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Corporate Policy and Guidance for Joint Working with the Pharmaceutical Industry

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Corporate

Policy and Guidance

For Joint Working with the

Pharmaceutical Industry

(Template based upon
**DH Best Practice Guidance for Joint Working between the NHS
 and the Pharmaceutical Industry, February 2008)**

| Version | Issue Date | Last Review | Next Review | Impact Assessed | Document Owner |
|------------|------------|-------------|-------------|-----------------|--|
| 1.3 | 11/06/2013 | | | | NHS Lambeth CCG Medicines Management Team Email: Lamccg.medicinesmanagement@nhs.net Phone: 020 3049 4197 |

| |
|---|
| Initial approval by & date |
| Joint Chair NHS Lambeth CCG and NHS Southwark CCG Joint Prescribing Committee – 11/06/2013 |

Document control

Change History

| Version | Date | Author | Approver | Reason |
|---------|------|--------|----------|--------|
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Superseded documents

Changes summary

Outstanding items

Contact details As set out above

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Introduction

DH Guidance¹ encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous.

1.1. Document statement and aim

The aim of this policy is to:

- assist NHS Lambeth Clinical Commissioning Group (CCG) achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry
- inform and advise 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.

1.2. Objectives

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

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

2.0 Scope of document

This document is intended as policy for NHS Lambeth Clinical Commissioning Group and its staff who are involved in working with the pharmaceutical industry. This will include joint working with the pharmaceutical industry as well as hospitality and sponsorship received from the pharmaceutical industry. For the purposes of this policy:

The term “staff “ refers to all healthcare staff employed by NHS Lambeth Clinical Commissioning Group and board members in their capacity as board members **and** as independent contractors, all other healthcare professionals including contractors and locum practitioners working under NHS terms and conditions.

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.

Sponsorship is defined as situations where pharmaceutical companies simply provide funds for a specific event or work programme.

3.0 Roles and responsibilities

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.

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.

It is the responsibility of the Head of Medicines Management to resolve any contentious issues and have the final say in determining the appropriateness of any collaboration with the industry.

The Director of Governance and Development is responsible for maintaining a register of gifts, hospitality and **sponsorship for employees of the CCG.**

Independent contractors are responsible for maintaining a register of gifts, hospitality and sponsorship for their employees

The NHS parties 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.

Final consideration and approval for any joint working arrangements will be sought from the NHS Lambeth Clinical Commissioning Group Governing Board

4.0 Principles and values of joint working

4.1. Values

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

4.2. Principles of sponsorship and hospitality that are 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 Lambeth

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- sponsorship of any staff or patient 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

Hospitality can only be provided to health professionals and managers as part of scientific or promotional meetings. Hospitality must be secondary to the meeting and of an appropriate standard i.e. not more lavish or deluxe than employees would usually have themselves e.g. sandwiches at lunch. Hospitality may include:

- meals
- meetings
- hotel and transport costs (including overseas travel) NB only economy air travel can be provided for delegates
- Samples of medicines should not be accepted under any circumstance by a health professional.
- Gifts from independent organisations to NHS Lambeth Clinical Commissioning Group employees or independent contractors
- Donations to the cost of buildings or premises.

4.3. Exceptions to sponsorship covered by this guidance

Gifts of the value of £10 or under per gift are acceptable as long as they are relevant to the person's profession (e.g. pens, post-it notes, pill counting triangles). The gifts must be declared in the register of gifts, hospitality and sponsorship if the total value is greater than £100 over a 12-month period.

Gifts for GPs from their patients: regulations concerning the acceptance by GPs of gifts from patients came into force in March 2004. The National Health Service (General Medical Service Contracts) Regulations 2004, statutory instrument 291, specify that a register should be kept of gifts from patients or their relatives which have a value of £100 or more unless the gift is unconnected to the provision of services.

Income generation schemes will be logged separately at a local level.

Discounts on particular pharmaceuticals. For example, where a community pharmacist or hospital pharmacy received a discount for buying a specified amount of a particular drug.

4.4. Principles of Joint Working

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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

NHS Lambeth Clinical Commissioning Group has a mechanism in place for recording and monitoring, and evaluating any joint working arrangements.

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.

4.5. Confidentiality and Data Protection

Patient confidentiality must always be protected under the terms of the Data Protection Act. Patient consent must be obtained to disclose any information to another organisation. Disclosures should also be in line with the NHS South East London information sharing protocol.

All employees are responsible for maintaining the confidentiality of information gained during their employment with NHS Lambeth Clinical Commissioning Group. The NHS Code of Confidentiality and NHS Lambeth CCG standard of business conduct policy should be read and understood prior to any contract of employment or other confidentiality agreement being signed.

4.6. Conflicts of interest

Individuals involved in the development or consideration of any proposal must declare any potential conflict of interest they, or their immediate family, may have at the beginning of the process. Examples could include:

- shareholding or directorship in a company
- speaking at industry sponsored events
- research or educational grant
- consultancy 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 outlined.

4.7. Payments

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.

A fee can be accepted for work carried out in the staff member's own time.

4.8. Bribery legislation

The 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.

A bribe is an inducement or reward of a financial or other advantage that is offered, promised or provided to a person in order to gain any commercial, contractual, regulatory or personal advantage through the improper performance of a relevant function or activity as a result of the bribe.

- 'Financial or other advantage', - payments, gifts, hospitality or anything else that could be reasonably perceived as an "advantage" as understood by its normal, everyday meaning.
- "Improper performance" means performance in breach of an expectation that a person will act in good faith, impartially, or in accordance with a position of trust.

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- A “relevant function or activity” means any function of a public nature, connected with a business, performed in the course of a person’s employment or performed by or on behalf of an incorporated or unincorporated body of persons.

All allegations or suspicions of bribery, fraud or corruption must be reported to the local Counter Fraud Specialist. Further information and guidance can be found in the NHS Lambeth CCG standard of business conduct policy.

5.0 Audit and monitoring criteria

| Document Audit and Monitoring Table | |
|---|--|
| Monitoring requirements *What in this document do we have to monitor (e.g. processes) Note specifically any monitoring needed to assure equality and equity of delivery | a) The number of requests to joint working and their outcome b) Monitor the source of the application (employee) and the sponsorship (commercial organisation) to ensure that the process is equitable to all concerned |
| Monitoring Method: (e.g. statistics, report) | a) Report |
| Monitoring prepared by :- (name job titles) | a) Senior Prescribing Advisor, Lambeth BSU |
| Monitoring presented to:- (e.g. Committees) | a) Joint Prescribing Committee |
| Frequency of presentation:- (e.g. annually, six-monthly etc) | a) Annually |

6.0 Statement of evidence/references

1. Department of Health, 2004. Code of Conduct: Code of Accountability in the NHS. 2nd Ed
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4116281
2. Commercial Sponsorship – Ethical Standards for the NHS (2000)
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135
3. ABPI Code of Practice which can be found at: <http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-2012.aspx>

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4. 'Standards of business conduct for NHS staff, and Commercial Sponsorship – Ethical Standards for the NHS (2000),
www.kch.nhs.uk/EasysiteWeb/getresource.axd?AssetID=793&type=Full&servicetype=Attachment
5. 'Moving beyond sponsorship : joint working between the NHS and the pharmaceutical industry'
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840
6. NHS SE London Information sharing
http://www.selondon.nhs.uk/your_resources/information_governance/information_sharing
7. Department of health confidentiality policy
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

7.0 Implementation and dissemination of document

Once this policy has been approved by NHS Lambeth CCG and NHS Southwark CCG Joint Prescribing Committee and the NHS Lambeth CCG Board it will be added to the intranet. Information will be included in the Lambeth weekly newsletter which is distributed to all practices. It will also be sent to all Lambeth community pharmacists.

8.0 Associated Documents

NHS Lambeth Clinical Commissioning Group Standards of Business conduct policy (including Conflicts of Interest)
NHS Lambeth Clinical Commissioning Group Counter fraud and corruption policy (2008)

9.0 Appendices

Appendix 1 Equality Impact Assessment Checklist

Appendix 2 Consultation history

Appendix 3 Declaration of personal and financial interests

Appendix 4 Register of hospitality, gifts and sponsorship

Appendix 5 Process for approval of joint working project

Appendix 6 Joint working proposal form

Appendix 7 NHS Lambeth CCG business case

Appendix 8 Framework for joint working

Appendix 9 Joint working agreement template

Appendix 1 Equality & Equity Impact Assessment Checklist

This is a checklist to ensure relevant equality and equity aspects of proposals, policy 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 (ie 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? | No | |
| 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 groups? | NA | |
| 6. | Does the document describe any specific opportunities to promote equality and human rights , good relations between people of different groups, to enhance participation, etc? | NA | |
| 7. | Does the document describe how the proposal, policy etc will address the identified inequalities , and | | |
| 8. | Does the document make recommendations to mitigate risks and enhance the opportunities to promote equality and equity? | | |
| 9. | Does the document describe how monitoring and reporting will take place to assure equality and equity in the future including to stakeholders. [audit and monitoring table may be used] | | |

* 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

Appendix 2 Consultation History

| Stakeholders Name | Area of expertise | Date sent | Date received | Comments | Changes made |
|---|-------------------------|------------|---------------|--|---|
| Vanessa Burgess Head of Medicines Management | Medicines management | 18.07.2012 | 23.07.2012 | To amend in light of the new Lambeth CCG Standards of Business conduct | Incorporated the details from NHS Lambeth CCG standards of business conduct |
| Joint Prescribing Committee | Medicines Management | 12.09.2012 | 01.10.2012 | | Corrected typos |
| | | | | To clarify roles and responsibilities | Amended the roles and responsibilities for independent contractors to include maintain a register of gifts, hospitality and sponsorship |
| Andrew Parker Director of Governance and Development | Governance | 19.04.2013 | 19.04.2013 | Letter to be sent to practices as part of the implementation, highlighting what needs to be recorded at practice level eg hospitality and what will need to be approved at corporate level i.e. joint working projects. Policy to be added to the intranet and highlighted to the organisation via Governance Manager. Medicines Management to manage and record all requests and provide a summary to Governance Director at agreed intervals | Letter drafted and approved by Joint Chair of JPC. |
| Joint Prescribing Committee | Medicines Management | 21.05.2013 | 11.06.2013 | Final draft approved by Joint Chair | |
| | | | | | |
| | | | | | |
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Appendix 3

Declaration of Personal and Financial Interests – Governing Body Member/Director

This form is required to be completed in accordance with the NHS Lambeth CCG's Constitution.

Notes:

- Within 28 days of a relevant event, NHS Lambeth CCG Governing Body and its Sub Committees and Directors need to register their financial and other interests.
- If any assistance is required in order to complete this form, then the member or employee should contact the Director of Governance and Development.
- The completed form should be sent by both email and signed hard copy to the Director of Governance and Development.
- Any changes to interest declared must also be registered within 28 days of the relevant event by completing and submitting a new declaration form.
- Declarations of interest made by members of the CCG Governing Body will be published on the NHS Lambeth website www.lambethccg.nhs.uk.
- The Register of Declarations of Interest will be reported to each meeting of the NHS Lambeth CCG Audit Committee.
- Members and employees completing this declaration form must provide sufficient detail of each interest so that a member of the public would be able to understand clearly the sort of financial or other interest the member or employee has and the circumstances in which a conflict of interest with the business or running of the CCG might arise.
- If in doubt as to whether a conflict of interest could arise, a declaration of the interest should be made.

Interests that must be declared:

- Roles and responsibilities held within member practices
- Directorships, including non-executive directorships held in private companies or public limited companies (with the exception of those of dormant companies)
- Ownership or part ownership of companies, businesses or consultancies which may seek to do business with the CCG
- Shareholdings (more than 5%) of companies in the field of health and social care;
- Membership of or a position of authority or trust in an organisation (eg, charity or voluntary organisation) in the field of health and social care;
- Any connection with a voluntary or other organisation contracting for NHS services
- Research funding/grants that may be received by the individual or any organisation they have an interest or role in
- Interests in pooled funds that are under separate management (any relevant company included in this fund that has a potential relationship with the CCG must be declared)
- Formal interest with a position of influence in a political party or organisation
- Current contracts with the PCT/CCG in which the individual has a beneficial interest

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- Any other employment, business involvement or relationship or those of a spouse or partner that conflicts, or may potentially conflict with the interests of the CCG.
- Any other role or relationship which the public could perceive would impair or otherwise influence the individual's judgement or actions in their role within the CCG. Whether such interests are those of the individual themselves or of a family member or close friend of the individual.
- Other specific interests

Conflict of Interest – Declaration:

| | | | |
|---|----------------|--|--|
| Name: | | | |
| Position within the CCG | | | |
| Interests | | | |
| Type of Interest | Details | Personal interests or that of a family member, close friend | |
| Roles and responsibilities held within member practices | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Directorships, including non-executive directorships, held in private companies or PLCs | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Ownership or part-ownership of private companies, businesses or consultancies likely or possibly seeking to do business with the PCT/CCG | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Shareholdings (more than 5%) of companies in the field of health and social care | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Positions of authority in an organisation (e.g. charity or voluntary organisation) in the field of health and social care | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |

| | | | |
|--|----------------|--------------------|--|
| Any connection with a voluntary or other organisation contracting for NHS services | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Research funding/grants that may be received by the individual or any organisation they have an interest or role in | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| [Other specific interests?] | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |
| Any other role or relationship which the public could perceive would impair or otherwise influence the individual's judgement or actions in their role within the PCT/CCG | <i>Details</i> | <i>Materiality</i> | |
| | | <i>Value</i> | |

To the best of my knowledge and belief, the above information is complete and correct. I undertake to update as necessary the information provided and to review the accuracy of the information provided regularly and no longer than annually. I give my consent for the information to be used for the purposes described in the CCG Constitution.

Signed:

Dated:

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Register of Hospitality, Gifts and Sponsorship**

| | |
|---|--|
| Name of recipient | |
| Department/Role in CCG | |
| Name of donor | |
| Hospitality, Gifts or sponsorship description | |
| Details of interest of donor | |
| Estimated value | |
| Date of hospitality, gift or sponsorship (or date range) | |
| Accepted or declined? | |

| | | | |
|----------------|--|---------------|--|
| Signed: | | Date: | |
| Name: | | Title: | |

**Please print a copy, sign and return to the Director of Governance and Development at NHS Lambeth CCG, 1 Lower Marsh, London SE1 7NT.
Independent contractors to keep in practice**

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Approval of Joint Working Arrangements

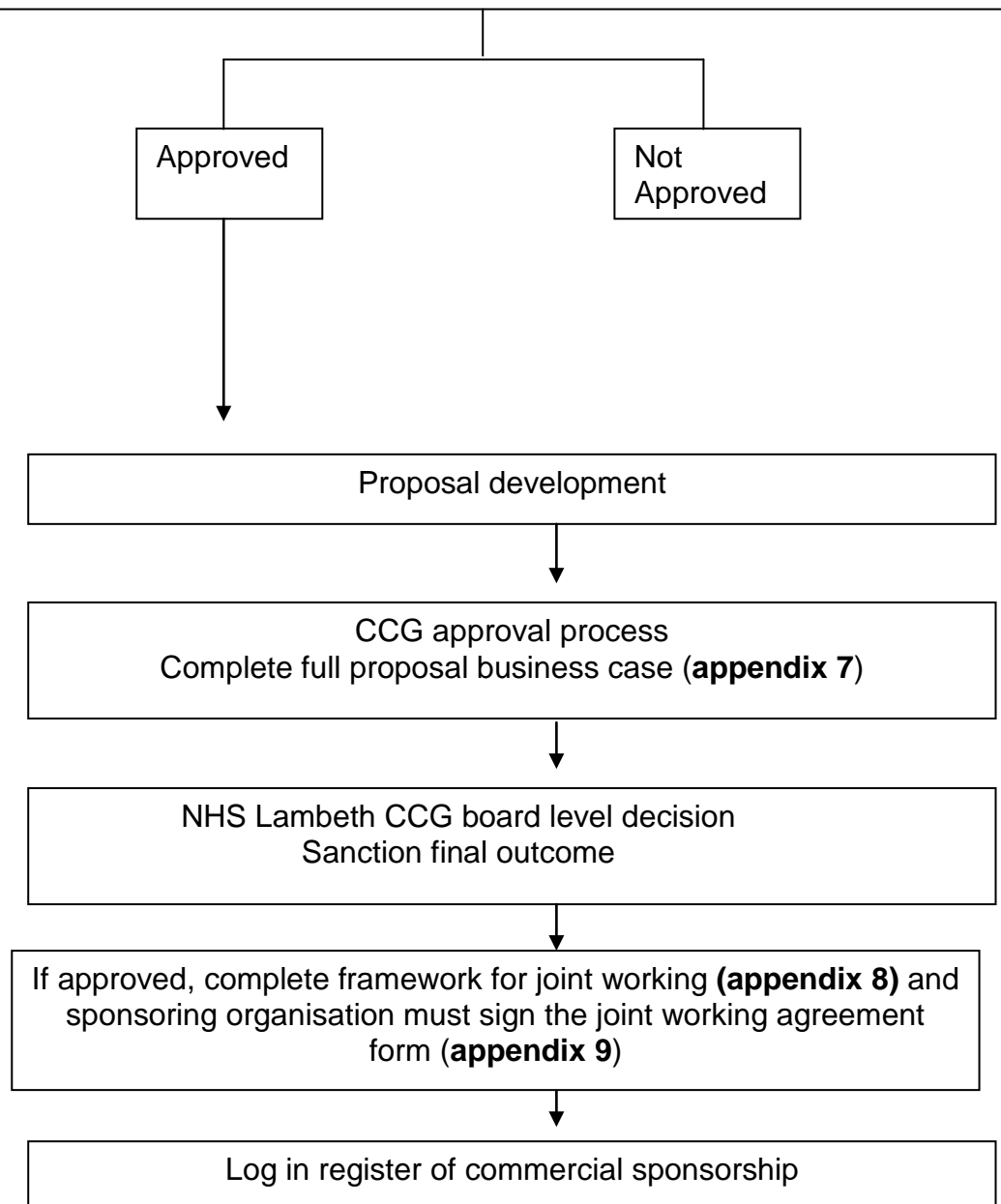
Collaborative working

CCG seeks, or pharmaceutical industry offers, collaborative working in relation to specific project/therapeutic area.

Complete joint working application form (see **appendix 6**) for submission to line manager.

Initial screening (appendix 6)

Chief Pharmacist reviews basic proposal and agree/disagrees course of action. Signposting to suitable contact points within the CCG if applicable



Procedure and framework for the approval of joint working projects between NHS Lambeth Clinical Commissioning Group and the Pharmaceutical Industry.

1. Identify potential collaborative work

Any collaboration with the pharmaceutical industry must be transparent and defensible with agreed aims and objectives

2. Complete joint working proposal (appendix 6, 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 application

The line manager must be satisfied that approval of the joint working project will not compromise trust decisions by using the checklist in **appendix 6**. They must ensure that the work is beneficial to the organization, that there is no conflict of interests and that the framework is adhered to. They must refer to the Lambeth medicines management team if they feel unable to judge the suitability of the proposal. In order to ensure congruence with the strategic aims of the CCG's prescribing 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 (**appendix 7**) to NHS Lambeth CCG board for approval. The decision should be recorded by the medicines management team and forwarded to the Director of Governance and Development on an annual basis.

Each project will require relevant documentation in place which includes a:

- Business case for project with the pharmaceutical industry (appendix 7)
- Framework for joint working (appendix 8)
- Joint working agreements (appendix 9)

This does not apply to procurement. One 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, NSF's, South London cardiac and stroke network guidelines, local formularies.
- **Healthcare priorities:** does this fit with nationally and locally agreed healthcare priorities.

Joint working 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?

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1. Is the joint working proposal consistent with the guidance given in the NHS Lambeth Clinical Commissioning Group Guidance for working with the pharmaceutical organisation and commercial organisations? **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.....

Name of Head of Medicines Management.....

*** delete as appropriate**



Lambeth Clinical Commissioning Group

Formal LCCCB Board Report Date

Report author:

Presented by:

Queries to:

Relevant background papers:

Also considered at:

Title:

What are the headline messages to consider from this paper?

Recommendation:

The LCCCB is asked to:

Are there resource implications for revenue, capital, staffing?
If yes, please explain.

Does this require an equality impact assessment (EIA)?
If yes, what has been the outcome of the EIA to date? How have the issues raised been addressed in this paper?

Will the proposals reduce health inequalities?
Please explain.

What has been the scope of PPI in this work?
How has feedback been incorporated/actioned to date?
Have clinicians been engaged in this work?

What are the key risks to delivery of this work.

Are there plans in place to address risks?

Are there legal issues to consider?

Business Case Governance Approval Sheet

The purpose of this template is to facilitate swift, rigorous decision making, taking account of the scale of the proposal (i.e. the cost) on service transformation business cases. The process should be used for all proposals, including those with strategic or revenue consequences from local providers.

| |
|--|
| 1. Business Case Title |
| 2. Business Case Submission Date |
| 3. Assigned Business Case Owner |
| 4. Date due for Clinical Board submission (within 28 days) |
| <p>Approval by public health on:</p> <ul style="list-style-type: none"> a. Needs assessment b. Evidence based approach c. Impact on population (including inequalities) d. Quality indicators <p>Signed (Director or AD equivalent) _____</p> <p>Name _____</p> <p>Date _____</p> |

4. Approval by programme management SRO:

- Consistency with strategic approach
- Clearly defined model pathway including how choice offered
- Appropriate stakeholder (clinical and patient involvement) engagement
- Feasibility and risk assessment
- Implementation and proposed monitoring arrangements

Signed (Director or AD equivalent) _____

Name _____

Date _____

5. Approval by Medicines Management:

Signed (Director or AD equivalent) _____

Name _____

Date _____

6. Impact on activity, finances and existing providers

Signed (Director or AD equivalent) _____

Name _____

Date _____

Finance (including affordability)

Signed (Director or AD equivalent) _____

Name _____

Date _____

| | | | |
|-------------------------------|--|------------------------|--|
| Name | | | |
| SRO (Sponsor) | | | |
| Commissioning Lead | | | |
| Project Leads | | | |
| Financials verified by | | | |
| Start date | | completion date | |
| | | | |

Decision Summary

Context

Background

Current Service

Drivers to Change Current Service

Strategic

QIPP shift and de-commissioning

Patient outcomes

Proposed service

Prescribing

Outcome measures

The tangible outcomes of delivering this project are:

| Description | Measure | Baseline | Target | Target Date |
|-------------|---------|----------|--------|-------------|
| | | | | |
| | | | | |

| | | | | |
|--|--|--|--|--|
| | | | | |
| | | | | |
| | | | | |

In addition, the intangible outcomes of delivering this project are:

Guidance, Legislation and Benchmarking

Options

The options that have been considered are:

Option 1:

Benefit

Risk

Option 2:

Cost:

Benefit:

Risk:

Option 3:

Cost:

Benefit

Risk

Option 4

Cost:

Benefit:

Risk:

-

INFO CLASSIFICATION**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. 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 INTERESTSYES NO **If Yes, qualify by inserting a tick in one box in column A and one in column B**

| A | | B | |
|--------------|--------------------------|--------------|--------------------------|
| Personal | <input type="checkbox"/> | Specific | <input type="checkbox"/> |
| Non-Personal | <input type="checkbox"/> | Non Specific | <input type="checkbox"/> |

Signature _____ Date _____

INFO CLASSIFICATION

Corporate Policy and Guidance for Joint Working with the Pharmaceutical Industry

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.

INFO CLASSIFICATION

JOINT WORKING AGREEMENT TEMPLATE

AN AGREEMENT FOR JOINT WORKING BETWEEN
NHS Lambeth 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 Director of Governance and Development for NHS Lambeth CCG.

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

Signed: _____ on behalf
of: _____

Document Title: Joint Working with the Pharmaceutical Industry

Issue Date: 11/06/2013

Document Status: FINAL

Review Date: 11/06/2015

File Pathway: S:\Lam\CCG\Lambeth CCG Shared Documents\Policies

Version: 1.3

INFO CLASSIFICATION

Corporate Policy and Guidance for Joint Working with the Pharmaceutical Industry

Print

Name: _____

Date: _____

Signed: _____

on behalf

of: _____

Print

Name: _____

Date: _____