Ethical Framework for Considering Rebate Applications from Pharmaceutical, Nutrition and Device Companies

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Copies of this document can be obtained from:

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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].** This is due to the potential wider impact on	3.1

		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 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. 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 covered or is prescribed for a restricted**	4.0

		pre-identified group) it should not: ▪ 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 should not:** ▪ 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

Approvals

This document must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Chair	GMMMG - CSB	13/12/2019	6.0

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This document has been distributed to:

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Background

The Pharmaceutical Price Regulation Scheme (PPRS) is 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 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.

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

The DHSC introduced a new PPRS in January 2019. The precise workings of the scheme are complex, and the full text of the 2019 PPRS is available on the DHSC website.

The PPRS 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 PPRS.

A number of manufacturers have established ‘rebate schemes’ for drugs used in primary care under the guise of contributing to the NHS QIPP 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.

Introduction

It is 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 PPRS 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[11] in 2012 concluded that primary care rebate schemes are not unlawful and are within the powers of Clinical Commissioning Groups (CCG) to agree to, provided they meet certain requirements. The GM CCGs obtained more up-to-date advice in 2019 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 CCGs in the management of rebate schemes in Greater Manchester (GM) the GM Medicines Management Group (GMMMG) has agreed that Strategic Medicines Optimisation at the GM Joint Commissioning Team (SMO GM JCT) will process any applications, received via GMMMG from pharmaceutical, nutrition and device companies, through this ethical framework and make the outcomes available to GM CCGs for individual consideration.

The GMMMG will only consider proposals submitted to them by companies and not actively approach them.

It will be up to GM CCGs 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.

Process Principles

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

Product Related

- **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.
- **A product considered for PCRS should normally be included in the GMMMG Formulary[2].**
- **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[2],
    - Have a negative decision by NICE[3].

  A clinical need for availability of the product should be demonstrated.
- **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 patient's clinical circumstances. The impact of a rebate scheme is a secondary consideration.
- **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[4].**
- **PCRS are not appropriate for medicines in Category A and Category M of the Drug Tariff[4]**. This is due to the potential wider impact on community pharmacy reimbursement.
- **Unlicensed vitamins and minerals. Those considered under a PCRS should be listed in the GMMMG Formulary[2].**
- **Consistent savings must be achievable for all pack sizes where applicable.**

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

Rebate Scheme Related

- **The primary purpose of PCRS must be to defray the CCG's expenditure of its prescribing budget, and any income received should be used solely for that purpose.**
- **The PCRS should not place any express or implied reciprocal obligations on the CCG in return for the rebate.** This includes an express or implied agreement to promote the prescription of a particular product.
- **Where a PCRS can be affected by a competitor's product price then a price change could make the PCRS unattractive**. It should be a requirement of the PCRS to maintain the price differential.
- **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.
- **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 individual patient's clinical need must be the driver for prescriber's choice.
- **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.
- **The rebate payable is based on a straight discount per item dispensed, without conditions or tapered payments based on prescribing volumes or growth.**
- **The rebate must never bring about a financial or other advantage to a CCG officer, member practice or individual prescriber.**
- **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.[5]

Information and Transparency

- **Details of the PCRS will be published by GMMMG.**
- **The PCRS must not place CCGs under any obligation to keep the existence or details of the PCRS confidential, or any similar obligation.**
- **The PCRS must not preclude CCGs from considering any other schemes subsequently offered by manufacturers of competitor drugs.**
- **There will be no requirement to collect or submit to the manufacturer any data other than volume of use or Total NiC as derived from ePACT data.**
- **PCRS that requires the provision of information to a manufacturer about a competitor's product market share will not be entered into.**

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

- **PCRS that requires provision of patient specific data will not be entered into.**
- **PCRS will be subject to Freedom of Information (FOI) requests.** Advice should be sought from the individual GM CCG's FOI Officer as to what information should be shared.

The Process

1. **Submission**

   The proposed Scheme application, including the contract, will be submitted electronically to the GMMMG email address GMMMG@nhs.net using the form at Appendix 1.

   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 the NHS Organisation - 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 areas / CCGs within the Greater Manchester area. For the sake of equity, all schemes must be available to all CCGs covered by GMMMG.

2. **The Review**

   A Senior Medicines Optimisation pharmacist the SMO JCT 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.
   - ePACT 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 GM CCGs.

Notification to GM CCGs will include basic details of the scheme and contact details for the company involved. It will be up to each CCG to contact companies should they wish to take part in the scheme offered and to take appropriate measures to ensure the scheme is operated lawfully. GMMMG strongly recommends to GM CCGs that they ensure the scheme is operated in accordance with the '***Process Principles***' detailed above.