NHS
Haringey
Clinical Commissioning Group

SPONSORSHIP AND JOINT WORKING WITH THE PHARMACEUTICAL INDUSTRY

1	**SUMMARY**	This document sets out Haringey Clinical Commissioning Group policy and advice to employees on sponsorship and joint working with the Pharmaceutical Industry.			
2	**RESPONSIBLE PERSON:**	Sarah Price, Chief Officer			
3	**ACCOUNTABLE DIRECTOR:**	Jill Shattock, Director of Clinical Commissioning			
4	**APPLIES TO:**	This policy must be adhered to by all staff (whole or part time) and by Governing Body and Committee Members.			
5	**GROUPS/ INDIVIDUALS WHO HAVE OVERSEEN THE DEVELOPMENT OF THIS POLICY:**	Pauline Taylor, Head of Medicines Management Jill Shattock, Director of Clinical Commissioning			
6	**GROUPS WHICH WERE CONSULTED AND HAVE GIVEN APPROVAL:**	Senior Management Team 1.7.14 & 24.7.14 Medicines Management Committee 10.9.14 Quality Committee 15.10.14 Audit Committee 10.11.14			
7	**EQUALITY IMPACT ANALYSIS COMPLETED:**	**Policy Screened**	**30.10.14**	**Template completed**	**30.10.14**
8	**RATIFYING COMMITTEE(S) & DATE OF FINAL APPROVAL:**	CCG Governing Body 27.11.14			
9	**VERSION:**	Final 1.0			
10	**AVAILABLE ON:**	**Intranet**	✓	**Website**	✓
11	**RELATED DOCUMENTS:**	Anti-fraud and Anti-bribery Policy Gifts, Hospitality and Declarations of Interest Policy			
12	**DISSEMINATED TO:**	All staff via briefing			
13	**DATE OF IMPLEMENTATION:**	10.12.14			

14	**DATE OF NEXT FORMAL REVIEW:**	**Every 2 years**

DOCUMENT CONTROL

Date	Version	Action	Amendments
3 June 2014	0.1	Draft	N/A
8 June 2014	0.2	Comments from Senior Management Team	Approval of policy by the Audit Committee 7.4 amended to no sponsorship of meetings or educational events 7.10 Conflicts of interest amended Appendix 6 Meeting request form shortened 3.1 & 5.2 Added medical goods & services
15 Oct 2014	0.3	Comments from Quality Committee	4.1 Amended to This Policy must be adhered to by all staff (whole or part time) and by Governing Body and Committee Members **in their role as representatives of the CCG.** 7.10 A fee can be accepted for work carried out in the staff member's own time – added '**and must be declared in the CCG register of interests'**.

Contents

1. Introduction

1.1 This document sets out Haringey Clinical Commissioning Group's (CCG) policy 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. This is consistent with Department of Health Best practice guidance for joint working between the NHS and pharmaceutical industry and other relevant organisations[1].

2. Policies statement

2.1 The aim of this policy is to assist Haringey CCG to achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry and to inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical industry.

2.2 It specifically aims to assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business and to highlight that NHS staff are accountable for achieving the best possible health care within the resources available.

2.3 The main objectives are to:

- provide all CCG employees a policy framework and guidance for independent contractors for communication with members of the pharmaceutical industry in an appropriate manner.
- make all employees and contractors aware of the limitations of the sponsorship they are at liberty to accept from the pharmaceutical industry.
- introduce mechanisms to recognise potential conflicts of interest
- ensure that all employees and independent contractors approached by the pharmaceutical industry respond in a consistent manner
- ensure the interests of patients, the public and the CCG are maintained
- ensure that any sponsorship accepted from the industry is declared publicly to ensure transparency
- ensure that clinical and financial decisions taken by NHS employees and independent contractors do not rely solely on the advice and interventions of the industry representatives

2.4 Staff are reminded that at all times they have a responsibility to comply with their own professional codes of conduct and the CCG gifts, hospitality and declarations of interest policy and that representatives of the pharmaceutical industry must comply with the ABPI Code of Practice for the Pharmaceutical Industry.

3. Scope of this policy

3.1 This document is intended as policy for NHS Haringey Clinical Commissioning Group and its staff who are involved in working with the pharmaceutical industry.

[1] Department of Health, 2008. Best practice guidance for joint working between the NHS and pharmaceutical industry and other relevant organisations.

This will include joint working with the pharmaceutical industry, sponsorship (including meeting) received from the pharmaceutical industry, medical education, goods & services and primary care rebate schemes.

4. Who this policy applies to

4.1 This Policy must be adhered to by all staff (whole or part time) and by Governing Body and Committee Members in their role as representatives of the CCG.

4.2 The term Staff includes individuals who are

- Employed under a contract of employment with the CCG;
- unpaid volunteers of the CCG;
- not employed by the CCG but who exercise functions on behalf of e.g. non-NHS contract staff.

4.3 This policy is recommended as a guide to good practice for independent contractors, their staff and locum practitioners.

5. Definitions used in this policy

5.1 Joint working is defined 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.

5.2 Sponsorship is defined as situations where pharmaceutical companies simply provide funds for a specific event or work programme. This could also include the provision of medical education, goods and services on an arm's length bases e.g. a specialist nurse working with General Practices on a fixed term bases.

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

6. Roles and responsibilities

6.1 It is the responsibility of each individual employee to follow the policy framework when accepting any commercial support. They must also refer to their line-manager for approval.

6.2 It is the responsibility of line-managers to ensure that employees are fully aware of this policy. They are responsible for checking that requests from all employees to form collaborations with the pharmaceutical industry are thoroughly examined. They must ensure that the work is beneficial to the organisation, that there is no conflict of interest and the framework is adhered to.

6.3 The CCG should be accountable for any agreement and be in a position to evaluate and monitor these agreements. No organisation should be given preferential treatment and individuals must be accountable for their reason for forming relationships with industry members.

6.4 Final consideration and approval for any joint working arrangements will be sought from Haringey Clinical Commissioning Group Audit Committee.

7. Main Body of The Policy

7.1 Values of Joint Working and Sponsorship

The seven principles of public life set out by the Nolan Committee underpin the work of the NHS:

- Selflessness
- Integrity
- Objectivity
- Accountability
- Openness
- Honesty
- Leadership

Where staff enter into any joint working arrangement 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

7.2 Principles of Joint Working and Sponsorship

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:

- staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in existing NHS guidance
- contract negotiations will be negotiated in line with NHS values
- 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 corporate, rather than at an individual level
- clinical and financial outcomes will be assessed through a process of risk assessment

7.3 Sponsorship that is covered by this guidance

Sponsorship to the NHS in the form of cash, goods, services or other benefits include but are not restricted to the following:

- funding for all or part of the costs of a member of staff
- funding to support NHS research being carried out by NHS employees or independent contractors in Haringey
- sponsorship of any training event that is undertaken or organised by NHS staff or contractors
- equipment being donated by an independent organisation in order to support the NHS or independent contractors

7.4 Sponsorship of Education and Training Events

There will be no sponsorship for meetings (including collaboratives), education and training events.

7.5 Consideration and Approval of Joint Working Arrangements

Potential joint working arrangements with the Pharmaceutical Industry will be considered through a process for consideration, approval, recording, monitoring and evaluation.

For a proposed initiative, the project lead should complete the Proposal Form (Appendix 2) and Project Framework (Appendix 3) for Joint Working Between the CCG and Pharmaceutical Industry and submit to the Senior Management Team and then the Medicines Management Committee for consideration and will make recommendations for decision to the Audit Committee.

The joint working proposal should be considered using the Joint Working checklist/framework (Appendix 4). This checklist and joint working proposal should be submitted as an agenda item for consideration at the Audit Committee.

Proposals and the outcome of assessment will be recorded by the Audit Committee.

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. Any other risks or governance issues (clinical or business) need to be considered at the planning stage for any joint working to remove or minimise risk to the CCG or patients.

7.6 Principles of Primary Care Rebate Schemes

The London Primary Care Medicines Use and Procurement QIPP group has recommended that primary care rebate schemes may be implemented if they are not in breach of UK legislation and that they offered genuine benefits to the NHS and to patients. 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

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 the DH guidance on Strategies to Achieve Cost-Effective Prescribing (October 2010). This states that the following principles should underpin local strategies:

- 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
- 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
- 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
- Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money
- Schemes should be reviewed whenever relevant NICE or alternative guidance are updated
- Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the CCG's website.

7.7 Consideration and Approval of Primary Care Rebate Schemes

The London Primary Care Medicines Use and Procurement QIPP rebate group review schemes, identify any issues and provide advice to primary care organisations. Primary care rebate schemes that have been reviewed by this group will be screened by the Head of Medicines Management and if of potential value to the CCG they will be considered by the Medicines Management Committee using the checklist developed to access compliance with the agreed principles (Appendix 5). Schemes recommended for acceptance by the Medicines Management Committee and will be considered and approved by the Senior Management Team.

7.8 Visits to CCG Premises

Pharmaceutical Company medical representatives will only be seen by a senior member of the Medicines Management or CCG Senior Management Team by appointment only.

Medical Representatives will be required to complete the Pharmaceutical Industry Meeting Request Form (Appendix 6). Request forms will be reviewed before agreeing to meet.

Visits to the premises should be made only to keep an agreed appointment, or to make such an appointment. Representatives are not allowed to tour the premises looking for staff.

7.9 Confidentiality and Data Protection

Patient confidentiality must always be protected under the terms of the Data Protection Act. Any joint working or sponsorship must comply with Haringey CCG policies for

- Confidentiality & Disclosure of Information
- Information Governance
- Information Security
- Information Management .

7.10 Conflicts of interest

Staff should follow the Haringey CCG Gifts, Hospitality and Declarations of Interest Policy.

All CCG staff must declare and record in the CCG register of interests any potential conflict of interest they, or their immediate family, may have when involved in

- the development or consideration of any proposal
- decision-making for medicines or providing medicines advice

Examples include

- speaking at industry sponsored events
- consultancy work
- payment for participating in market research or an advisory board

Participation of CCG staff in advisory boards or surveys is at the discretion of the CCG and should be agreed with a senior manager. If any outside work for the pharmaceutical industry is carried out in NHS time i.e. during the normal working day, without the member of staff taking annual leave, any fee should either be refused, or if accepted, be paid to a budget agreed with the line manager in advance of undertaking the activity. Any outside work must be in a personal or professional capacity and not as a representative of the CCG.

A fee can be accepted for work carried out in the staff member's own time and must be declared in the CCG register of interests.

7.11 Bribery legislation

Bribery Act 2010 ("the Act") imposes extensive obligations on all commercial organisations, including those in the healthcare sector, to ensure that they have adequate procedures in place to prevent bribery from occurring within their organisation.

Please refer to the Haringey CCG Anti-fraud and Anti-bribery Policy

8. Training

8.1 This Policy will be drawn to the attention of newly appointed CCG employees in the staff induction programme.

8.2 Executive directors and managers and equivalent staff will have responsibility for implementation and for ensuring that all staff under their direction are made aware of this Policy directly. Those teams involved in joint working and organising training and education events will be asked to draw its content to the attention of medical representatives where practicable and appropriate.

8.3 If staff are in any doubt about matters concerning this Policy they should seek advice from their manager or director in the first instance. Any individual who provides advice to staff under this Policy should record the advice given in writing by either email or letter and keep a copy as this may be required for audit purpose.

9. Dissemination and implementation

This Policy and all associated forms will be made available on the CCG's Intranet or copies of the forms can be requested from the CCG administrator.

10. Monitoring

10.1 Forms for approval of Sponsorship of Educational Events will be held by the Head of Medicines Management.

10.2 The Audit Committee will hold a register of all Proposal Forms and Project Frameworks for Joint Working Between the CCG and Pharmaceutical Industry.

10.3 The Medicines Management Committee will hold a register of Primary Care Rebate Schemes.

10.4 Summaries of the respective registers will be provided to the Director of Quality and Integrated Governance and will be subject to a corporate review. A report of the review will be made annually to the audit committee.

10.5 Internal audit will be invited to undertake a periodic review of compliance with this Policy.

10.6 The outcome of audit findings and monitoring will be incorporated into a 2 yearly review of the Policy.

11. Review

This policy will be reviewed every 2 years.

Appendix 1

Procedure and Framework for the Approval of Joint Working Projects between Haringey Clinical Commissioning Group and the Pharmaceutical Industry

1. Identify potential joint work
   Any joint work with the pharmaceutical industry must be transparent and defensible with agreed aims and objectives

2. Complete joint working proposal (appendix 2, available on CCG internet or from medicines management team).
   It is the responsibility of each individual employee to follow the policy framework when accepting any commercial support. CCG staff must gain permission from their line manager and the Head of Medicines Management before undertaking any joint projects with the pharmaceutical industry.

3. Line manager and the Head of Medicines Management assess appropriateness of joint working proposal
   The line manager must be satisfied that approval of the joint working proposal will not compromise the CCG by using the checklist in appendix 2. They must ensure that the work is beneficial to patients and the organisation, that there are no conflict of interests and that the framework is adhered to. In order to ensure alignment with the aims of the CCG's Medicines Optimisation agenda, each project will require approval by the Head of Medicines Management. It is their responsibility to resolve any contentious issues and have the final say in determining the appropriateness of any collaboration with the industry.

4. Submission of full business case
   If the joint working proposal is approved then the applicant must submit a business case to the Finance & Performance Committee for approval. The decision should be recorded by the Head of Medicines Management and forwarded to the Chief Officer on an annual basis.
   Each proposal will require relevant documentation in place which includes a:
   - Business case
   - Framework for joint working & working agreements (appendix 3)
   - Joint Working Agreement (appendix 4)

   Of particular concern is the impact of commercial sponsorship on prescribing. This will need to be assessed against certain criteria e.g.

   - **Affordability**: an increase in prescribing in one area may deprive funding and resources for other areas of healthcare.
   - **Current evidence-based guidelines**: e.g. NICE, North Central London Joint Formulary Committee decisions, local guidelines, recommendations and pathways.
   - **Healthcare priorities**: does this fit with locally agreed healthcare priorities.

Appendix 2

Joint Working with the Pharmaceutical Industry Proposal Form

Name of applicant…….

Position/ directorate…….

Name of sponsoring organisation……..

Sponsor contact name…… Date…….

Please summarise the joint work proposal

What is the proposed contribution by the sponsoring organisation?

Please answer the following questions:

1. Is the joint working proposal consistent with the guidance given in the Haringey Clinical Commissioning Group policy for joint working with the pharmaceutical industry? **Y / N***

2. Is the proposed involvement of the sponsoring organisation of an appropriate level for the purpose? **Y / N***

3. Is the CCG satisfied with its knowledge of the sponsoring organisation, e.g. is it known to the CCG? Is there evidence of audited accounts? Is it capable of being independently audited? **Y / N***

4. Is the CCG satisfied that the offer is independent of purchasing or prescribing decisions? **Y / N***

5. Can it be confirmed that there is no current conflict of interest for any parties in relation to the service offered? **Y / N***

6. Are you satisfied that all materials and information supplies are valid, evidence-based, balanced and non-promotional? **Y / N***

7. Have you reached an agreement with all members of your team involved that the service is appropriate? **Y / N***

8. If patients are involved have arrangements been made to ensure the patients are aware of the service where appropriate? **Y / N / Not applicable***

N.B. If the answer is no to any of the above questions the proposed sponsorship is likely to be unsuitable and should be reviewed before submission.

Once complete please pass this to your line manager and the Head of Medicines Management for approval.

Signature of approval…… Date…….

Name and position……

Signature of Head of Medicines

Management…… Date…….

Name of Head of Medicines

Management……..

Appendix 3

PROJECT FRAMEWORK FOR JOINT WORKING BETWEEN THE CCG AND PHARMACEUTICAL INDUSTRY

I. JOINT WORKING PROJECT SUMMARY	
1. TITLE OF PROJECT	
2. SUMMARY OF INTENDED AIMS & OBJECTIVES	
3. SUMMARY OF EXPECTED OUTCOMES	
4. NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT	
5. NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION	
6. EXACT NATURE OF THE JOINT WORKING PROPOSAL	
7. START DATE	
8. FINISH DATE	
9. EXIT STRATEGY	
II. RESOURCES AND COSTS	
1. OVERALL COST OF THE JOINT WORKING PROJECT	
2. DIRECT AND INDIRECT RESOURCES / COST COMMITMENTS BY EACH PARTNER	
3. METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS	

4. INFORMATION ON COST EFFECTIVENESS (Has value for money been shown?)	
5. ARRANGEMENTS FOR LONGER TERM FUNDING IMPLICATIONS OF PROJECT (To be clear and unambiguous)	

III.	GOVERNANCE ARRANGEMENTS	
1.	PARTIES CONSULTED PRIOR TO INITIATING JOINT WORKING PROJECT AND HOW CONSULTATION WAS CONDUCTED	
2.	METHOD FOR INFORMING PATIENTS OF THE JOINT WORKING PROJECT	
3.	DECISION MAKING PROCESSES WITHIN THE JOINT WORKING PROJECT (To be open and transparent)	
4.	OPERATIONAL AND MANAGEMENT ACCOUNTABILITIES (Include identified conflicts of interest)	
5.	PILOTING ARRANGEMENTS (State if this project is a pilot)	
6.	RELATIONSHIP TO EXISTING SYSTEMS OF CARE IN PRIMARY AND SECONDARY CARE SECTORS	
7.	FOR CLINICAL SERVICES, PROFESSIONAL INDEMNITY AND LIABILITY ARRANGEMENTS	
8.	WRITTEN AGREEMENT STATING OBLIGATIONS OF CONFIDENTIALITY, SECURITY STANDARDS AND LIMITS OF USE OF INFORMATION TO THE	

	PURPOSES SPECIFIED	
IV.	**MONITORING AND EVALUATION**	
1.	MANAGEMENT ARRANGEMENTS	
2.	LIST DESIGNATED RESPONSIBILITY AT EACH STAGE OF THE PROPOSAL	
3.	METHOD OF EVALUATING PATIENT BENEFITS ON COMPLETION	
4.	LEARNING OPPORTUNITIES FROM THIS PROJECT	
5.	AUDIT ARRANGEMENTS	
6.	METHOD FOR HIGHLIGHTING SIGNIFICANT PROBLEMS	
V.	**DATA AND PATIENT PROTECTION**	
1.	LIST INTERESTS OF PARTNERS IN RELATION TO THE JOINT WORKING PROPOSAL, AND WHERE THESE COINCIDE	
2.	LIST POTENTIAL CONFLICTS OF INTEREST	
3.	IDENTIFY "OWNERSHIP" OF THE DATA GENERATED BY THE PROJECT	
4.	DESCRIBE ACCESS ARRANGEMENTS FOR THE DATA, AND FORMAT (Bearing in mind the requirements of the Data Protection Act and patient confidentiality of healthcare records)	
5.	USE DATA WILL BE PUT TO	

VI. DECLARATION OF INTERESTS YES ☐ NO ☐

If Yes, qualify by inserting a tick in one box in column A and one in column B

A		**B**	
Personal	☐	Specific	☐
Non-Personal	☐	Non Specific	☐

Signature _____ Date _____

Personal implies that you (or your spouse / partner) receive direct payment for services or hold shares in the relevant company concerned or a competitor.

Non-Personal implies that your unit benefits by receiving funding from the company.

Specific implies that you have undertaken work or given advice on other products made by the relevant manufacturer.

This system is based on that used by the Commission on Human Medicines and other national drug regulatory bodies.

Appendix 4

JOINT WORKING AGREEMENT FORM

AN AGREEMENT FOR JOINT WORKING BETWEEN

Haringey Clinical Commissioning Group

AND

Insert second party (and any others as necessary)

FOR

Insert title of joint working initiative

1. Principles governing this Joint Working agreement

The following principles and those defined in the framework for joint working will apply:

- All joint working must be for the benefit of patients;
- Joint working will be conducted in an open and transparent manner;
- Arrangements will be of mutual benefit, the principal beneficiary being the patient;
- Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project;
- The CCG retains overall control of the project outlined above
- All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act; Patient confidentiality will be maintained at all times.
- Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
- No data will be disclosed to any third party except on the explicit agreement of all parties;
- Joint working must not be used or seen as endorsement or promotion of any specific medicine or product;
- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;

2. Declaration of Interests

All declarations of interest must be declared. Declarations of interest will be recorded and maintained by the Medicines Management team and forwarded to the Chief Officer for Haringey CCG.

I have read and commit to the terms of the Joint Working Agreement and the framework for Joint Working.

Signed: _____ on behalf of: .....

Print Name: ..... Date: _____

Signed: _____ on behalf of: .....

Print Name: ..... Date: _____

Appendix 5
Checklist for Assessment of Primary Care Rebate Schemes (PCRS) (Adapted from LPP / NHS London Principles Document)

Agent: **Indication:** **Company:**
Contract: **Review Date:**
Financial Implication of Pricing Agreement
For example, per 100 patients treated for one year:
Total potential savings Haringey CCG for one year =

Issue	Principles	Scheme compliance and notes
1. Product related	• Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by established local decision-making processes. The clinical decision should inform the financial/procurement decision and not vice versa. • Health professionals should always base their prescribing decisions primarily on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration. • 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. • Rebate schemes promoting unlicensed or off label uses must not be entered into. All recommendations for use of a medicine within a PCRS must be consistent with the Marketing Authorisation of the medicine in question i.e. the PCRS should only advocate the use of the drug in line with the data sheet for the drug in question. • Medicines not recommended by NICE might still be the subject of a PCRS, but specific and documented consideration must be given to how such a product can properly be recommended to prescribers notwithstanding NICE's position. CCGs will need to explain how the scheme helps it meet its duty to use its resources effectively, efficiently and economically.	
2. Rebate Scheme related	• Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate. • Rebate schemes should be approved through robust local governance	

	processes that include Medicines Management Committee/Area Prescribing Committee (or equivalent) approval, involving both primary and secondary care and Director level approval. • The administrative burden to the NHS of setting up and running the scheme must be factored into 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. • Primary care rebate schemes should be agreed at a statutory organisational level, they should not be agreed at GP practice level. • Schemes encouraging exclusive use of a particular drug should be avoided. • Rebate schemes for medicines in Category M and some medicines in Category C of the Drug Tariff, should be especially carefully considered because of the potential wider impact on community pharmacy reimbursement. Short term local savings are likely to be offset by increased costs to the wider NHS in the longer term. Schemes which promote prescribing of branded generics or original brands in preference to generics pose the added risk that they undermine the concept of generic prescribing. • Ideally the PCRS should not be directly linked to requirements to increase market share or volume of prescribing. • Schemes which link a rebate directly to increase in volume of prescribing above a defined threshold could be judged to be an attempt to influence prescribing inappropriately and should generally be avoided. The administrative burden of monitoring such schemes should be carefully considered. • Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure (i) that the terms of the scheme are clear and (ii) to maximise the legal protection. 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 (i.e., without having to have any reason for doing so) with a sensible notice period e.g. three or six 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. • Is the value of the offer quantifiable and proportionate to the administrative burden? Is there an appropriate return on investment? • Schemes which link a rebate to prescribing of more than one drug should be especially carefully considered to avoid the risk that savings made on one are indirectly offset by costs incurred on another.	
3. Information and Transparency	• Primary Care Organisations should make public (for example on their website) the existence of any PCRS they have agreed to. • Primary care organisations should not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These PCRS should all be considered using the same criteria. • There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data. • PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised. • Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share. • Freedom of Information – As a general principle information relating to rebate schemes is likely to be releasable, these issues should be discussed with the manufacturer before a commissioner enters into any agreement with them. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract. As a general principle, information about rebate schemes may be released under FOI requests, but commercially sensitive information is usually withheld. See legal advice for more details. • Discounts and details of any PCRS offered should be allowed to be shared within the NHS. This should be agreed as part of the PCRS contract. • Is the invoicing process transparent as per NHS financial requirements?	

Appendix 6

Pharmaceutical Industry Meeting Request Form

- Meeting requests will be priorities based on CCG priorities
- Only one area will be discussed per meeting. For any other information, a further meeting will be considered within this process
- Completing this pro-forma does not guarantee a meeting.

Conduct of Meetings

Each meeting will last for 20 minutes. It is expected that that the last 10 minutes will be for discussion.

Your Name:	
Company Name:	
Contact Telephone No. & email	
Have you seen a Member of the CCG before?	
Have you met or visited any of the local GP's regarding this issue?	
If yes, when did you last see them & which product was it regarding?	
What is the nature of your meeting? i.e. content of meeting	
Is your visit regarding a new product or service?	
If yes, what is the service offer, or products name?	
Does your product or service have a budget /cost implication on NHS Haringey? And if so how much?	
How can your product benefit the patients of NHS Haringey clinically ?	
Any Additional Comments? (Maximum of 50 Words) or feel free to add additional evidence to your email	
Will you be bringing a colleague with you? If yes Who?	

Office Use Only	
Need to Meet in Person	
Need teleconference/call	
Written communication required	
No further action	
Other	