equivalent) will not be considered unless they have current positive approval for another indication.
* Rebate schemes 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 a senior member of the ICB's MMT or MOT or the ICB Rebate Sub-group regarding any Category A products.

**Rebate Scheme Related**

* When selecting treatment for a patient, any and all decision-making processes will be clinically led and involve appropriate stakeholders, including patients as appropriate.
* Rebate schemes should not be linked directly to requirements to increase market share or volume of prescribing and such rebates could be excluded on this basis alone.
* Rebate schemes will be approved through robust local governance processes that include early-stage approval by the ICB's Rebate Sub-group, which will include direct representation from the ICB's MMT (NYY) and MOT (Humber) and an ICB Finance/contracting lead.
* The administrative burden to the NHS of setting up and running the scheme must be factored into the 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.
* 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 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.
* Each existing rebate will be re-assessed and approved prior to resigning a new contract.

## Interface with the Pharmacy Industry

The ICB must be able to demonstrate that all suppliers wishing to offer rebates are provided with equal access. When appointments to discuss a rebate offer are requested, the supplier should be given access to a copy of this policy. Meetings to discuss rebates should be attended by a senior member of the ICB's MMT or MOT.

Suppliers should not make guideline or formulary positioning of any product a condition to any rebate offer. Equally, the ICB must not offer or expect any favourable positioning of a product with respect to the local formulary in return for a rebate offer. To avoid misunderstandings, meetings pertaining to rebates must not influence formulary or guidelines status, positioning relative to competitor products or any other actions resulting from the rebate offer. This includes the execution of any medicines change programmes within the ICB. Suppliers must not discuss any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes. Exceptions are where these elements are explicitly part of the commercial offer and are included in a legal contract.

In the event of the above not being adhered to in a meeting, the meeting must be terminated immediately, and the incident reported to the Executive Director of Finance and Investment to ascertain appropriate action.

## Contracts

ICB's Director of Pharmacy or a Head of Medicines Management/Optimisation and the Executive Director of Finance and Investment (or their Deputy) must ensure that a formal written contract is in place, signed by both parties to ensure:

* The terms of the scheme are clear.
* Legal protection is maximised.

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.

PCRS agreements should include a right to terminate on notice (see 7.1, i.e. without having to have any reason for doing so) with a sensible notice period, e.g. three 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.

Freedom of Information issues (see below) should be discussed with the manufacturer before a commissioner enters into any agreement with them and should be contained in the contract.

## Accountability

The MMT/MOT will assess schemes against the principles outlined in section 7.1 above. The “Rebate Scheme Decision Form” in Appendix 2 will be used to record the assessment against the principles and arrange first stage approval at the ICB's Rebate Sub-group. If supported the Rebate Sub-group will provide a recommendation to the ICB's IPMOC, which is responsible for final committee approval of rebate agreements on behalf of HNY ICB.

Decision making process:

|  |  |  |
| --- | --- | --- |
| Step | Group/individual | Function |
| 1 | MMT/MOT | Identify potential PCRSs and channel those to the ICB Rebates Sub-group for consideration |
| 2 | Rebate sub-group | Review and appraise rebate scheme in line with ICB policy criteria and make and record recommendation on rebate scheme decision form |
| 3 | IPMOC | Discuss the rebate 'decision form', affirm adherence to due process and endorse |
| 4 | Head of MM and Senior Strategic Lead Pharmacist | Approve (or otherwise) on behalf of Places (as delegated), recording on rebate scheme decision form |
| 5 | Place based Director of Finance (Lead for Prescribing) | Review and approve the rebate contract for signing, recording on the rebate scheme decision form |
| 6 | Executive Director of Finance and Investment | Signs contract and exchanges with company |

The ICB will ensure that the testing of compliance and effectiveness of this policy is undertaken in the Internal Audit programme.

## Information Governance

The ICB supports the principles of transparency enshrined in the Freedom of Information Act 2000 (FOIA). Rebate schemes often contain confidentiality clauses, which may restrict what information may be disclosed under Freedom of Information. The ICB will publish its policy for accepting rebate agreements.

Whilst manufacturers often attempt to impose requirements for confidentiality that would restrict the ICB from disclosing the existence and level of any discount to any third party, the ICB recognises that such agreements are likely not to be in the interests of the NHS. This is on the basis both that it will compromise the ability of the ICB to evaluate whether it is obtaining the best possible terms and that in the medium to longer term it is likely to lead to price inflation.

The ICB will ensure that all rebate scheme agreements meet the requirements of Data Protection Legislation, and patient confidentiality must never be compromised. The Freedom of Information Act 2000 provides the right of public access to information held by public authorities. The main principle behind freedom of information legislation is that people have a right to know about the activities of public authorities, unless there is a good reason for them not to. This may be described as a presumption or assumption in favour of disclosure. The ICB fully supports the principle of openness and accountability.

There may be occasions where specific information requested is considered to be exempt under section 43 “Commercial Interests” of the Freedom of Information Act. Some information appertaining to rebate agreements may meet the criteria advised by the Information Commissioner’s Office as being “Commercially Sensitive”. This Exemption would only be applied where the information requested would be considered to prejudice the commercial interests of the company to which it relates. This would be decided on a case-by-case basis.

### Sharing of information with prescribers and other stakeholders

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. The Rebate Policy will be published on the ICB's website, as will details of PCRS entered into by the ICB, listing companies and the product(s) involved and the start and finish dates of the relevant contract. This information will continue to be published for the full financial year (to 31st March) following termination.

Information on the financial values of any rebate (in terms of rate and/or total monetary value) will be limited to those closely involved in considering and managing the rebate. For this reason, these details will be withheld from the papers submitted to IPMOC for consideration and approval, and instead the Rebate Sub-group will identify to IPMOC if the scheme is predicted to be financially worthwhile.

### Freedom of Information Requests

The ICB supports the principle of openness about its activities. Any Decision from the Information Commissioner’s Office to disclose information must be adhered to.

## Use of Rebates

It is vital that any funds received by the ICB as part of a rebate are managed in a transparent, legal and ethical way. Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Executive Director of Finance and Investment. This will include oversight of the process to disseminate rebate income to Place based budgets based on prescribing activity (as per each rebate's methodology) in the respective Places.

No one individual should be in a position to benefit personally from the level of rebate received by the ICB.

Examples of unacceptable practice:

* A GP Local Enhanced Service for diabetes is funded by an insulin rebate. The higher the rebate payment, the more funds available for the LES.
* The MMT/MOT create a budget for special projects. All rebates are paid into this budget and the team can use this for short term posts.

Examples of acceptable practice:

* A diabetes ‘invest to save’ project is approved by the ICB or a Place. The business case includes an investment which is offset by a rebate scheme. The projected savings are in line with analysis of appropriate use and the project funding is secure even if rebate savings are not fully realised. Any surplus is not automatically allocated to the project.

# Consultation

This Policy has been reviewed by the MMT and MOT and the Finance Team prior to endorsement by the Rebate Sub-group and IPMOC, and approval by the Quality Committee.

# Training

Training needs will be identified via the annual appraisal process and training needs analysis.

# Monitoring Compliance

The ICB will monitor compliance with this policy through the internal audit programme.

# Arrangements for Review

This policy will be reviewed after a period of no longer than 2 years as stated or in response to any relevant changes in local and/or national policies and guidance, whichever is sooner.

# Dissemination

All staff will be made aware of the policy via the ICB website, staff newsletter and other appropriate internal communication mechanisms.

Staff directly impacted by this policy, such as colleagues in the MMT/MOT and the Finance Team, will be provided with a copy of the policy.

# Associated Documentation

The policy relates only to 'primary care rebates', based on NHS prescribing in primary care. It should be used in conjunction with the following policies or procedures in place or in development:

* Operational Scheme of Delegation
* Commercial Sponsorship Policy

# References

1. London Procurement Programme Legal Response from DAC Beachcroft LLP – Personnal Communication
2. Department of Health. Strategies to Achieve Cost-Effective Prescribing (2010)

# Appendices

[Appendix 1 - Anti-Fraud, Bribery and Corruption](#_Appendix_1_-)

[Appendix 2 - Primary Care Rebate Scheme - Approval Process](#_Appendix_2:_Primary)

[Appendix 3 - ICB Primary Care Rebate Scheme: Assessment and Decision Form](#_Appendix_3:_)

# Impact Assessments

## Equality

NHS Humber and North Yorkshire ICB is committed to creating an environment where everyone is treated equitably and the potential for discrimination is identified and mitigated. It aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

In developing this policy an Equality Impact Analysis (EIA) has been undertaken. As a result of the analysis, the policy, project or function does not appear to have any adverse effects on people who share Protected Characteristics, and no further actions are recommended at this stage.

## Sustainability

A Sustainability Impact Assessment has been undertaken. No positive or negative impacts were identified against the twelve sustainability themes. The results of the assessment are displayed on the internet with this policy.

## Bribery Act 2010

Due consideration has been given to the Bribery Act 2010 in the development (or review, as appropriate) of this policy document, further details can be found in [appendix 1](#_Appendix_1_-).

## General Data Protection Regulations (GDPR)

The UK General Data Protection Regulation (GDPR)/ Data Protection Act 2018 includes the requirement to complete a Data Protection Impact Assessment for any processing that is likely to result in a high risk to individuals. Consideration should be given to any impact the policy may have on individual privacy; please consult NHS Humber and North Yorkshire ICB Data Protection Impact Assessment Policy. If you are commissioning a project or undertaking work that requires the processing of personal data, you must complete a Data Protection Impact Assessment.

The ICB is committed to ensuring that all personal information is managed in accordance with current data protection legislation, professional codes of practice and records management and confidentiality guidance. More detailed information can be found in the Data Protection & Confidentiality Policy and related policies and procedures.

## Appendix 1 - Anti-Fraud, Bribery and Corruption

The ICB has a responsibility to ensure that all staff are made aware of their duties and responsibilities arising from the Bribery Act 2010.  Under the Bribery Act 2010 there are four criminal offences:

•           Bribing or offering to bribe another person (Section 1)

•           Requesting, agreeing to receive or accepting a bribe (Section 2);

•           Bribing, or offering to bribe, a foreign public official (Section 6);

•           Failing to prevent bribery (Section 7).

These offences can be committed directly or by and through a third person and, in many cases, it does not matter whether the person knows or believes that the performance of the function or activity is improper.

It should be noted that there need not be any actual giving and receiving for financial or other advantage to be gained, to commit an offence.

All individuals should be aware that in committing an act of bribery they may be subject to a penalty of up to 10 years imprisonment, an unlimited fine, or both.  They may also expose the organisation to a conviction punishable with an unlimited fine because the organisation may be liable where a person associated with it commits an act of bribery.

Individuals should also be aware that a breach of this Act renders them liable to disciplinary action by the ICB, whether or not the breach leads to prosecution.  Where a material breach is found to have occurred, the likely sanction will be loss of employment and pension rights.

To raise any suspicions of bribery and/or corruption please contact the Executive Director of Finance and Investment.  Staff may also contact the Local Counter Fraud Specialist (LCFS) at – Audit Yorkshire, email:  [nikki.cooper1@nhs.net](mailto:nikki.cooper1@nhs.net)  or mobile 07872 988939.

The LCFS or Executive Director of Finance and Investment should be the contact for any suspicions of fraud. The LCFS will inform the Executive Director of Finance and Investment if the suspicion seems well founded and will conduct a thorough investigation.  Concerns may also be discussed with the Executive Director of Finance and Investment or the Audit Committee Chair.

If staff prefer, they may call the NHS Counter Fraud reporting line on 0800 028 40 60 between 8am-6pm Monday-Friday or report online at [www.reportnhsfraud.nhs.uk](http://www.reportnhsfraud.nhs.uk).  This would be the suggested contact if there is a concern that the LCFS or the Executive Director of Finance and Investment themselves may be implicated in suspected fraud, bribery or corruption.

## Appendix 2: Primary Care Rebate Scheme - Approval Process

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| --- | --- | --- |
| **Rebate Offer** |  | It is essential that any product subject to a rebate offer has been previously reviewed by both Area Prescribing Committees (or equivalent), commissioned, and included in both joint formularies within H+NY ICS |
|  |  |  |
| **PrescQIPP** |  | PrescQIPP is an organisation hosted and funded by NHS England to support quality and optimise the use of medicines within the NHS. Their Pharmaceutical Industry Scheme Governance Review Board assesses rebate schemes for clinical, financial and contractual issues to support the ICB in addressing the risk of perverse incentives from such schemes. Otherwise, this can be undertaken by the ICB's MMT/MOT. |
|  |  |  |
| **Rebates sub-group** |  | The role of this ICB joint Senior Pharmacy and Finance representative group is to consider each rebate and recommend approval or otherwise based on criteria defined in the policy, including status in formularies and guidance, administrative burden, financial implications, MMT/MOT priorities and policy adherence. |
|  |  |  |
| **Integrated Pharmacy and Medicines Optimisation Committee** |  | This allows senior management, including GP leads and lay members, to state assurance that appropriate decision-making processes have been followed. |
|  |  |  |
| **Head of Medicines Management and Senior Strategic Lead Pharmacist** |  | With delegated decision-making authority by the six place directors in HNY, they will approve the rebate for sign-off by the Executive Director of Finance and Investment. |
|  |  |  |
| **Chief Finance Officer** |  | To formally sign and approve the contract following approval by the IPMOCommittee. |
|  |  |  |
| **MMT/MOT** |  | Activate and monitor the contract with the company in conjunction with the ICB Finance Team and to ensure publication of the approved rebate schemes on the ICB website. |

## Appendix 3: ICB Primary Care Rebate Scheme: Assessment and Decision Form

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product** | |  | | | | | | |
| **Manufacturer** | |  | | | | | | |
| **Contact Details** | |  | | | | | | |
|  | | | | | | | | |
| **Brief details of rebate scheme** | |  | | | | | | |
|  | | | | | | | | |
| **Assessment Criteria** | | | | | | | | **Yes/No** |
| **Is the product listed in both H+NY ICB joint formularies?** | | | | | | | |  |
| **Does the product have NICE approval?** | | | | | | | |  |
| **Is there a requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?** | | | | | | | |  |
| **If the product is a medicine, is it licensed in the UK?** | | | | | | | |  |
| **Is the rebate scheme designed to increase off label use of the drug?** | | | | | | | |  |
| **If the product is a device or nutritional supplement is it contained in the current Drug Tariff?** | | | | | | | |  |
| **If the product is a vitamin or classed as a food supplement, is it recommended for NHS use in the ICB?** | | | | | | | |  |
| **Does the rebate scheme require exclusive use of one specific brand ahead of any other product (i.e. preferential positioning)?** | | | | | | | |  |
| **Is the product listed in Category A or M of the Drug Tariff?** | | | | | | | |  |
| **Is the rebate scheme linked directly to a requirement for an increase in market share or volume of prescribing?** | | | | | | | |  |
| **Does the rebate scheme prevent consideration of other schemes?** | | | | | | | |  |
| **Is there a requirement to submit additional information beyond the volume of prescribing of the product?** | | | | | | | |  |
| **Are there any requirements to collect patient specific data?** | | | | | | | |  |
| **Other Considerations:** | | | | | | | | |
| **PrescQIPP Pharmaceutical Industry Scheme Governance Board assessment** | | | | | |  | | |
| **No. of years scheme is available? (Is it >2 years?)** | | | | | |  | | |
| **Estimated potential savings (per patient and for ICB population per annum)?**  **DETAIL IS 'COMMERCIAL IN CONFIDENCE': full detail to be considered by ICB Rebate Sub-group but IPMOC only to be advised if 'financially viable'** | | | | | | **Limit detail for IPMOC to clarity if financially viable for ICB:**  **YES / NO** | | |
| **Have any other contractual or legal issues been identified during the evaluation?** | | | | | |  | | |
| **Further information. Including the following where relevant:**  ***• Administrative burden:***  ***• Governance issues:***  ***• Freedom of Information issues:***  ***• Any other pertinent issues:*** | | | | | | | | |
| **Recommendation**  If PrescQIPP reviewed this PCRS, what was their recommendation?  If MMT/MOT reviewed this PCRS, what was their recommendation? | | | | | | | | |
| **Rationale:** |  | | | | | | | |
| **Evaluation carried out by:**  (Name, Title & Date) | | |  | | | | | |
| **Reviewed by:**  (Name, Title & Date) | | |  | | | | | |
|  | | | | | | | | |
| **ICB Rebate Sub-group** | | | | | **Recommendation to approve:** | | | |
| **Date:** | | |  | | **YES or NO** | | | |
|  | | | | | | | | |
| **Discussion at H&NY ICB's Integrated Pharmacy and Medicines Optimisation Committee** | | | | | | | | |
| **The Committee does support the decision to agree to this primary care rebate scheme** | | | | | | | **YES or NO** | |
| **Place MM/MO representatives** | | | |  | | | **Date:** | |
| **Place Finance representative** | | | |  | | |  | |
| **Date sent to Executive Director of Finance and Investment:** | | | | | | |  | |