Ethical Framework for Considering Rebate Applications from Pharmaceutical, Nutrition and Device Companies in primary care.

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Copies of this document can be obtained from:

Name:	Strategic Medicines Optimisation Team
Address:	3 Piccadilly Place Manchester M1 3BN
Email:	gmicb-old.medsman@nhs.net

Revision History

The latest and master version of this document is held in the medicines management library and represents the only approved copy.

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
15/04/2014	S Woods	Final version produced for website	3.0
22/02/2016	S Woods	New format used. Removed some sections from the 'Background' in order to update. Under '*Product Related*' changed the bullet point: ▪ **Where a product is not included in the GMMMG formulary[2] (because it is not covered or belongs to a class of drugs not covered) it <u>should not</u>:** ▪ Be included in the GMMMG 'Do not prescribe list[2], ▪ Have a negative decision by NICE[3]. A clinical need for availability of the product should be demonstrated. To: ▪ **Where a product is not included in the GMMMG formulary[2] (because it is not covered or belongs to a class of drugs not covered or it falls outside the 80:20 rule for inclusion) it <u>should not</u>:** ▪ Be included in the GMMMG 'Do not prescribe list[2], ▪ Have a negative decision by NICE[3]. A clinical need for availability of the product should be demonstrated. Moved: ▪ **PCRS are not appropriate for medicines in Category A and Category M of the Drug Tariff[4].**	3.1

		This is due to the potential wider impact on community pharmacy reimbursement. From **'***Rebate Scheme Related'* to **'***Product Related'* Under '*Rebate Scheme Related*' Amended: ▪ **All PCRSs will be expected to run for a minimum period of 2 years with a notice period of 6 months.** To: ▪ **All PCRSs will be expected to run for a minimum period of 2 years with a notice period of 6 months,** but it will be up to CCGs to make their own decision with regard to this matter. Added details covering the process involved.	
18/04/2016	S Woods	Amendment after submission to GMMMG: Under '*Product Related*' changed the bullet point: ▪ **Where a product is not included in the GMMMG formulary[2] (because it is not covered or belongs to a class of drugs not covered or it falls outside the needs of the majority of adult patients) it <u>should not</u>:** ▪ Be included in the GMMMG 'Do not prescribe list[2], ▪ Have a negative decision by NICE[3]. A clinical need for availability of the product should be demonstrated. To: ▪ **Where a product is not included in the GMMMG formulary[2] (because it is not covered or belongs to a class of drugs not covered or is prescribed for a restricted pre-identified group) it <u>should not</u>:** ▪ Be included in the GMMMG 'Do not prescribe list, ▪ Have a negative decision by NICE. A clinical need for availability of the product should be demonstrated.	3.2
22/04/2016	S Woods	After review by the Chair of GMMMG, changed; ▪ **Where a product is not included in the GMMMG formulary[2] (because it is not covered or belongs to a class of drugs not**	4.0

		covered or is prescribed for a restricted pre-identified group) it <u>should not</u>: ▪ Be included in the GMMMG 'Do not prescribe list, ▪ Have a negative decision by NICE. A clinical need for availability of the product should be demonstrated. To: ▪ **Where a product is not included in the GMMMG formulary[2] it <u>should not</u>:** ▪ Be included in the GMMMG 'Do not prescribe list, ▪ Have a negative decision by NICE. A clinical need for availability of the product should be demonstrated.	
05/06/2019	Kenny Li – Head of Medicines Optimisation Manchester Health and Care Commissioning	Adapted based on legal recommendations and changes in the Greater Manchester NHS architecture.	5.0
13/11/2019	S Woods GM Joint Commissioning Team	Added wording to reflect comments from CSB, Amended organisational name from GM Shared Services to Strategic Medicines Optimisation at the Greater Manchester Joint Commissioning Team.	5.1
13/12/2019	S Woods GM Joint Commissioning Team	Final formatting for publication after approval at CSB (GMMMG)	6.0
08/09/21	A Martin, E. Radcliffe GM Joint Commissioning Team	Address for GM Joint Commissioning Team updated. Phone number replaced with email contact details. Amended to remove reference to Category A products not being suitable for consideration. Insertion of minimum 6 months' guaranteed supply should all GM CCGs sign up. Minor formatting changes	7.0
19/10/21	A. Martin	Background amended to include note that rebate schemes are legal, based on the Abbot / Aymes judgement	7.1

		Financial threshold inserted as approved by GMMMG 14/10/2021 Process paragraphs numbered instead of bullet points	
22/02/22	A. Martin	Amendments after consultation References to PPRS updated to DH Voluntary scheme	7.2
03/05/22	A. Martin	Statement inserted (page 7) to clarify that this only applies to schemes offered to CCGs / ICB locally. Updated to include legal advice received in 2022. Updated to refer to Greater Manchester Integrated Care instead of Clinical Commissioning Groups (CCGs)	9.0
06/09/2022	A White	Updated email contact details for GM ICB	9.1
January 2024	A. Martin	Revised after receipt of legal advice to enable a more risk-based approach. References updated.	10.0

Approvals

This document must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Chair	GMMMG	01/07/2022	9.0
IPMO Value subgroup		19/02/2024	10.0
After consultation	GMMMG	09/05/2024	10.0
NHS GM	Clinical Effectiveness and Governance Committee	23/05/2024	10.0
NHS GM	NHS GM Executive	12/06/2024	10.0

Distribution

This document has been distributed to:

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Ethical Framework for Considering Rebate Applications from Pharmaceutical, Nutrition and Device Companies in primary care.

Background

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

The PPRS did not apply to devices or nutritional products; nor did it apply to generic medicines whose prices tend to be controlled by their Drug Tariff agreed pricing.

The DHSC introduced an updated PPRS in January 2019 when it became a Voluntary Scheme for Branded Medicines Pricing and Access. This was further updated in 2023, to commence 1st January 2024. The precise workings of the scheme are complex, and the full text of the 2024 voluntary scheme is available on the DHSC website.

The scheme is a voluntary agreement to control the prices of branded drugs sold to the NHS. It is negotiated between the DH, acting on behalf of the UK government and Northern Ireland, and the branded pharmaceutical industry, represented by the Association of British Pharmaceutical Industry (ABPI). The DHSC will maintain a list of those companies (suppliers or manufacturers) involved on their website.

Any pharmaceutical company which is not subject to the voluntary scheme is automatically subject to a statutory scheme and shall be subject to any regulations or directions made by the Secretary of State pursuant to his powers under sections 262 to 264 of the NHS Act 2006. Those sections do not apply to members of the voluntary scheme.

More recently, NHS England has undertaken a national procurement for direct acting oral anticoagulants (DOACs), through which savings on DOACs can be realised via rebates and investments by relevant pharmaceutical companies. It is possible further similar national arrangements will become available to the NHS over time.

A number of manufacturers have established ‘rebate schemes’ for drugs used in primary care under the guise of contributing to the NHS QIPP (Quality, Innovation, Productivity and Prevention) agenda, but basically to make their products appear more cost effective. Under these schemes the NHS is charged the Drug Tariff price for primary care prescriptions dispensed, and then the manufacturer provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data.

Some schemes offered to the NHS are straight discounts and are not volume based, whilst others have varying discount rates available dependent upon the volume of drug prescribed.

The legality of rebate schemes has been tested in Court via a challenge from Abbott to an NHS CCG and Aymes and they have been found to be legal.

The framework applies to Schemes offered to the NHS in Greater Manchester in primary care only.

Introduction

It is always preferable for pharmaceutical, nutrition and device companies to supply medicines to the NHS using transparent pricing mechanisms that do not create an additional administrative burden to the NHS.

In utilising rebate schemes offered by companies there is a risk that they may impact on the funding arrangements in place for the community pharmacy contract, whereby part of the remuneration for community pharmacy services is derived from the profit margins available to pharmacies on prescription drug purchases, and the adjustments to category M prices. There is potential that savings made against one product may be lost by an adjustment against the price paid to pharmacies for other products. There is also potential for an impact on the Voluntary Scheme for Branded Medicines Pricing and Access and the overall costs of drugs to the NHS.

Rebate schemes can at the same time deliver significant savings to the NHS's expenditure, and help achieve budgetary balance, defray pharmaceutical expenditure, and deliver services efficiently and economically.

Concerns have been raised that potential difficulties could be encountered in relation to a number of legal issues. These include conflicts of interest, the Bribery Act, competition law and procurement rules. However legal advice sought by the London Procurement Partnership[1] in 2012 concluded that primary care rebate schemes are not unlawful and are within the powers of Clinical Commissioning Groups (CCGs) to agree to, provided they meet certain requirements. More recently, in 2019, the legality of rebate schemes has been tested in Court via a challenge from Abbott to an NHS CCG and Aymes[2] where they were found to be legal.

Also in 2019, the GM CCGs obtained more up-to-date legal advice as part of the review of this policy, which reached broadly the same conclusion, but emphasised the importance of managing the legal issues arising.

In order to support NHS Greater Manchester (NHS GM) in the management of rebate schemes in Greater Manchester the GM Medicines Management Group (GMMMG) agreed that Strategic Medicines Optimisation at the GM Joint Commissioning Team (now the central team at NHS GM) will process any applications, received via GMMMG from pharmaceutical, nutrition and device companies, through this ethical framework and make the outcomes available to NHS GM for consideration.

[1] London Procurement Programme Legal Response from DAC Beachcroft LLP – Personal communication.
[2] R. (on the application of Abbott Laboratories Limited vs NHS Herts Valleys Clinical Commissioning Group and Aymes International Limited [2019] EWHC 1999 (Admin) (17 July 2019).

GMMMG will only consider proposals submitted to them by companies and not develop or submit proposals to companies.

It will be up to NHS GM to:

1. Decide whether to take up any offer made and manage the claims directly with the relevant company;
2. Take appropriate measures to ensure the scheme is operated lawfully.

Scope

This Framework applies to proposals for rebate schemes submitted by pharmaceutical, nutrition and device companies directly to NHS GM.

This Framework does not apply to national rebate schemes (or similar arrangements) that have already been approved by NHS England and made available to Integrated Care Systems (ICSs), for example NHS England's national procurement for direct acting oral anticoagulants (DOACs). This is because such arrangements have already been approved following an appropriate process determined by NHS England.

If there is ever any doubt as to whether this Framework applies this should be raised with GMMMG.

Principles

The following will be used to determine the eligibility and suitability of taking a Primary Care Rebate Scheme (PCRS) to GMMMG for consideration and ratification.

The **principles** are categorised into:

1. Product Related
2. Rebate Scheme Related
3. Information And Transparency Related.

Each category includes:

- **Eligibility Criteria** that must be met for the PCRS to be eligible for consideration and ratification by GMMMG.
- **Additional Considerations** that will be considered by GMMMG in determining whether the PCRS is suitable and should or should not be approved. This is not an exhaustive list – GMMMG may take account of, and weigh up, all relevant considerations as it sees fit.

1. *Product Related*

Eligibility Criteria

1.1. Any medicine considered under a PCRS must be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be linked to a particular indication for use.

1.2. A product considered for PCRS should normally be included in the GMMMG Formulary[3].

1.3. Where a product is not included in the GMMMG formulary[3] because it is not covered or belongs to a class of drugs not covered or is prescribed for a restricted pre-identified group it should not:

- Be included in the GMMMG 'Do not prescribe list[3],
- Have a negative decision by NICE[4].

However, a clinical need for availability of the product MUST be demonstrated.

1.4. There shall be no directive for health professionals to prescribe a specific product, only because of an existing PCRS. Prescribing decisions should be made on assessments of individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.

1.5. Any device or nutritional supplement considered under a PCRS should be included within Parts IX, IXA, IXB, IXC, IXR and XV of the Drug Tariff[5].

1.6. PCRS are not appropriate for medicines in Category M in Part VIII of the Drug Tariff[5]. This is due to the potential wider impact on community pharmacy reimbursement.

1.7. Unlicensed vitamins and minerals. Those considered under a PCRS should be listed in the GMMMG Formulary[3].

Additional Considerations

1.8. Ideally, consistent savings should be achievable for all pack sizes where applicable. If this is not the case, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

1.9. The rebate application should provide assurance of resilience of supply, preferably in excess of 6 months' availability at all times based on an assumption that all of NHS GM takes up the rebate offer. If this is not the case, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

[3] The GMMMG Formulary and 'Do not prescribe list' can be found at: http://gmmmg.nhs.uk/
[4] NICE – National Institute for Health and Care Excellence. http://www.nice.org.uk/
[5] The Drug Tariff can be found at: http://www.nhsbsa.nhs.uk/924.aspx

2. *Rebate Scheme Related*

Eligibility Criteria

2.1. The primary purpose of PCRS must be to defray the expenditure of NHS GM's primary care prescribing budget, and any income received should be used solely for that purpose.

2.2. The PCRS should not place any express or implied reciprocal obligations on NHS GM in return for the rebate. This includes an express or implied agreement to promote the prescription of a particular product. This does not preclude a requirement for NHS GM to undertake administration, provide returns or correspond with a company where this is solely for the purpose of administration of the scheme.

2.3. PCRS encouraging exclusive use of a particular brand of product will not be entered into. Where specific brand prescribing is required due to the nature of the product e.g. glucose testing strips or specific drugs, then an increase in that particular product usage may be seen but an individual patient's clinical need must be the driver for a prescriber's choice.

2.4. The PCRS will not be directly linked to requirements to increase market share or volume of prescribing, although an increase in market share may be a consequence of the PCRS. This does not preclude variable rebate pricing based the market share or volume of prescribing but see additional consideration 2.7.

2.5. The rebate must never bring about a financial or other advantage to an officer of NHS GM, member practice or individual prescriber.

2.6. The rebate scheme must not give rise to a conflict of interest. Potential conflicts of interest should be managed appropriately in accordance with NHS England's statutory guidance to CCGs on managing conflicts of interest.[6]

Additional Considerations

2.7. Ideally, the rebate pricing should be based on a straight discount per item dispensed, without variable rebate pricing based on market share or volume of prescribing. Variable rebate pricing increases administration and presents the risk of being perceived as incentivising increased prescribing of the product in question. However, variable pricing may be considered by GMMMG, and may be approved in appropriate circumstances, provided always that appropriate measures are in place to ensure compliance with the Eligibility Criteria, including in particular the requirement not to promote the prescription of a particular product.

2.8. Ideally, rebate pricing should not be based on a competitor's product price, as a subsequent change to the competitor's price could affect the value of the rebate and make the PCRS unattractive. Ideally, it should be a requirement of the PCRS to maintain the price differential. If this is not the case, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

[6] https://www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-for-ccgs-2017/

2.9. Ideally, a PCRS will be expected to run for a minimum period of 2 years with a notice period of 6 months. If this is not the case, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

2.10. Due to the considerable amount of administration associated with PCRSs, typically they will only be considered where potential savings, based on the latest available primary care prescribing data from ePACT2 and current prescribing patterns, are in excess of £10,000 per annum across all of Greater Manchester. If this is not the case, or the rebate is not based on such data, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

3. Information and Transparency

Eligibility Criteria

3.1. Details of the PCRS will be published by GMMMG.

3.2. The PCRS must not place NHS GM under any obligation to keep the existence or details of the PCRS confidential, or any similar obligation.

3.3. The PCRS must not preclude NHS GM from considering any other schemes subsequently offered by manufacturers of competitor products.

3.4. A PCRS that requires the provision of information to a manufacturer about a competitor's product market share will not be entered into.

3.5. A PCRS that requires provision of patient specific data will not be entered into.

3.6. PCRS will be subject to Freedom of Information (FOI) requests. Advice should be sought from the NHS GM FOI Officer as to what information should be shared. NHS GM retains sole discretion as to what should be disclosed in response to FOI requests. Rebates to which NHS GM is signed up to are listed on a rebate page at the GMMMG website.

Additional Considerations

3.7. Ideally, there will be no requirement to collect or submit to the manufacturer any data other than volume of use or Total NIC (Net Ingredient Cost) as derived from ePACT2 data. If this is not the case, or the rebate is not based on such data, the impact on the potential benefits and efficiency of administering the PCRS should be considered.

The Process

1. **Submission**

The proposed scheme application, including the contract, will be submitted electronically to the GM ICB email address gmicb-old.medsman@nhs.net using the form from the GMMMG website.
Receipt will be acknowledged and date of submission of the recommendation to GMMMG will be notified.

Please do submit:

- The Scheme Submission form with as much relevant information as possible
- The Commercial details of the scheme - we cannot assess the scheme without them.
- The Contract that would be provided to NHS GM - this will need to be a final contract and not a suggested guide to terms.
- Any other relevant supplementary contracts / templates (e.g. claim forms)

All such information must be consistent with the '***Process Principles***' detailed above.

Do **not** submit:

- Supplementary promotional information around the drug or related evidence
- Presentations, flyers etc. these are not required and will not be submitted with the recommendation to GMMMG.
- Requests or mandates for non-disclosure to GMMMG members - as a policy we will not share any information to any parties outside of the NHS circulation, but will as part of the process, be sharing with NHS colleagues within the GMMMG area.
- Stipulations around schemes only being available to certain localities within NHS Greater Manchester will not be accepted.

2. **The Review**

A Senior Medicines Optimisation pharmacist in the NHS GM strategic team will consider the submission against the '***Process Principles***' detailed above and make a recommendation to GMMMG. The review process will consider the product in relation to the following:

- GMMMG formulary.
- GMMMG 'Do not prescribe list'.
- NICE guidance.
- Drug Tariff.
- Whether licensed or not.
- ePACT2 data.
- PCRS contract and application form as submitted by the company.

3. **Notification**

Providing that there are no objections to the recommendation submitted to GMMMG, the submitting company will be informed of the outcome and where it is recommended that a PCRS is accepted by GMMMG, these will be notified to NHS GM.

Notification to NHS GM will include basic details of the scheme and contact details for the company involved. It will be expected that NHS GM will take up schemes and a contract prepared for signature by financial colleagues and appropriate measures taken to ensure the scheme is operated lawfully.

GMMMG strongly recommends to NHS GM that they ensure the scheme is operated in accordance with the '***Process Principles***' detailed above.