



Working in Partnership with the Pharmaceutical Industry Policy

Joint Working for the Benefit of Patients

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Summary

This policy sets out the approach Lewisham Clinical Commissioning Group (CCG) will take in joint working with the pharmaceutical industry, ensuring it is in line with the Lewisham CCG Constitution and local and national guidance.

The aim of this policy is to:

- Set out a framework for Lewisham CCG to build effective and appropriate working relationships with the pharmaceutical industry and other third party commercial organisations to achieve its strategic objectives and delivery of national and local priorities
- Inform and advise staff of their main responsibilities when entering into joint working and sponsorship arrangements with the pharmaceutical industry. Specifically, it aims to: assist staff in maintaining appropriate ethical standards in the conduct of NHS business
- Highlight that NHS staff are accountable for achieving the best possible health care within the resources available.
- Encourage member practices of Lewisham CCG to adhere to the principles of this policy in any interactions they have with the Pharmaceutical Industry and other commercial organisations

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1. Introduction

Increasing financial pressures and a growing improvement agenda make it more important for primary care to consider strategic partnerships that will enable it to achieve national and local targets.

DH Guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous. NHS organisations are required to consider fully the arrangements of any sponsorship deal on the wider impact on healthcare services.

2. Scope

This document is intended as policy for Lewisham CCG and its staff who are considering sponsorship, joint working and training arrangements with the pharmaceutical industry or other organisations potentially supplying NHS with clinical support (including third party commercial organisations).

For the purposes of this policy, the term 'staff' refers to all health professionals working for Lewisham CCG and independent contractors, locum practitioners working under the NHS terms and conditions in Lewisham. It applies to any member of CCG employed staff and anyone representing Lewisham CCG e.g. in a board role, or local expert and is recommended as good practice for GP practices and community pharmacists.

DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry ¹ defines joint working as situations where for the benefit of patients organisations pool skills, experience and /or resources for the joint development and implementation of patient centered projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for specific event or work programme.

However for the purpose of this policy all collaborative projects with the pharmaceutical industry should be considered as joint working. Primary Care Rebate arrangements are also considered under the scope of this policy.

3. Aims & Objectives

To assist Lewisham CCG achieve its objectives in delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry.

Inform and advise staff of their main responsibilities when entering into joint working arrangement with the pharmaceutical industry.

Staff are reminded that at all times they have a responsibility to comply with their own professional codes of conduct and that representatives of the pharmaceutical industry must comply with the ABPI Code of Practice for the Pharmaceutical Industry² and ABPI Guidance notes on Joint working between pharmaceutical companies and the NHS and others for the benefit of patients³.

4. Values

In line with the NHS Code of Conduct⁴ three public service values underpin the work of the NHS

Accountability – everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgments of propriety and professional codes of conduct.

Probity – there should be an absolute standard of honesty in dealing with the assets of the NHS. Integrity should be the hallmark of all personal conduct in decisions affecting patients, staff and suppliers, and in the use of information acquired in the course of NHS duties; and

Openness – there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public

Where staff enter into any joint working with the pharmaceutical industry, their conduct should also adhere to the following values in order to ensure:

- Transparency and trust
- Appropriateness of projects
- Patient focused
- Value for money
- Reasonable contact
- Responsibility
- Impartiality and honesty
- Truthfulness and fairness
- Information Governance (IG) - Data Protection and Confidentiality rules.

5. Principles of Joint working

Joint working must be for the benefit of patients or of the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner. Arrangements should be of mutual benefit, the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working. The following principles will also apply to joint working:

- Professional codes of conduct as described in existing NHS guidance.
- Schemes must not be linked to the purchase and supply of particular products and company must agree not to promote or advertise its own products within the work it is supporting.
- Development of guidelines or protocols should be under local control via the Lewisham CCG Prescribing & Medicines Optimisation Group (PMOG).
- Clinical responsibility for prescribing remains with the prescriber and no agreement can be made to prescribe specific company products without the prescriber's consent.
- Contract negotiations will be negotiated in line with NHS values and in line with Lewisham CCG standing financial instructions.
- Confidentiality of information received in the course of duty must be respected and never used outside the scope of the specific project.
- Joint working arrangements should take place at a corporate, rather than an individual, level.
- Clinical and financial outcomes will be assessed through a process of risk assessment.
- Recommendations made to prescribers to support prescribing of particular products will have been approved by the PMOG.
- A mutually agreed and effective exit strategy will be in place at the outset of any joint working arrangement detailing the responsibilities of each party and capable of dealing with a situation where premature termination may become necessary.

Examples of particular areas of potential joint working include:

- Training and development of staff – some companies offer management and organisational development training
- Development and implementation of prescribing strategies, protocols or guidelines (including guideline publication costs).
- Educational leaflets-companies may contribute to the cost of producing leaflets in exchange for the company logo being printed on the leaflet.
- Information technology and other data collection tools
- Funding of all or part of the costs of a member of staff

Joint working is unlikely to be approved in the following areas:

- The provision of free pharmaceutical starter packs -This promotes prescribing of a particular product and compromises purchasing decisions.
- Business meetings / General Medical Services - The NHS organisation should be seen to be impartial and independent of a commercial organisation. Sponsorship will not be accepted for any service that attracts an item of service fee
- Equipment- Equipment for use in the NHS should be procured by the NHS. Small items of equipment with low intrinsic value may be acceptable.

6. Confidentiality and Data Protection

NHS data is confidential, and may also be copyright, therefore may not be shared with pharmaceutical companies. Any joint working agreement should comply with the legal and ethical requirements for the protection and use of patient information and other NHS information, following Lewisham CCG Information Governance Policy⁵

- All patient identification should be removed from data before it is given to the company, data should not be removed by the third party or used for any other purpose.
- Reports or information from the work should not be used or published elsewhere without explicit permission from the NHS organisation concerned.
- Patients should be made aware that their treatment may involve input from the pharmaceutical industry working with the NHS in accordance with this policy.

7. Approval of Joint Working Arrangements

See **Appendix 1** for the Lewisham CCG approval mechanism for joint working arrangements.

Individuals seeking joint approval should initially fill out **Appendix 2** Joint Working with the Pharmaceutical Industry Screening Checklist and discuss with a member of the Lewisham CCG medicines optimisation team.

If it is agreed that the project has potential, **Appendix 3** Lewisham CCG Joint Working Framework should be submitted to the Lewisham CCG head of Medicines Management who will review taking into consideration the impact on medicines optimisation priorities both in Lewisham CCG and local formulary decisions.

A recommendation will be made to the Lewisham CCG Prescribing & Medicines Optimisation Group. For more complex projects may require a business case, Joint Working Agreement and Project Initiation Document (PID). *Information on these frame works can be found on DH Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry August 2010*⁶

Proposals and the outcome of assessment by the CCG medicines optimisation team will be entered on the Lewisham CCG register of submitted proposals. Where appropriate, proposals should be accompanied by an Action Plan that sets out what should be done by whom and by when. Joint working agreements will be monitored according to agreed outcome measures. Either side can terminate if these outcome measures are not achieved.

8. Sponsorship: Hospitality and meetings

NHS staff should follow the principles outlined in the Standards of Business Conduct for NHS Staff: HSG (93)54 and ABPI Code of Professional Conduct relating to meetings and hospitality from the pharmaceutical/external industry 2008⁷

Any acceptance of sponsorship will take into account the principles outlined in 4. & 5. Sponsorship should not influence purchasing decisions and it must be clear that sponsorship does not imply Lewisham CCG endorsement of any product or company. There should be no promotion of products apart from that agreed in writing in advance.

Industry representatives may sponsor the venue, refreshments, expenses of practitioners attending the event etc. for local educational meetings. Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings. Hospitality must be secondary to the purpose of the meeting and the level of hospitality should be appropriate. Where training is sponsored by external sources, the fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Lewisham CCG medicine optimisation should be notified of any pharmaceutical industry sponsorship.

Sponsorship for training is accepted on the understanding that:

- The course organiser retains overall control of the event
- The sponsor does not have the right to present any material
- Where the organiser considers additional value may be gained from presentation by the sponsor, the content of the material is agreed in advance of the meeting.
- The course organiser will assess any educational content provided by the sponsor and refer on to a member of the CCG pharmacy team for advice where appropriate.
- Where course material is provided by the pharmaceutical company, that there is no promotion of specific products (the name of the company supporting the training event is acceptable)
- The sponsor does not use Lewisham CCG contact to promote products outside the meeting
- Any stand the sponsor uses to promote products is to be outside the main meeting room where practicable
- Attendance of the meeting by the sponsor is at the discretion of the course organiser
- Flyer is advertisement free and must be agreed by the CCG prior to circulation
- Honorarium received by speaker is declared if appropriate

9. Lewisham CCG staff relationship with the Pharmaceutical Industry – Hospitality/Gifts, Conflicts of Interest and Payments

Staff should follow the principles outlined in:

- Lewisham CCG Gifts and hospitality policy⁸
- Lewisham CCG Conflicts of Interest policy⁹
- Lewisham CCG Anti Fraud Bribery & Corruption Policy¹⁰

10. Primary Care prescribing rebates

A number of manufacturers have established 'rebate schemes' for drugs used in primary care to support the NHS QIPP agenda. The NHS is charged the Drug Tariff price for primary care prescriptions dispensed then the manufacturer provides a rebate to the primary care organisation based on an agreed discount price and verified by ePACT data.

Rebate agreements usually take the form of legal agreements between the manufacturer and CCG. It is important that Lewisham CCG has a process to support evaluation and sign off of rebate schemes to ensure that schemes are only signed off where they provide good value for money to the public purse and the scheme's terms and conditions are in line with the organisation's vision, values policies and procedures.

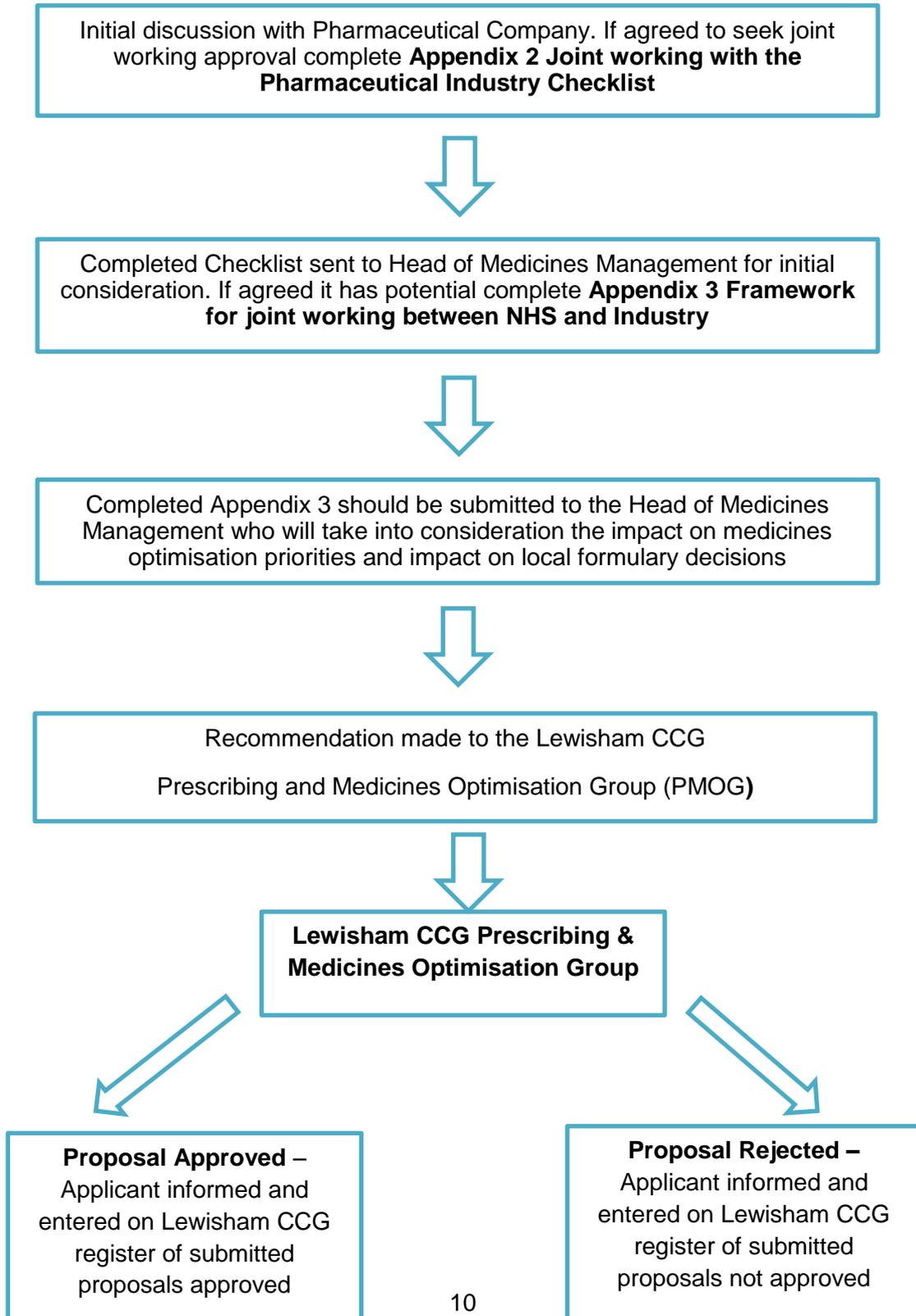
Any prescribing rebate agreement should comply with the requirements within the Lewisham CCG policy for approving primary care rebate schemes¹¹

References

- 1.DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry ¹
- 2.ABPI Code of Practice for the Pharmaceutical Industry²
- 3.ABPI Guidance notes on Joint working between pharmaceutical companies and the NHS and others for the benefit of patients³
- 4.NHS Code of Conduct⁴
- 5.Lewisham CCG Information Governance Policy⁵
- 6.DH Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry August 2010⁶
- 7.Standards of Business Conduct for NHS Staff:HSG(93)54 and ABPI Code of Professional Conduct relating to meetings and hospitality from the pharmaceutical/external industry 2008⁷
- 8.Lewisham CCG Gifts and hospitality policy⁸
- 9.Lewisham CCG Conflicts of Interest policy⁹
- 10.Lewisham CCG Anti Fraud Bribery & Corruption Policy¹⁰
11. Lewisham CCG policy for approving primary care rebate schemes¹¹

Appendix 1

Joint Working – Lewisham CCG Process for Decision Making



Appendix 2

Joint Working with the Pharmaceutical Industry Checklist - Issues to Consider

Question	Yes/No	Comments
1. Is the commercial organisation a legitimate registered company?		
2. Does the scheme have aims and objectives? Are they written, and been signed by a responsible Officer?		
3. Are copies of protocols that will be used available? Who will be using them?		
4. Are the clinical aspects of the scheme of sufficiently high quality? e.g. in line with local guidelines, CCG strategic priorities and best evidence		
5. Are there any patient-related clinical responsibility or accountability issues to consider?		
6. Will outcomes be measured or will the scheme be audited?		
7. Are there any patient interest issues to consider?		
8. Are there any potential conflicts of interest for the NHS and the organisation?		
9. Who owns the data and how will it be used?		
10. Are there any legal issues to consider? Does the scheme comply with the law?		
11. Does the scheme fit in with existing NHS services?		
12. Does the scheme have any implications for other aspects of healthcare? e.g. create demand for lab tests, increase demand on other services		
13. How will the scheme be managed and who is accountable for the scheme?		
14. Will there be any recurrent costs to pick up, and who will be responsible for these?		

Appendix 3

FRAMEWORK FOR JOINT WORKING BETWEEN THE NHS AND PHARMACEUTICAL INDUSTRY

I. JOINT WORKING PROJECT SUMMARY	
1. TITLE OF PROJECT	
2. SUMMARY OF INTENDED AIMS & OBJECTIVES	
3. CCG STRATEGIC FIT	
4. SUMMARY OF EXPECTED OUTCOMES	
5. NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT	
6. NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION	
7. EXACT NATURE OF THE JOINT WORKING PROPOSAL AND SUPPORTING EVIDENCE— INCLUDE COMPLETED CCG QUALITY , EQUALITY, PRIVACY AND OTHER IMPACT ASSESSMENTS	
8. BENEFITS FOR PATIENTS	
9. START DATE	
10. FINISH DATE	
11. EXIT STRATEGY	