

**Corporate
Policy and Guidance
For: Joint Working with the Pharmaceutical Industry
and
Sponsorship by the Pharmaceutical Industry
Version 6.0**

(Template based upon DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008 Commercial sponsorship, ethical standards for the NHS, November 2000)

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1. Scope

This document is intended as policy for Croydon Clinical Commissioning Group (CCG) and its 'officers' who are involved in joint working with the pharmaceutical industry and sponsorship by the pharmaceutical industry.

For the purposes of this policy, the term 'officers' refers to:

- all CCG staff including interims, agency workers, specialist contractors, consultants and secondees working for Croydon CCG.
- independent contractors and locum practitioners working under the NHS terms and conditions in Croydon.
- In addition, some people who work with, but are not employed by Croydon CCG are required to comply with this policy, for example members of prescribing committees (Croydon Prescribing Committee, New Drugs sub-group, Primary Care Prescribing Group), advisory groups such as transformation/QIPP groups and patient representation. It is noted that members of prescribing committees are 'key decision making officers for prescribing'.
- All 'officers' are expected to comply with the NHS England Standards of Business Conduct Policy July 2017 including gifts and hospitality. Declarations of interest by 'key decision making officers for prescribing' will be made in line with this policy. These will be available on request according to Croydon CCG policy on Standards of Business Conduct. 'key decision making officers for prescribing' should be aware that external organisations e.g. ABPI may also publish information relating to commercial sponsorship or other payments. Croydon CCG will review such publications to ensure that appropriate internal declarations have been made in accordance with the policy and take appropriate action where they have not.

DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry 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 centred 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, with the exception of Sponsorship: hospitality and meetings, should be considered as joint working. Primary Care Rebate Schemes are also considered under the scope of this policy.

2. Introduction

DH Guidance¹ 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.

3. Aims and Objectives

The aim of this policy is to:

- Assist Croydon CCG achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry
- Inform and advise officers of their main responsibilities when entering into joint working and sponsorship arrangements with the pharmaceutical industry. Specifically, it aims to:
 - assist NHS employers and 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

Officers 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 Industry 2016*² and ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients March 2009⁵.

4. Values

In line with the NHS Code of Conduct for NHS Managers October 2002³ 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 judgements of propriety and professional codes of conduct; agreements should include arrangements for monitoring and evaluation.*
- *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 officers enter into any joint working with the pharmaceutical industry, their conduct should also adhere to the following values:

- *Transparency and trust*
- *Appropriateness of projects*
- *Patient focused*
- *Value for money*
- *Reasonable contact*
- *Responsibility*
- *Impartiality and honesty*
- *Truthfulness and fairness.*

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:

- Officers should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant NHS guidance. Schemes must not be linked to the purchase and supply of particular products and the company must agree not to promote or advertise its own products within the work it is supporting.
- Clinical aspects of care, including the development of guidelines or protocols, should be under local control via Croydon Prescribing Committee (CPC), although local groups may choose to use or adapt information produced elsewhere.
- Clinical responsibility for prescribing remains with the prescriber and no agreement can be made to prescribe specific company products without the prescriber's consent and the ratification of CPC and Croydon CCG.
- Contract negotiations will be negotiated in line with NHS values and in line with Croydon CCG standing financial instructions and NHS England Standards of Business Conduct Policy July 2017.
- 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.

All joint working schemes will require approval by the Croydon Primary Care Prescribing Group (PCPG).

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. It is noted that sponsorship of business meetings must not be provided according to the APBI Code of Practice for the Pharmaceutical Industry 2016. 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 as outlined in the NHS England Standards of Business Conduct Policy 2017.*

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, NHS Information Governance: Guidance on legal and professional obligations September 2007 and follow Croydon CCG Information Governance Policy.

- 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.

7. **Approval of Joint Working Arrangements**

Croydon CCG has a mechanism in place for approval, recording and monitoring, and evaluating any joint working arrangements (Appendix A1).

The project lead should fill out the ***Croydon CCG Joint Working Framework (Appendix A2)*** and send it to the Chief Pharmacist, Croydon CCG. The joint working proposal will be considered by Croydon Primary Care Prescribing Group (PCPG) using the Joint Working with the pharmaceutical industry – Issues to consider checklist (Appendix A3) and a decision made **within 4 weeks**. Croydon PCPG meets quarterly, therefore if there is no meeting within 4 weeks, members will receive the proposal for approval by email. A decision will be made by the Chair provided a quorum of responses has been received from a GP, Chief Pharmacist and Chair.

For more complex projects, Croydon CCG may require a Business Case, Joint Working Agreement and Project Initiation Document (PID). Information on these frameworks can be found on ***DH Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry August 2010***⁷.

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

Proposals and the outcome of assessment by Croydon Primary Care Prescribing Group will be entered on Croydon CCG register of submitted

proposals (Appendix A4). 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.

Incentive scheme declaration

GP practices are required to complete an annual declaration of working with the pharmaceutical industry as part of the Incentive Scheme using the following form: **Appendix A5 Croydon CCG Joint Working with the Pharmaceutical Industry Declaration form**. This declaration will be assessed against the CCG register of submitted proposals.

8. Sponsorship: Hospitality and meetings

Officers should follow the principles outlined in the NHS England Standards of Business Conduct Policy⁴, Croydon CCG Standards of Business Conduct Policy⁶ and the ABPI Code of Practice for the Pharmaceutical Industry 2016 clause 22.

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 Croydon 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.

Croydon CCG should be notified of any pharmaceutical industry sponsorship: hospitality and meetings using the process outlined in Appendix B1 using notification form: **Appendix B2 Sponsorship: Hospitality and Educational Meetings**. Summary reports will be presented to Croydon PCPG.

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 teaching 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 pharmaceutical 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 NHS Croydon 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

9. **Primary Care Rebate Schemes**

Primary care rebate schemes (PCRS) are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s).

Following legal advice and consultation with stakeholders, a set of principles of good practice for primary care organisations to use to facilitate robust scrutiny and identification, adoption and implementation of primary care rebate schemes have been developed, and are outlined below^{8,9}

- ◆ 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, and the clinical need for the product and its place in care pathways has been agreed by Croydon Prescribing Committee.
- ◆ 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.

In addition pharmaceutical companies should not use Primary Care Rebates schemes as a reason for contacting Croydon CCG staff.

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

- i. *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;*
- ii. *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;*
- iii. *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;*
- iv. *Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;*

- v. *Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.*
- vi. *Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the CCG website.*

Approval of Primary Care Rebate Schemes (PCRS)

Croydon CCG has a mechanism in place for approval of all PCRS (Appendix C1).

- (i) The project lead should submit proposed Primary Care Rebate Scheme to Chief Pharmacist, Croydon CCG. For the scheme to be considered locally an application must have been made to the London Procurement Programme (LPP) Rebates Group and advice from the group received¹⁰
- (ii) The Chief Pharmacist will consider the proposed scheme against the Summary of Assessment from the LPP Rebates Group. Only those schemes considered having “no reservations” or “minor reservations only” will be considered locally for use in Croydon.
- (iii) Croydon Primary Care Prescribing Group (PCPG) will consider the scheme against the LPP: Advice for primary care organisations on the suitability of rebate schemes⁹, and a decision made **within 4 weeks**.
- (iv) The PCPG meets quarterly, therefore if there is no meeting within 4 weeks, members will receive the scheme for approval by email. A decision will be made by the Chair provided a quorum of responses has been received from a GP, Chief Pharmacist and Chair. Decisions made by email will be ratified at the next PCPG.
- (v) Rebate Schemes and the outcome of assessment by Croydon PCPG will be entered on Croydon CCG register of submitted rebate schemes (Appendix C2). Approved schemes will be ratified by the CCG Senior Management Team.
- (vi) Rebate Schemes will be monitored according to agreed outcome measures, either side can terminate within the terms of the contract if these outcome measures are not achieved.

10. Standards of Business Conduct relating to the relationship between individual officers and the Pharmaceutical Industry

Officers should follow the principles outlined in the NHS England Standards of Business Conduct Policy⁴, Croydon CCG Standards of Business conduct Policy⁶ and ABPI Code of Practice for Pharmaceutical Industry 2016².

Hospitality/Gifts

All officers should ensure they are not placed in a position that risks, or appears to risk, compromising their role e.g. as a member of a prescribing committee, transformation group or Croydon CCGs public and statutory duties or reputation. Officers must not, or be perceived to, secure valuable gifts or hospitality by virtue of their role.

The Bribery Act 2010 makes it a criminal offence to give, or offer a bribe, or to request, offer to receive or accept a bribe.

Conflicts of Interest

All officers must declare links with the pharmaceutical industry. There will be a standing item at the start of each meeting to determine whether anyone has any conflict to declare in relation to the business of the meeting. The Chair will decide how to manage that conflict according to the Croydon CCG Standards of Business Conduct Policy.

Annual declarations of interest by 'key decision making officers for prescribing' will be made in line with Croydon CCG Standards of Business Conduct Policy. These will be available on request according to Croydon CCG policy on Standards of Business Conduct. 'key decision making officers for prescribing' should be aware that external organisations e.g. ABPI may also publish information relating to commercial sponsorship or other payments. Croydon CCG will review such publications to ensure that appropriate internal declarations have been made in accordance with the policy and take appropriate action where they have not.

Payments for Outside Work

All officers (depending on the details of their contract as regards outside employment and private practice) are required to seek approval from their line manager if they are engaged or wish to engage in outside employment in addition to their work with Croydon CCG.

Outside employment or private practice must neither conflict with nor be detrimental to the NHS work of the officer. Where a risk of conflict of interest is identified these will be managed in accordance with Croydon CCG Standards of Business Conduct Policy.

¹Department of Health, 2008. Best practice guidance for joint working between the NHS and the pharmaceutical industry.

²ABPI, 2016. *Code of Practice for the Pharmaceutical Industry*.

³Department of Health, 2004. *Code of Conduct: Code of Accountability in the NHS*. 2nd Ed

⁴NHS England Standards of Business Conduct Policy July 2017

⁵ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients

⁶Croydon CCG Standards of Business Conduct Policy

⁷DH Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry August 2010.

⁸LPP Principles and Legal Implications of Primary Care Rebate Schemes October 2012

⁹Legal Advice from DAC Beechcroft from 20th September 2012

¹⁰LPP Rebates Group Terms of Reference.