NHS
Merton
Clinical Commissioning Group

REPORT TO MERTON CLINICAL COMMISSIONING GROUP GOVERNING BODY

Date of Meeting: 29TH January 2015

Agenda No: 6.7 **Attachment:** 16

Title of Document: Merton CCG – Working with the Pharmaceutical Industry policy	**Purpose of Report:** For approval
Report Author: Ben Vinters & Louise Morgan, South East CSU Sedina Agama, Chief Pharmacist & Assistant Director Medicines Optimisation	**Lead Director:** Adam Doyle- Director for Commissioning and Planning
Contact details: sedina.agama@mertonccg.nhs.uk	

Executive Summary:

This policy sets out how NHS Merton Clinical Commissioning Group (Merton CCG) will work with the pharmaceutical industry and is in line with the NHS Merton CCG Constitution and local and national guidance.

The aim of this policy (in conjunction with the Merton CCG Hospitality and Gifts Policy) is to:

- Set out a framework for Merton CCG to build effective and appropriate working relationships with the pharmaceutical industry 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 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

Although not mandatory for GP practices, it will be promoted as best practice to GP practices in Merton.

Key sections for particular note (paragraph/page), areas of concern etc:
The whole document

Recommendation(s):
The Governing Body is asked to approve and adopt the policy as a way of assurance of appropriate working relationships with the pharmaceutical industry and best practice in Merton CCG .

Committees which have previously discussed/agreed the report:
This policy is substantially based on a policy developed by Croydon and reviewed by the Sutton CCG and Merton CCG Medicines Management Committee. Croydon CCG gratefully acknowledged. Approved at Executive Management Team meeting in December 2014.

Financial Implications: Joint working with the pharmaceutical industry agreed under this policy may have financial implication which will be identified as part of the governance process. Approval of funding for such initiatives will be as per the Merton CCG financial policies.

Implications for CCG Governing Body:
This policy has been developed in line with Merton CCG Policy on Managing Conflicts of Interest and Hospitality and Gifts policy and will form part of the organisational policies of Merton CCG. It forms part of the CCG governance and assurance processes. Any changes to policies mentioned would be taken account of in a refresh of this policy.

How has the Patient voice been considered in development of this paper:
Patient representative on the Sutton and Merton Medicines Management Committee had an opportunity to comment in the development.

Other Implications: (including patient and public involvement/Legal/Governance/Risk/Diversity/ Staffing)

Equality Assessment: This document has been assessed for equality impact on the protected groups, as set out in the Equality Act 2010. This document demonstrates Merton CCG's commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners**.** The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief**,** and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities.

Information Privacy Issues:
This policy and the hospitality and gifts register is subject to FOI requests.

Communication Plan: (including any implications under the Freedom of Information Act or NHS Constitution) This policy will be available to Merton CCG employed staff and all staff working on behalf of Merton CCG via the Merton CCG intranet and available to the public including the pharmaceutical industry representatives on request.

NHS
Merton
Clinical Commissioning Group

WORKING WITH THE PHARMACEUTICAL INDUSTRY

WORKING WITH THE PHARMACEUTICAL INDUSTRY

MCCG Policy Reference:

THIS POLICY WILL BE APPROVED BY THE CLINICAL COMMISSIONING GROUP (CCG) GOVERNING BODY, AND WILL HAVE EFFECT AS IF INCORPORATED INTO THE CONSTITUTION AS PART OF THE SCHEME OF DELEGATION.

Target Audience	Governing Body members, sub-committee members, Clinical Directors and all staff working for, or on behalf of, the CCG.
Brief Description (max 50 words)	This policy sets out how NHS Merton Clinical Commissioning Group (Merton CCG) will work with the pharmaceutical industry and is in line with the NHS Merton CCG Constitution and local and national guidance.
Action Required **STANDARD**	Following approval at the CCG Governing Body, the CCG Staff will ensure that the requirements of this policy are discussed at CCG team meetings, and the requirements raised with the chairs of each Committee, CCG Directors and with CCG executives. Chairs of Committees will identify the programme of review with the Lead Director for each policy within their committee remit. Lead Directors will identify policy owners for each policy within their remit. The South East Commissioning Support Unit Senior Associate for Corporate Affairs will establish and maintain a corporate register of all policies and their status. The CCG will ensure all policies are appropriately reflected on the CCG website.

Approved: [to be completed following governing body]

Review date: December 2016 unless otherwise indicated

Document Control	
Title:	Working with the Pharmaceutical Industry
Original Author(s):	Merton CCG
Owner:	Sedina Agama, Chief Pharmacist & Assistant Director – Medicines Optimisation
Reviewed by:	Adam Doyle, Director of Commissioning and Planning
Quality Assured by:	XXX Merton CCG Director of Quality
File Location:	[to be completed following approval]
Approval Body:	Merton CCG Governing Body
Approval Date:	[to be completed following approval]

Amendment History

This Policy is substantially based on a Policy developed by Croydon Clinical Commissioning Group and this is gratefully acknowledged.

Version	Date	Reviewer Name(s)	Comments

Document Information

Title /Version Number/(Date)	Working with the Pharmaceutical Industry
Document Status (for information/ action etc)and timescale	For implementation (0//201*) [to be completed following approval]
Accountable Executive	Director of Commissioning
Responsible Post Holder/Policy Owner	Sedina Agama, Chief Pharmacist & Assistant Director –Medicines Optimisation
Date Approved	[to be completed following approval]
Approved By	CCG Governing Body
Publication Date	(**/**/201*) [to be completed following approval]
Review Date	August 2016 unless otherwise indicated
Authors	Ben Vinters/ Louise Morgan/Sedina Agama
Stakeholders engaged in development or review	Merton CCG Medicines Management Committee
Equality Analysis	**Equality Analysis** This Policy is applicable to the Governing Body, every member of staff within the CCG and those who work on behalf of the CCG. This document has been assessed for equality impact on the protected groups, as set out in the Equality Act 2010. This document demonstrates Merton CCG's commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners**.** The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief**,** and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 and to promote positive practice and value the diversity of all individuals and communities.
Contact details for further information	Merton Clinical Commissioning Group Sedina.agama@mertonccg.nhs.uk

This policy progresses the following Authorisation Domains and Equality Delivery System (tick all relevant boxes).

Clear and Credible Plan		Commissioning processes	
Collaborative Arrangements	x	Leadership Capacity and Capability	x
Clinical Focus and Added Value		Equality Delivery System	
Engagement with Patients/Communities		NHS Constitution Ref: Section 8 p25	

Associated Policy Documents

Title
Conflicts of Interest Policy
Hospitality and Gifts Policy

Glossary

Term	**Definition**
Accountable Executive	CCG Executive accountable for development, implementation and review of the policy
Policy Owner	Post holder responsible for the development, implementation and review of the policy
Document definitions	These are provided in Section 1

Contents:

1. Scope

1.1 This document is intended for staff who are involved in joint working with the pharmaceutical industry and sponsorship by the pharmaceutical industry. This policy is linked to Merton CCG's Hospitality and Gifts policy.

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

1.3 Department of Health (DH) Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry defined **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.

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

2. Introduction

2.1 DH Guidance[i] 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

3.1 The aim of this policy is to:

3.1.1 Assist Merton CCG achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry.

3.1.2 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 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.

3.2 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[ii] must comply with the *ABPI Code of Practice for the Pharmaceutical Industry* and ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients[iii].

4. Values

4.1 In line with the NHS Code of Conduct[iv] three public service values underpin the work of the NHS:

- Accountability
- Probity
- Openness

4.2 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 when third parties access GP notes to perform audits and case note reviews.

5. Principles of Joint Working

5.1 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.

5.2 The following principles will also apply to joint working:

5.2.1 Professional codes of conduct as described in extant NHS guidance.

5.2.2 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.

5.2.3 Clinical aspects of care, including the development of guidelines or protocols should be under local control via the Medicines Management Committee (MMC) and Clinical Reference Group (CRG) where deemed appropriate.

5.2.4 Clinical responsibility for prescribing remains with the prescriber and no agreement can be made to prescribe specific company products without the MMC approval.

5.2.5 Recommendations made to prescribers to support prescribing of particular products will have been approved by MMC and not the basis of the arrangement.

5.2.6 Contract negotiations will be negotiated in line with the NHS values and in line with MCCG standing financial instructions.

5.2.7 Confidentiality of information received in the course of duty must be respected and never used outside the scope of the specific project.

5.2.8 Joint working arrangements should take place at a corporate, rather than an individual level.

5.2.9 Clinical and financial outcomes will be assessed through the process of risk assessment.

5.2.10 All joint working schemes will require approval by the Executive Management Team (EMT).

5.2.11 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.

5.2.12 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, where the size and position of the logo is agreed by the CCG.*
- *Information technology and other data collection tools.*
- *Funding of all or part of the costs of a member of staff.*

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

5.3.1 *The provision of free pharmaceutical starter packs. This promotes prescribing of a particular product and compromises purchasing decisions.*

5.3.2 *The NHS organisation should be seen to be impartial and independent of commercial organisation.*

5.3.3 *Equipment –Large equipment for use in the NHS should be procured by the NHS. Small items of equipment with low intrinsic value may be acceptable e.g. pulse oximeters, spirometers, peak flow meters, nebulisers.*

6. Confidentiality and Data Protection

6.1 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 Merton CCG Information Governance Policy.

6.2 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 Arrangments

7.1 Merton CCG has a mechanism in place for approval of any joint working arrangements see **Appendix A1**.

7.2 The CCG Clinical Director & Commissioning Manager should initially fill out ***Appendix A2 Joint working with the Pharmaceutical Industry Checklist*** and discuss with the Chief Pharmacist & Assistant Director - Medicines Optimisation. If it is then agreed that the project has potential, ***Appendix A3 Merton CCG Joint Working Framework*** should be completed and submitted to the CCG Clinical Reference Group (CRG). If approved by the CRG as being a clinically appropriate scheme that fits with the Merton CCG Operating Plan and key clinical and commissioning priorities, the final document should be sent to the Chief Pharmacist & Assistant Director –Medicines Optimisation Merton CCG for consideration by the Medicines Management Committee (MMC).

7.3 The MMC will review taking into consideration impact on medicines optimisation priorities both in Merton and local NHS landscape as well as local formulary decisions. A recommendation will be made to the Executive Management Team for the final decision.

7.4 For more complex projects MCCG will 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 NHS and the pharmaceutical industry August 2010**[v].

7.5 Proposals and the outcomes of assessment by the EMT will be entered on Merton CCG register of submitted proposals. 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 to agreed outcome measures. Either side can terminate if these outcome measures are not achieved.

8. Sponsorship: Hospitality and meetings

8.1 NHS staff should follow the principles outlined in the Standards of Business Conduct for NHS Staff: HSG(93)5[vi] and ABPI Code of Professional Conduct relating to meetings and hospitality from the pharmaceutical/external industry 2008[III].

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

8.3 Industry representatives may sponsor the venue, refreshments, expenses of practitioners attending the event etc. for local educational meetings. Authorisation to do so must be sought by completion of **Appendix A4 Sponsorships Form : Hospitality and 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 and 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.

8.4 Summary reports will be presented to the MMC & EMT every 6 months, and to the Governing Body as per the Hospitality and Gifts policy.

8.5 Sponsorship for training is accepted on the understanding that:

8.5.1 The CCG course organiser retains overall control of the event.

8.5.2 The sponsor does not have the right to present any material.

8.5.3 Where the organiser considers additional value may be gained from a presentation by the sponsor, the presentation is agreed by the Chief Pharmacist and CCG Clinical Director in advance of the meeting.

8.5.4 Course material provided by the pharmaceutical company has no promotion of specific products (the name of the company supporting the training event is acceptable) and to be approved by Chief Pharmacist and CCG Clinical Director/Education Lead.

8.5.5 The sponsor does not use Merton CCG contact to promote products outside the meeting.

8.5.6 Any stand the sponsor used to promote products is to be outside the main meeting room where practicable.

8.5.7 Attendance of the meeting by the sponsor is at the discretion of the CCG course organiser and must be agreed before the meeting and disclosed.

8.5.8 Advert for the education event excludes product advertisement and must be agreed by the CCG Education Lead and Chief Pharmacist prior to circulation.

8.5.9 Honorarium received by any speakers or chair are declared.

9. Primary Care Rebate Schemes

9.1 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).

9.2 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.[vii][viii]

9.2.1 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.

9.2.2 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 the MMC prior to rebate agreement.

9.2.3 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.

9.2.4 All rebate schemes must be reviewed by MMC and approved by EMT.

9.3 In addition pharmaceutical companies should not use Primary Care Rebate schemes as a reason for contacting Merton CCG staff.

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

9.4.1 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;

9.4.2 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;

9.4.3 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;

9.4.4 Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;

9.4.5 Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.

10. Merton CCG staff relationship with Pharmaceutical Industry - Hospitality/Gifts, Conflicts of Interest and Payments

10.1 NHS staff should follow the principles outlined in the Standards of Business Conduct for NHS Staff: HSG (93)5[VI], Merton CCG Hospitality and Gift Policy[ix], Merton CCG Anit-Bribery Policy[x] and ABPI Code of Professional Conduct relating the pharmaceutical/external industry 2008.[2]

10.2 **Hospitality/Gifts**

In line with the Merton CCG Hospitality and Gifts policy, all staff are expected to record all gifts, hospitality or material benefits received by themselves or the practice they work for which in any way relates to their appointment or position on the Hospitality & Gift Register. Gifts of small or inexpensive nature such as calendars or diaries or other inexpensive items such as flowers or chocolates may be accepted. This type of gift can easily be distinguished from more expensive, substantial items which cannot on any account be accepted. If there is any doubt as to whether the acceptance of such an item is appropriate, or there is a regular giving of such gifts then the matter should be referred to the lead director, or Chief Finance Officer.

10.3 Staff must seek permission in advance, from their line manger, to receive commercial sponsorship for attendance at relevant conference and courses. The manager must be satisfied that acceptance will not compromise purchasing decisions.

10.4 **Anti-Bribery**

Merton CCG wishes to encourage anyone having reasonable suspicions of bribery to report them. Merton CCG policy, which will be rigorously enforced, is that no individual will suffer any detrimental treatment as a result of reporting reasonably held suspicions. The Public Interest Disclosure Act 1998 came into force in July 1999 and gives statutory protection, within defined parameters, to staff who make disclosures about a range of subjects, including bribery and corruption; which they believe to be happening within the Group employing them. Within this context. "reasonably held suspicion" means any suspicions, other than those which are raised maliciously and are subsequently found to be groundless.

10.5 **Conflicts of interest**

All staff of Merton CCG must declare links with the pharmaceutical industry (see Merton CCG Declaration of Interest policy); Staff involved in decisions involving medicines must do so by completing ***Appendix B : Annual declaration of interests*** and submitting to the Governing Body Secretary. The information should be made widely available so that any conflicts of interest can be avoided.

10.6 **Payments for Outside Work**

NHS employees are advised not to engage in outside employment which may conflict with their NHS work, or be detrimental to it. They are advised to tell their NHS employing authority if they think they may be risking a conflict of interest in this area: the NHS employer will be responsible for judging whether the interests of patients could be harmed, in line with the principles in 4.

10.6.1 Prior approval must be obtained by Merton CCG staff from the CCG Governing Body, before taking on any outside work for the pharmaceutical industry e.g. chairing meetings, speaking at meetings, industry guideline developments.

10.6.2 If the work is carried out in the NHS time, i.e. during the normal working day, without the member of staff taking annual leave, the fee should either be refused, or if accepted, be paid to a budget agreed with the line manager in advance of undertaking the activity.

10.6.3 A fee can be accepted for work carried out in the staff member's own time, but this should be approved by their line manager in advance of undertaking the activity.

10.6.4 It must be made clear to the audience the capacity in which the member of staff is engaging, i.e. unless officially representing the CCG, their role at the CCG must not be used on the materials.

10.6.5 If working in an approved CCG capacity, the views of the CCG need to be reflected. If it involves Medicines related issues, speak to the Chief Pharmacist before the event.

10.6.6 Contact details e.g. CCG e-mail groups available to staff in their CCG capacity should not be used to disseminate meeting information or shared with the pharmaceutical industry.

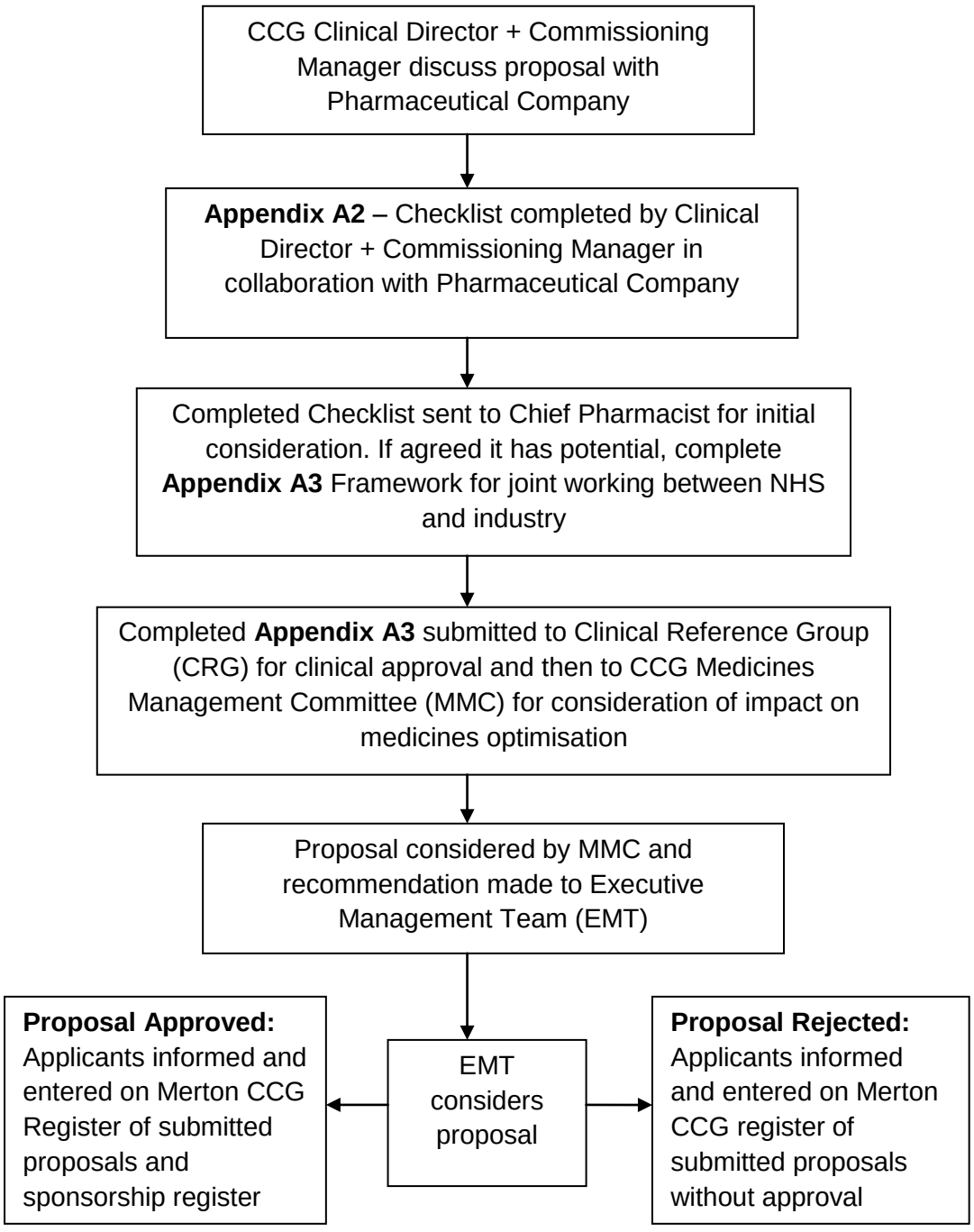
10.6.7 Information gathered in the capacity of a CCG role must not be disclosed to the members of the pharmaceutical industry without explicit approval from the relevant CCG.

11. References

[ii] Department of Health, 2008. Best practice guidance for joint working between the NHS and the Pharmaceutical industry.
[ii] ABPI, 2008. Code of Practice for the Pharmaceutical Industry.
[iii] ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of
patients.
[iv] Department of Health, 2004. Code of Conduct: Code of Accountability in the NHS. 2nd Ed
[v] DH Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry August 2010.
[vi] Standards of Business Conduct for NHS Staff:HSG(93)5
[vii] LPP Principles and Legal Implications of Primary Care Rebate Schemes October 2012.
[viii] Legal advice from DAC Beechcroft from 20th September 2012
[ix] Merton CCG Hospitality and gifts policy.
[x] Merton CCG Anit-Bribery Policy

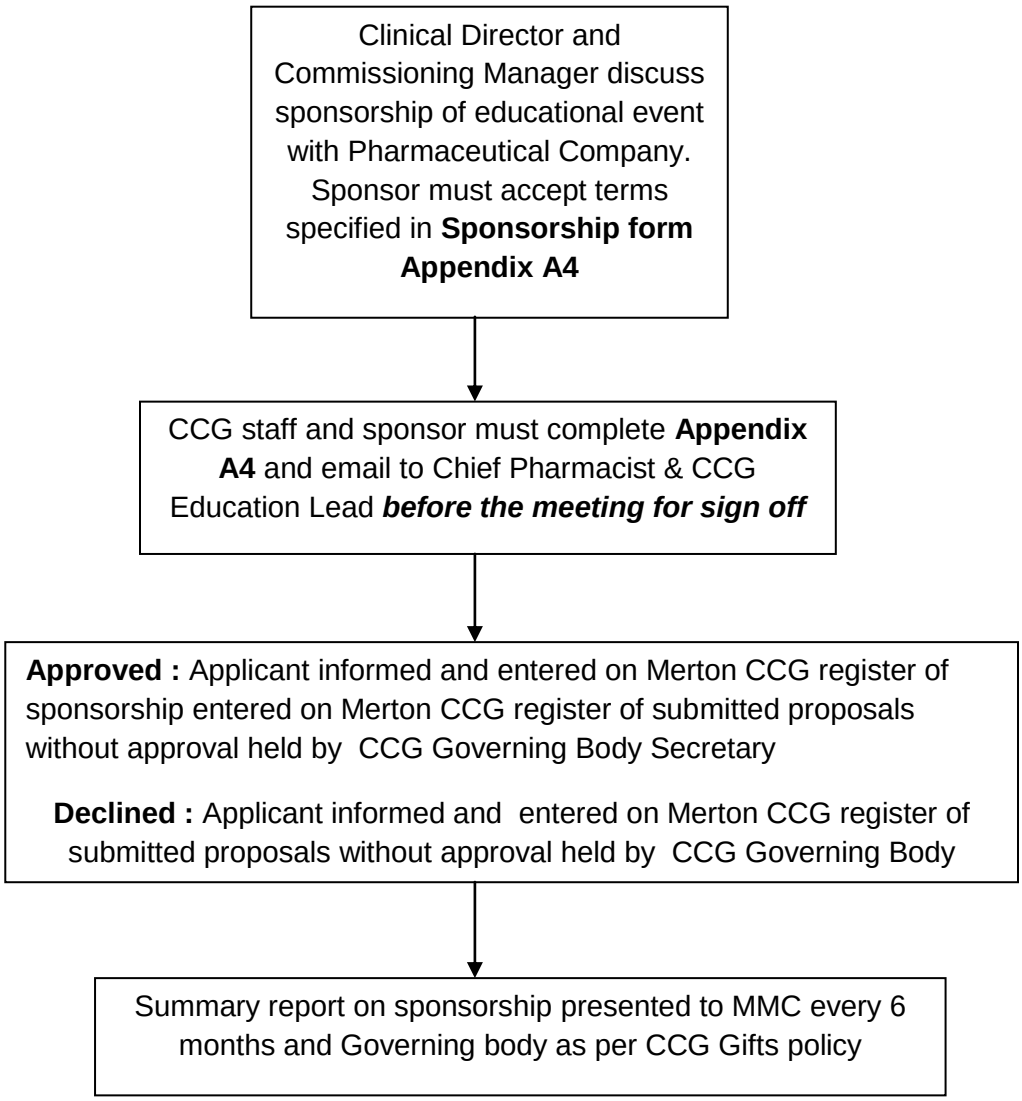
Policy for the Pharmaceutical Industry

Appendix A1: Joint Working – Process for Decision Making



Policy for Working with the Pharmaceutical Industry

Appendix A1 contd : Sponsorship: Hospitality and Educational Meetings - Process for approval



Appendix A2 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. How 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 A3: 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 equality and other impact assessments	
8.	Benefits for patients	
9.	Start date	
10.	Finish date	
11.	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	
9.	Risks identified, risk score (use CCG risk matrix) and mitigation	

IV. Monitoring and evaluation	
1. Project Management arrangements	
2. List designated responsibility at each stage of the proposal	
3. Method of evaluating outcomes including patient benefits/ outcomes	
4. Learning opportunities from this project	
5. Audit arrangements	
6. Method for highlighting significant problems /incidents	

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, information governance and patient confidentiality of healthcare records)	
5. How will data be used?	

VI. DECLARATION OF INTERESTS YES NO

If Yes, indicate below name of person and whether personal/non-personal/specific or nonspecific

Name	Personal/Non-personal	Specific/non-specific	Details

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.

Completed by:

Responsible CCG Clinical Director:	Name:	Signature	Date
Responsible Pharmaceutical Industry Manager:			

For CCG Use

Date considered by Medicines Management Committee		**Outcome : Approved/Declined/Deferred**
Date considered by Clinical Reference Group		**Outcome : Approved/Declined/Deferred**
Date considered by Executive Management Team		**Outcome : Approved/Declined/Deferred**
Final CCG Approval- Quality Committee Name:	**Signature**	**Designation**

Appendix 4 Sponsorship Form: Hospitality and Educational Meetings

To be completed by CCG Clinical Director or Manager. Please attach details of meeting.

To (Name of Company Lead) .....

of (Insert company name) .....

Thank you for agreeing to sponsor the meeting on (Date).....

Venue: .....

Entitled .....

I agree to sponsor on the understanding that: -

- The CCG course organiser retains overall control of the training event.
- The sponsor does not have a right to present material.
- Where the organiser considers additional value may be gained from a presentation by the sponsor, the presentation is agreed by the Chief Pharmacist and CCG Clinical Director in advance of the meeting.
- Course material provided by the pharmaceutical company had no promotion of specific products (the name of the company supporting the training event is acceptable) and to be approved by Chief Pharmacist with discussion with CCG Clinical Director/Education Lead
- The sponsor does not use Merton 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 CCG course organiser and must be agreed before the meeting and disclosed.

- Advert for the education event excludes product advertisement and must be agreed by the CCG Education Lead and Chief Pharmacist prior to circulation.

- Honorarium received by any speakers or chair are declared.

- Attendance of the meeting by the sponsor is at the discretion of the CCG course organiser and must be agreed before the meeting and disclosed.
  If a sponsor is attending, please indicate name below. If approved, this must be made clear to attendees and chair of meeting at the start of the meeting.

  Name : .....

  Designation:.....

- Where course material is provided by a pharmaceutical company, that there is no promotion of specific products (the name of the company supporting the training event is acceptable). These materials must be approved by the Chief Pharmacist in discussion with the CCG Clinical Director.

Please confirm that you accept the terms detailed above

Name of CCG Clinical Director	**Signature**	**Designation**	**Date**
Name of Pharmaceutical Industry Personnel	**Signature**	**Designation**	**Date**
Approved/declined Chief Pharmacist		**Signature:**	**Date**
CCG Education Lead		**Signature:**	**Date**

Appendix B: Annual Declaration of Interest Form

CONFIDENTIAL

Name	
Job Title	
Department / Division	
Organisation	

PART 1: Potential **personal** conflicts of interest which are current or applicable for the last 10 years

Conflict of Interest	**Y / N**	**Pharmaceutical company (list)**
I hold a direct holding of stock in a Pharmaceutical company (other than in a Trust or pooled investment over which one has no direct control of individual stocks)		
I have received teaching or training from the Pharmaceutical Industry		
I have provided a consultancy service for the Pharmaceutical Industry		
I have acted as a trainer / teacher for the Pharmaceutical Industry		
I have received hospitality from a Pharmaceutical Company (including gifts, meals, costs for hotels and transport to meetings / conferences etc) at local or regional international conferences.		
Other e.g. I have accepted invitations for regional or international meeting(s) from the Pharmaceutical Industry I have received or accepted fees for chairing educational event (s) from the Pharmaceutical Industry I have accepted a clinical leadership role directly or indirectly funded by the Pharmaceutical Industry		

Declaration of Interest from Members (Insert year) (continued)

Name

PART 2: Potential **non**- **personal** conflicts of interest which are current or applicable for the last 10 years

Conflict of Interest	**Y / N**	**Pharmaceutical company (list)**
Contractual arrangements with a pharmaceutical company or its agent of a pecuniary nature or non-pecuniary nature (e.g. supply of a specialist nurse, payment for nursing hours, support for research projects, audits or database development)		
Equipment purchased for the department / clinic/ practice		
Non-contractual arrangement for research, audit support or other activity		
Staff training		
Other Practice educational events- when sponsored by Pharmaceutical company, the topics and speakers are chosen by the sponsoring organisation.		

Appendix C: Equality Impact Assessment

This is a checklist to ensure relevant equality and equity aspects of Policies, protocols or guidance have been addressed either in the main body of the document or in a separate equality & equity impact assessment (EEIA)/ equality analysis. It is not a substitute for EEIA/ equality analysis which is normally required unless it can be shown that a proposal has no capacity to influence equality. The checklist is to enable the Policy lead and the relevant committee to see whether the EEIA has covered the ground and to give assurance that the proposals will not only be legal but also fair and equitable and lead to reduced health inequality.

	Challenge questions	**Yes/No DK/NA**	**Comments**
1	Does the document set out the health care needs of the groups intended to benefit from the proposal, including any differences in need in terms of the legally protected or other characteristics (such as socioeconomic position)	NA	
2	Does the document set out any known existing inequality in access, quality, experience and outcome of care for populations relevant to the proposal (i.e. as defined in 1. and in relation to the existing health or care service)?	NA	
3	Are there any particular public concerns about equality about the Policy area than need to be addressed?	NA	
4	Has the Policy described any gaps in knowledge about 1 -3, and any action taken to fill gaps (or recommendations for action)	NA	
5	Does the document set out risks to equity of access, quality, experience and outcomes including risk of direct or indirect discrimination, and risk to good relations between people of different protected characteristics*?	NA	
6	Does the document describe any specific opportunities to promote equality and human rights, good relations between people of different protected characteristics, to enhance participation, etc.?	NA	
7	Does the document describe how the proposal, Policy etc. will address the identified inequalities?	NA	
8	Does the document make recommendations to mitigate risks and enhance the opportunities to promote equality and equity?	NA	
9	Does the document describe how monitoring and reporting will take place to assure equality and equity in the future including to stakeholders?	NA	

* Race/ ethnicity, gender (including gender reassignment) age, religion or belief, disability, sexual orientation, marriage or civil partnership, pregnancy and maternity. This will include groups such as refugees and asylum seekers, new migrants, Gypsy and Traveller communities; and people with long term conditions, hearing or visual impairments, mental health problems or learning disability.