

Governing Body meeting (held in public)

DATE: 24 November 2016

Title	Working with pharmaceutical industry, commercial sponsorship Policy and associated framework
This paper is for Decision	
Recommended action for the Governing Body	<p>That the Governing Body:</p> <p>Approve</p> <ol style="list-style-type: none"> 1. Policy and guidance for joint working with the pharmaceutical industry. 2. Commercial sponsorship policy and code of conduct. 3. Framework for commercial sponsorship and joint working with the pharmaceutical industry.
Potential areas for Conflicts of interest	None.
Executive summary	<p>Following expiry of the old policy and to strengthen the governance around joint working and commercial sponsorship, two policies and a framework for using the 2 policies have been produced:</p> <p><u>1 Policy and guidance for joint working with the pharmaceutical industry</u> This is an update of the previous policy from 2012 to strengthen conflict of interests following the latest NHS England guidance for CCGs. The updated parts are highlighted in green.</p> <p><u>2 Commercial sponsorship policy and code of conduct</u> This is a new policy.</p> <p><u>3 Framework for commercial sponsorship and joint working with the pharmaceutical industry</u> This is an update of the previous framework from 2013 to include commercial sponsorship and strengthen conflict of interests following the latest NHS England guidance for CCGs.</p>

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	These 3 documents have been circulated for comments and comments and amendments included within the 3 documents.	
How does this paper support the CCGs objectives?	Patients:	
	People:	
	Pounds:	
	Process:	Ensure and enable effective joint working between NHS Bexley CCG and the pharmaceutical industry and any other commercial sponsorships.
What are the Organisational implications	Key risks	
	Equality	
	Financial	
	Data	
	Legal issues	
	NHS constitution	
Engagement		
Audit trail	Reviewed and approved by Quality and Safety Sub-Committee in November 2016	
Comms plan	Via bulletin once approved	
Author: Dibya Rai Governance Pharmacist	Clinical lead: Clare Fernee AD Medicines Management	Executive sponsor: Anne Douse Director of Quality, Performance and Business Services (Interim)
Date	14 November 2016	

**Policy and Guidance for Joint Working with the
Pharmaceutical Industry**

Author's name and title:	Dibya Rai, Governance Pharmacist
Sponsor's name and title:	
Review date:	
Supersedes:	V1.2
Description:	This document is intended to provide a policy to enable and ensure effective joint working between NHS Bexley Clinical Commissioning Group (CCG) and its staff who are involved, or are considering projects which involve, joint working with the pharmaceutical industry.
Audience:	Employees and contractors who are engaged to undertake duties on behalf of NHS Bexley CCG

Consultation:		
Date	Name	Title and/or organisation
22/7/2016	All Directors and Assistant Directors	NHS Bexley CCG

Approved by:		Date:	
Ratified by:		Date	

Version control

(First version should be labeled 'V0.1', once ratified, please label 'V1.0')

Name	Date	Version	Reason	Status
<i>Person making the entry</i>	<i>Date of entry</i>	<i>Version control</i>	<i>New / revision / consultation etc</i>	<i>Draft / for approval / approved</i>
Clare Fernee	30/10/2012	V1	New	Draft
Clare Fernee	19/11/2012	V1.1	Comments from LMC incorporated	Draft
Clare Fernee	20/12/2012	V1.2		Final
Dibya Rai	04/07/2016	V1.3	Comments from Clare Fernee	Draft
Clare Fernee	22/7/2016	V1.4	Comments from Anne Douse	Draft



Contents page

1. Scope.....	5
2. Introduction.....	5
3. Aims & Objectives	6
4. Core Values.....	6
5. Key Principles.....	7
6. Joint Working Agreement.....	8
7. Clinical Accountability	9
8. Audit	9
9. Review	10
10. Conflict of Interest, Payments and Hospitality	10
11. Breaches in Policy.....	10
12. Equality and Diversity Statement.....	10
13. References	11
14. Appendices	
Appendix A	13
Appendix B	18

1. Scope

This document is intended to provide a policy to enable and ensure effective joint working between NHS Bexley Clinical Commissioning Group (CCG) and its staff who are involved, or are considering projects which involve, joint working with the pharmaceutical industry.

For the purposes of this framework, the term 'staff' refers to all employees and contractors who are engaged to undertake duties on behalf of NHS Bexley CCG.

For the purposes of this framework, joint working is defined as:

“Situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery”¹

Joint working differs from sponsorship, where commercial companies simply provide funds for a specific event or work programme. Refer to the policy on Commercial Sponsorship and Code of Conduct for further guidance.

This policy should be read in conjunction with:

- NHS Bexley CCG Framework for Commercial Sponsorship and Joint Working with the Pharmaceutical Industry
- NHS Bexley CCG Policy on Conflict of Interest
- NHS Bexley CCG Privacy Impact Assessments Policy & Process
- NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCG's, June 2016
- Guidance from relevant professional organisations, such as the General Medical Council, the Nursing and Midwifery Council and the General Pharmaceutical Council about working in partnership with commercial (Pharmaceutical) companies

2. Introduction



*'The New NHS: Modern and Dependable places an obligation on NHS organisations to work together in partnership with other agencies to improve the health of the population and the quality of health services provided to that population'*⁷.

In 2008, the DoH published a document³ which states;

*"NHS organisations and staff are encouraged to consider the 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. A philosophy of developing appropriate partnerships to help achieve high quality patient care could further enhance the objectives of a patient-centred NHS. Such initiatives should be managed in an effective and efficient way. The development of effective and clinically appropriate joint working with external stakeholders can contribute to building an NHS that is truly a beacon to the world."*³

3. Aims and Objectives

The aims of this policy are to:

- assist NHS Bexley CCG to achieve its objectives and to help deliver national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry
- inform and advise staff of their main responsibilities when entering into joint working 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

Staff members 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*⁵.

4. Core Values

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

- *accountability* – everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements of propriety and professional codes of conduct;

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- *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 there is a NHS Bexley CCG decision for any joint working with the pharmaceutical industry, staff conduct should 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. Key Principles

The key principles are:

- Joint working must be for the benefit of patients or of the NHS and preserve patient care. 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.
- Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner.
- Staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant NHS guidance.
- Contract negotiations will be negotiated in line with NHS values.

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- 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.
- Joint working cannot benefit an individual
- Clinical and financial outcomes will be assessed through a process of risk assessment
- 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.
- Joint working can be terminated with immediate effect
- *Bexley CCG* has a mechanism in place for recording, monitoring and evaluating any joint working arrangements. This consists of:
 - Establishment of a joint Project Group who will retain overall accountability and agree outcomes and deliverables
 - Programme of activity detailing deliverable milestones to be produced
 - Management structures and governance arrangements to be agreed
 - Appointment of a project manager to manage budget and oversee project plan
 - Development of a business case identifying resources required
 - More complex initiatives to receive senior management or governing body level approval
 - Regular monitoring and evaluation to be carried out

6. Joint Working Agreements

- All proposed collaborations must be submitted on the appropriate pro-forma to the Executive Management Committee for NHS Bexley CCG approval (see Appendix B)
- Have a formal Joint Working Agreement (Appendix C)
- NHS Bexley CCG Medicines Management Team will maintain a register of Joint Working agreements. This register will record submitted and approved proposals, as well as proposals not approved and the applicable reason(s) for this. This register will be presented to the Information Governance sub-committee on a quarterly basis and will also be open to inspection by the public.

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- All Pharmaceutical companies entering into joint working agreements must comply with the ABPI code of practice 2014 and also adhere to the NHS Bexley CCG policy on Joint Working.
- NHS Bexley CCG participation in any joint working projects should not be advertised as endorsements to any products, packages or company without specific permission of the CCG. The CCG should agree the nature of any endorsement or linked publications.
- Any conflict of interests must be declared at the outset
- Joint working agreements will have no impact on purchasing decisions with NHS Bexley CCG.
- Joint Working Projects that involve exchange of patient information must have a legal basis; additional approval must be sought from the CCG's Senior Information Risk Officer (SIRO) and the Caldicott Guardian.
- Any joint working projects that require development of clinical/ prescribing proposals, should seek expert input from the NHS Bexley CCG Medicines Management sub-committee.
- Pharmaceutical companies are required to publicly disclose details of transfers of values (payments and benefits) made to individual Health Care Professionals (HCPs) and Organisations (HCOs) on a yearly basis. Individual disclosure will include registration fees for events, travel/ accommodation expenses for events, consultancy/ services fees and expenses. All NHS Bexley CCG staff receiving any form of funding in the course of joint working should consent to this disclosure.

7. Clinical Accountability

- Once approved by the Executive Management Committee the clinical aspects of projects will be controlled and monitored by the Assistant Director-Medicines Management.
- Prescribing and clinical guidelines or protocols will be developed and endorsed through the Medicines Management sub-Committee.



- Approval of the Chief Financial Officer will be required if there are financial implications to NHS Bexley CCG. However, larger more complex initiatives will require governing body level approval in accordance with scheme of delegation.

8. Audit

NHS Bexley CCG Management team will undertake regular audits to provide assurance of compliance to this policy.

9. Review

This document was updated on July 2016 and will be reviewed every 2 years.

10. Conflicts of Interest, Payments and Hospitality

NHS Staff are required to declare and record financial or personal interests (e.g. company shares, research grant, consultancies) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations. Nor should they misuse their official position or information acquired in the course of their official duties to further the private interests of themselves or others. Staff and Governing Body members are reminded of the requirement to acquaint themselves with the NHS Bexley CCG on the acceptance of gifts and other benefits in kind. This policy follows the guidance contained in the Department of Health circular HSG (93) 5 'Standards of Business Conduct for NHS Staff' and is also deemed to be an integral part of these Standing Orders and Standing Financial Instructions (see overlap with SO No. 6). Staff and independent contractors working in NHS Bexley CCG should follow existing Professional codes of conduct and the Standards of Business conduct for NHS Staff. All Staff are also expected to: Refuse gifts, benefits, hospitality or sponsorship which might reasonably be seen to compromise their personal judgement or integrity; Declare and register gifts, benefits, or sponsorship within 20 working days of the offer being made (provided that they are worth at least £25) whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related



source in a 12 month period. Additional information can be sought from 'Commercial Sponsorship Policy and Code of Conduct'.

11. Breaches of Policy

Employees are reminded that breaches of rules, including breaches of policy, could be regarded as misconduct under the CCGs Disciplinary Procedure and/or as criminal activity which will be reported to the Local Counter Fraud Specialist/Local Security Management Specialist and/or police accordingly.

12. Equality and Diversity Statement

In applying this framework, NHS Bexley CCG will have due regard for the need to eliminate unlawful discrimination, promote equality of opportunity, and provide for good relations between people of diverse groups, in particular on the grounds of the following characteristics protected by the Equality Act (2010); age, disability, gender, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, and sexual orientation, in addition to offending background, trade union membership, or any other personal characteristic.

13. References

1. Association of the British Pharmaceutical Industry (ABPI) (March 2009). Guidance notes on Joint Working between Pharmaceutical Companies and the NHS and others for Benefits of Patients [Online]. Available from: http://www.abpi.org.uk/media-centre/newsreleases/2009/Documents/ABPI_Code_Guidance_Notes.pdf (accessed 12/09/2013)
2. Department of Health and Association of the British Pharmaceutical Industry (ABPI). *Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry* [Online]. Available from: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_119052.pdf (accessed 12/09/2013)
3. Department of Health (February 2008). Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations [Online]. Available from: <http://www.networks.nhs.uk/nhs->

networks/joint-working-nhs-pharmaceutical/documents/dh_082569.pdf (accessed 12/09/2013)

4. Department of Health, 2004. *Code of Conduct: Code of Accountability in the NHS*. 2nd Ed
5. Association of the British Pharmaceutical Industry (ABPI): *Code of Practice for the Pharmaceutical Industry 2014* [Online]. Available from: <http://www.abpi.org.uk/our-work/library/guidelines/Documents/Code%20of%20Practice%202014.pdf> [Accessed 23/06/2016].
6. Association of the British Pharmaceutical Industry (ABPI): *Disclosure UK* [Online]. Available from: <http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx> [Accessed 24 June 2016].
7. Department of Health: *The New NHS Modern Dependable*. [Online]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/266003/newnhs.pdf [Accessed 23 June 2016]
8. NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCG's, June 2016. [Online]. Available from: <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/revsd-coi-guidance-june16.pdf> [Accessed on 04/07/2016]

Appendix A

Pro forma for assessment of Joint Working collaboration with the pharmaceutical Industry

[Copy to be held with project documentation]

Section 1: Pre collaboration considerations

Negative responses to the following questions may stop the collaboration	Yes	No
1. Are you satisfied with your knowledge of the collaborating organisation(s) i.e. is there evidence of audited accounts, is the organisation and its ownership known?		
2. Is the main benefit of the proposal focused on the benefit of the patient?		
3. Does the proposal on offer align with current views on evidence-based clinical practice?		
4. Is the proposal on offer consistent with CCG priorities?		
5. Are you satisfied that the arrangement will be independent of purchasing or prescribing decisions?		

6. Can you confirm that there is no current or potential conflict of interest for the CCG in relation to the proposed collaboration project?		
7. Does the proposal enable outcomes to be measured and /or audited?		
8. Does the proposal specify an exit strategy?		
9. Have conflict of interest declarations been completed?		

Section 2: Partnership Project Summary

1. Names of the partners entering the Partnership Names of the lead representative of each partner	
2. Project details: Exact nature of the partnership proposal Summary of intended aims/objectives	
3. Summary of expected outcomes / benefits to the NHS e.g. improvement in services defined by strategies in the NSF, NICE	
4. Start date	
5. Finish date	
6. Exit strategy – What are the termination arrangements? The arrangements should be capable of early termination	

Section 3: Resources and costs

1. What is the overall cost of the partnership project	
2. What are the direct and indirect resource/cost commitments by each partner?	
3. How will the resources/costs be	

monitored and recorded?	
4. List valid and relevant information on cost effectiveness.	
5. Has value for money been shown – if so please indicate.	

Section 4: Governance arrangements

1. Who has been consulted prior to the partnership project and how was this done?	
2. Has an Equality Impact Assessment been carried out on the proposal? Equality Impact Assessment Forms can be accessed from the CCG website. Yes/No Please delete as appropriate. An assessment form will need to be completed before the project can be signed off.	
3. Has a Quality Impact Assessment been carried out on the proposal? A Quality Impact Assessment form can be accessed from the CCG website Yes/No Please delete as appropriate. An assessment form will need to be completed before the project can be signed off.	
4. Has a Privacy Impact Assessment been carried out on the proposal? Privacy Impact Assessment screening questions and assessment forms can be accessed from the	

<p>CCG website</p> <p>Yes/No Please delete as appropriate. This will need to be completed before the project can be signed off.</p>	
<p>5. How will patients be informed of the partnership?</p>	
<p>6. What is the decision making process of the project?</p>	
<p>7. What are the Operational and management arrangements?</p>	
<p>8. How does the project relate to, and mesh with, existing systems of care in the primary and secondary care sectors?</p>	
<p>9. Has the project been piloted or are there plans to do this? How would this be done?</p>	
<p>10. Has the proposal been compared with other partnerships proposals currently on offer?</p>	
<p>11. Is sponsorship in line with National and local priorities and does it comply with NHS Bexley CCG Guidance for Joint Working with the pharmaceutical industry policy?</p>	
<p>12. Who provides indemnity for negligent harm?</p>	
<p>13. Who has entitlement to</p>	

intellectual property rights and how will they be managed?	
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Section 5: Monitoring and Evaluation

1. Management of the project What is the Formal Process?	
2. Who has designated responsibility at each stage of the proposal? [please list]	
3. On completion for the project how will it be evaluated in terms of patient benefits?	
4. What have been the learning outcomes / opportunities?	
5. What are the audit and re-audit arrangements?	

Section 6: Interests and Data Governance

1. What interests do the company and the NHS have in relation to the partnership proposal - where do those interests coincide?	
2. Who “owns” the data generated by audit and monitoring of the partnership?	
3. Who has access to the data and in what form, i.e. aggregation and anonymity criteria?	
4. What arrangements have been put in place to ensure patient confidentiality? (Bearing in mind the Data Protection Act and the requirements for patient confidentiality of healthcare records.)	

5. How will the data be used?	
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Signature (NHS Bexley CCG Governing Body member)	Date
Signature (NHS Bexley CCG Clinical lead)	Date
Signature (Sponsor)	Date

Appendix B

Agreement for Collaborative Working

Funding of: (e.g. name of project) **From:** (Non-NHS organisation)

Application for funding of £.....

Basis for the Work: Justification for the work, brief background, purpose and objectives of the work to be funded. To include the contribution from NHS Bexley CCG, if any, defining the work is to be held.

Description of the Work and Personnel involved: Overall and detailed objectives, personnel / organisations involved, expected benefits and outcomes.

Project Action Plan: Detailed description of the project to show how funding will be used and timescales including start and end dates if known.

Exit Strategy: What are the termination arrangements?

It is agreed that:

- 1) (Non-NHS organisation) agrees to abide by the NHS Bexley CCG’s Policy and Guidance for Joint Working with the Pharmaceutical Industry and Framework for Joint Working with the Pharmaceutical Industry.
- 2) (Non-NHS organisation) may only be involved to the extent defined in this agreement, consistent with NHS Bexley CCG’s Framework for Joint Working with the Pharmaceutical Industry.

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- 3) Any reports resulting from the work may acknowledge (Non-NHS organisation's) contribution.
- 4) Such reports will be used for the purposes described above. (Non-NHS organisation) cannot use any reports or information from this work without explicit permission from the CCG.

(Non-NHS organisation) know of no potential embarrassment that would accrue to NHS Bexley CCG as a result of this agreement. (Non-NHS organisation) shall not use the name of NHS Bexley CCG including logos or its employees or services to infer endorsements of products or activities of (Non-NHS organisation) without explicit agreement.

Name of clinical lead or CCG representative	Signature Designation	Date
Name of Non-NHS organisation representative	Signature, Designation and Non-NHS organisation name	Date
Name of Chair or nominated Representative	Signature and date	Approved? y/n

Commercial Sponsorship Policy and Code of Conduct



Author's name and title:	Dibya Rai, Governance Pharmacist
Sponsor's name and title:	Anne Douse, Director of Quality and Governance
Review date:	
Supersedes:	New
Description:	This document is intended to provide a policy to ensure that staff at NHS Bexley Clinical Commissioning Group (CCG) can work jointly with commercial (including pharmaceutical) companies in an open way that addresses potential conflict of interest.
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Date	Name	Title and/or organisation
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Dibya Rai	24/06/2016	0.1	New	Draft
Dibya Rai	04/07/2016	0.2	Comments from Clare Fernee	Draft
Clare Fernee	22/7/2016	0.3	Comments from Anne Douse	Draft
Clare Fernee	24/8/2016	0.4	Comments from Theresa Osborne	Draft



Contents page

1. Introduction	5
2. Scope	5
3. Key Principles	6
4. Sponsorship Agreements	7
5. Responsibilities	9
6. Code of Conduct	9
7. Management Arrangements.....	9
8. Audit.....	10
9. Review	10
10. Breaches in Policy	10
11. Equality and Diversity Statement	10
12. References	10
13. Appendices	
Appendix A – Code of Conduct.....	12
Appendix B – Commercial Sponsorship Agreement.....	13
Appendix B – Authorisation Procedure.....	18





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1. Introduction

'*The New NHS: Modern and Dependable* places an obligation on NHS organisations to work together in partnership with other agencies to improve the health of the population and the quality of health services provided to that population'.⁴

Department of Health guidance *Commercial Sponsorship: Ethical Standards for the NHS* November 2000 suggests that joint working with commercial companies may be beneficial if approached in a transparent way and if properly managed.¹

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice allows pharmaceutical companies to commit up to 9% of their total resources to educational work with NHS organisations.² However, there are concerns that in accepting sponsorship from pharmaceutical companies whose primary aim is to make profits, the quality of patient care may be compromised and priorities may be distorted by sponsorship agreements which look attractive in one part of the NHS, but may lead to increased costs or poorer care of patients in other parts of the service.

Commercial Sponsorship Ethical Standards for the NHS requires NHS bodies to have formal arrangements, with clear policy statements, codes of practice in working with sponsors, and codes of conduct for Clinical Commissioning Group (CCG) members and staff.¹

2. Scope

This document is intended to provide a policy to ensure that staff at NHS Bexley Clinical Commissioning Group (CCG) can work jointly with commercial (including pharmaceutical) companies in an open way that addresses potential conflict of interest.

For the purpose of this policy, the term 'staff' refers to all employees and contractors who are engaged to undertake duties on behalf of NHS Bexley CCG.

For the purpose of this policy 'Commercial Sponsorship' is defined as including:

*"NHS funding from an external source, including funding of all or part of the cost of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs, (including trips abroad), provision of free services and buildings or premises."*¹



This policy must be read in conjunction with:

- NHS Bexley CCG Framework for Commercial Sponsorship and Joint Working with the Pharmaceutical Industry
- NHS Bexley CCG Policy on Conflict of Interest
- NHS Bexley CCG Privacy Impact Assessments Policy & Process
- Commercial Sponsorship Ethical Standards for the NHS – published by the Department of Health (DoH) in November 2000
- NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCG's, June 2016
- Guidance from relevant professional organisations, such as the General Medical Council, the Nursing and Midwifery Council and the General Pharmaceutical Council about working in partnership with commercial (Pharmaceutical) companies

3. Key Principles

The key principles are that:

- Clinical and professional decisions must always be made in the best interests of patients and the service. Involvement of a commercial sponsor should not compromise the CCG or any member of staff/officer in undertaking their duties within the NHS.
- Any relationship must respect and safeguard confidential patient information.
- No agreements are permissible which lead to higher costs or reduce the quality of service to patients in other parts of the NHS. Only projects which have a positive impact for patients and the service will be acceptable.
- All agreements with a commercial sponsor will be handled in an open and transparent manner as befits a publicly funded body and are open to scrutiny and be a matter of public record.
- Any relationship must put patients first.
- No agreements will be entered into with sponsors whose products or services are prejudicial to health or conflict with the principles and objectives of the NHS and the CCG.

Clinical Commissioning Group

- No agreements will be entered into with organisations whose business or function is ethically unacceptable to the CCG, its staff or the public.
- There should be no overt commercial advantage to the sponsor in terms of the direct sale of products or brands as a result of their association with the CCG. Their involvement should be seen as secondary to the aims of the CCG.
- In areas such as clinical trials or commissioning, there is sufficient distance between the commercial sponsor and the clinicians involved in the day-to-day operation of the clinical trial/commissioning decision, to ensure no undue influence is exerted to promote a particular company's product or service.

4. Sponsorship Agreements

- 4.1 All sponsorship arrangements will be subject to prior written agreement between authorised officers (refer to Appendix C for details) and prospective sponsors.
- 4.2 All sponsorship agreements must be in writing and must clearly specify the exact nature of sponsorship including potential risks and benefits. The benefits to the CCG, the patient and the sponsor should also be clearly indicated.
- 4.3 Clinical aspects of sponsored projects should always be under local control. Development of guidelines and advice will be by a local group, which should not include a representative of the sponsors. The local group may decide that advice and guidelines developed by a sponsor are suitable for promotion locally.
- 4.4 Training events which rely heavily on the use of sponsored materials should be discouraged, unless they promote good practice agreed to by the CCG. Service Level Agreements with training agencies must include a clause which requires the approval of the CCG to the use of commercially sponsored materials.
- 4.5 All members and officers of the CCG who are taking part in sponsored projects must comply with both the CCG and their own professional codes of conduct.
- 4.6 All pharmaceutical companies entering into sponsorship agreements must comply with the ABPI code of practice 2014.
- 4.7 Formal meetings of NHS Bexley CCG should not be the subject of sponsorship agreements. Sponsorship for local training may be acceptable subject to the necessary authorisations.



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- 4.8 Projects which involve the use of clinical guidelines or protocols prepared by sponsors should only be agreed following advice from the CCGs Medicines Management Team.
- 4.9 Projects which involve the exchange of patient information must have a legal basis; additional approval must be sought from the CCG's Senior Information Risk Officer (SIRO) and the CCG's Caldicott Guardian. Ethics approval may also be required depending on the project.
- 4.10 All staff including CCG members involved in the development of a sponsorship agreement must declare any prior interest in terms of previous sponsorship or relationship to any of the individual sponsors in question.
- 4.11 Sponsors should not advertise NHS Bexley CCG participation in their project as an endorsement to their product, packages or company without specific written permission of the CCG. The CCG should agree the nature of any endorsement or linked publication.
- 4.12 Any proposed collaboration should be without prejudice to any of the CCG's Standing Orders, Scheme of Reservation and Delegation, and within the spirit and letter of the Department of Health guidance and relevant codes of practice.
- 4.13 Commercial organisations must not be in breach of article 85 (1) of the EC treaty which prohibits agreements preventing, restricting or distorting competition or section 21 (1) of the Competition Act 1980 which makes it unlawful to engage in practice preventing, restricting or distorting competition in the supply and acquisition of goods.
- 4.14 All agreements must include a 'break' clause enabling the termination of the agreement at short notice, or immediately if necessary. NHS Bexley CCG reserve the right to terminate the agreement with immediate effect
- 4.15 Sponsors should be informed that any sponsorship arrangement will have no effect on purchasing decisions with NHS Bexley CCG.
- 4.16 Sponsorship agreements which involve several sponsors are to be preferred to those which involve a single sponsor.
- 4.17 All sponsors should be provided with copies of this policy document before draft arrangements are agreed.
- 4.18 A record will be maintained of all appointments with commercial sponsors (including starting date, time, duration and subject discussed).



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4.19 The pharmaceutical companies are required to publicly disclose details of transfers of values (payments and benefits) made to individual Health Care Professionals (HCPs) and Organisations (HCOs) on a yearly basis. Individual disclosure will include registration fees for events, travel/ accommodation expenses for events, consultancy/ services fees and expenses. All NHS Bexley CCG staff receiving commercial sponsorship should consent to this disclosure.

5. Responsibilities

- **Employees:** All staff members are responsible for following the policy and for declaring any Commercial Sponsorship covered within the confines of this policy.
- **Line Managers:** Managers are responsible for ensuring that their staff are aware of, and adhere to the policy.
- **Directors/Chief Officers/Heads of Service:** Directors/Chief Officers/Heads of Service must ensure that managers are made aware of the provisions set out within this policy and that it is implemented within their teams.
- **Assistant Director Medicines Management:** Responsible for providing advice on sponsorship and ensuring that breaches of policy are dealt with in a fair and consistent manner. (Refer to Appendix C for more details)
- **Accountable Officer:** The Accountable Officer has the overall accountability and responsibility for implementation of this policy.

6. Code of Conduct

The Code of Conduct approved by NHS Bexley CCG, for officers and CCG members, who are not subject to professional codes is included in Appendix A.

7. Management Arrangements

- **The Register:** A register of sponsorship agreements will be maintained by the CCG. The register will be open to inspection by the public. This register will record submitted and approved proposals, as well as proposals not approved and the applicable reason(s) for this.
- **Written Agreements:** All sponsorship arrangements will be subject to written agreements. A proforma is available at Appendix B and should be completed in every case. Completion of the proforma alone will usually be sufficient for low value proposals. Higher value proposals will need to be accompanied by additional supporting information and may need to be the subject of a formal contract. Details



Clinical Commissioning Group

of levels are included at Appendix C (if advice is required this should be sought from the Medicines Management team).

8. Audit

NHS Bexley CCG Medicines Management team will undertake periodic audits to provide assurance of compliance to this policy.

9. Review

This document was updated in **August** 2016 and will be reviewed every 2 years.

10. Breaches of Policy

Employees are reminded that breaches of rules, including breaches of policy, could be regarded as misconduct under the CCGs Disciplinary Procedure and/or as criminal activity which will be reported to the Local Counter Fraud Specialist/Local Security Management Specialist and/or police accordingly.

11. Equality and Diversity Statement

NHS Bexley CCG is committed to ensuring that all patients, employees and members of the public are treated fairly, equitably and reasonably and that it does not discriminate against individuals or groups on the basis of their ethnic or national origin, physical or mental abilities, gender, age, religious beliefs or sexual orientation, social and employment status or domestic circumstances.

12. References

1. Department of Health Guidance: *Commercial Sponsorship: ethical standards for the NHS* (November 2000) [Online] Available from: <http://www.uhb.nhs.uk/pdf/DohGiftsGuide.pdf> [Accessed 23/06/2016].
2. Association of the British Pharmaceutical Industry (ABPI): *Code of Practice for the Pharmaceutical Industry 2014* [Online]. Available from: <http://www.abpi.org.uk/our-work/library/guidelines/Documents/Code%20of%20Practice%202014.pdf> [Accessed 23/06/2016].
3. Association of the British Pharmaceutical Industry (ABPI): *Disclosure UK* [Online]. Available from: <http://www.abpi.org.uk/our-work/disclosure/Pages/disclosure.aspx> [Accessed 24 June 2016].



Clinical Commissioning Group

4. Department of Health: *The New NHS Modern Dependable*. [Online]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/266003/newnhs.pdf [Accessed 23 June 2016].
5. NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCG's, June 2016. [Online]. Available from: <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/revsd-coi-guidance-june16.pdf> [Accessed on 04/07/2016]



CODE OF CONDUCT

Staff employed by NHS Bexley CCG, members of the CCG and anyone undertaking work on behalf of the CCG should follow the following principles and abide by any professional codes of conduct:

- Act impartially in all their work;
- Refuse sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, or seek to exert influence to obtain preferential consideration.
- Complete an annual conflict of interest declaration
- Declare and register sponsorship of any kind (provided that this is worth at least £25), whether refused or accepted.
- Declare financial or personal interest in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by commercial considerations;
- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others;
- Beware of bias generated through sponsorship; where this might impinge on professional judgement and impartiality;
- Neither agrees to practice under any conditions which compromise professional independence or judgement, nor impose such conditions on other professionals.
- Commercial sponsorship agreements should be recorded on the relevant CCG register.



COMMERCIAL SPONSORSHIP AGREEMENT

1 Details of project: <i>Describe the project. What are its aims and objectives? How long will it last?</i>			
2 Recipient. <i>Give names of CCG service area and the responsible officer.</i>			
3 Sponsor			
Organisation		Nature of business	
Address			
Contact name			
Tel number			
4 Value of sponsorship			



5	Payment arrangements (e.g. Direct to CCG)
6	Benefits to the recipient or CCG and patient
7	Benefits to the sponsor
8	Will the sponsorship arrangements lead to higher costs elsewhere in the NHS?
9	PATIENT CONFIDENTIALITY <i>Projects which involve the exchange of patient information must have the approval of the CCGs Information Governance Group – Has this been sought? Has the Caldicott Guardian been consulted? Has the patients' consent been sought?</i>

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10 PROTOCOLS AND GUIDELINES <i>Does the project include the use of protocols or guidelines? The advice of CCG professional advisers should be sought and recorded.</i>
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11 PHARMACEUTICAL COMPANY SPONSORSHIP <i>The Assistant Director Medicines Management must be consulted in all cases If the project is valued at more than £25.</i>
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Signature		Date	
	Assistant Director-Medicines Management		

12 TERMINATION ARRANGEMENTS

The agreement should be capable of early termination by the CCG or GP Practice. Please state the arrangements.

FOR THE RECIPIENT

I have read the NHS Bexley CCG Commercial Sponsorship Policy and Code of Conduct, have acted in accordance with it and will abide by it.

Organisation			
Contact Name			
Position/designation			
Tel number			
Signature		Date	
Director/Chief Officer approval			
Signature		Date	

Clinical Commissioning Group

FOR THE SPONSOR

I have read the NHS Bexley CCG Commercial Sponsorship Policy and Code of Conduct, have acted in accordance with it and will abide by it.

Organisation			
Contact Name			
Position/Designation			
Tel number			
Signature		Date	

Return completed form to: Medicines Management, 221 Erith Road, Bexleyheath, Kent, DA7 6HZ

Authorisation Procedures

Sponsorship Value	CCG/Executive Members and Staff
Less than £25	<ul style="list-style-type: none"> • No authorisation required • Consult line manager • Entry to be made in the 'Register'
£25 - £500	<ul style="list-style-type: none"> • Authorisation required • Approved by Director of Quality and Governance • Entry to be made in the 'Register'
£500 - £4999	<ul style="list-style-type: none"> • Authorisation required • Consult Assistant Director Medicines Management • Approved by NHS Bexley CCG Executive Management Committee • Entry to be made in the 'Register'
£5000 and over	<ul style="list-style-type: none"> • Authorisation required • Consult Assistant Director Medicines Management • Approved by NHS Bexley CCG Governing Body • Entry to be made in the 'Register'