NHS
Luton
Clinical Commissioning Group

Policy for Pharmaceutical and Industry Sponsorship and Joint Working

Version:	2
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Contents

1. Introduction

Good governance within the public sector is based upon the seven 'Nolan principles' (See Appendix A). It is important that all employees of Luton CCG understand these principles and embed them in their working practices and behaviours, so that the public and patients we serve have confidence and trust in the organisation. Joint working with industry and receiving hospitality from industry are key areas where CCG employees should apply the 'man in the street' test as perception of an action can be as significant as the factors involved.

This Policy translates the Nolan principles into a protocol to support staff in situations for working with industry, particularly the pharmaceutical industry, and incorporates updated statutory guidance to CCGs on Managing Conflicts of Interest (published April 2016).

2. Purpose

Pharmaceutical companies, and other companies that provide products to the NHS, wish to work with CCGs through offering sponsorship or joint working initiatives, in line with their company objectives. There is a national imperative for NHS organisations to work with industry as this can be mutually beneficial and may introduce innovation into practice. The CCG acknowledges and recognises the interdependent relationship between the NHS and industry, and their need to promote medicines and other products to maintain their profitability.

The purpose of this Policy is to provide a framework within which the CCG can develop sponsorship arrangements or joint working with Pharmaceutical and other Health related companies such that assurance is provided to the CCG Governing Body, to clinicians, and to the public, that any agreements made do not adversely influence prescribing advice or choice of products. These decisions should always be based on evidence of value for money, safety and efficacy, and it should be demonstrable that the governance surrounding such decisions is independent from sponsorship and joint working arrangements with industry.

3. Scope

The Policy applies to:

- The Governing Body, and its committees.
- Employees of the CCG, including seconded and sessional staff, and temporary staff such as agency staff and interims.
- Member practices and their employees when undertaking duties on behalf of the CCG. This includes clinicians undertaking roles with the CCG, e.g. Clinical Directors, Cluster Chairs and Clinical Leads, and any other roles where a clinician from a member practice undertakes duties on behalf of the CCG.
- Third parties acting on behalf of the CCG and services contracted by the CCG, e.g. Commissioning Support Services.

4. Guidance and Legal Framework

4.1. Definitions

For the purposes of the Policy the term **commercial sponsorship** is defined as including any funding to the NHS from an external source, including funding all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs, provision of free services including guest speakers, buildings or premises.

Where hospitality is involved reference should also be made to the CCG's 'Conflict of Interest Policy' for further guidance and for details of how to declare a Conflict of Interest or to declare Hospitality.

Joint working is defined as including 'situations where, for the benefit of patients, the NHS and Industry organisations pool skills, experience and resources for the joint development and implementation of patient centred projects, and share a commitment to successful delivery'.

Where such collaborative partnerships involve a pharmaceutical company the proposed arrangements must comply fully with the Medicines (Advertising) Regulations 1994 (regulation 21 'inducements and hospitality').

Secondary employment is a term used to describe any employment additional to the work with the CCG. The CCG takes all reasonable steps to ensure that employees, committee members, contractors and others engaged under contract with them are aware of the requirement to inform the CCG if they are employed or engaged in, or wish to be employed or engaged in, any employment or consultancy work in addition to their work with the CCG. The purpose of this is to ensure that the CCG is aware of any potential conflict of interest. Examples of work which may conflict with the business of the CCG, including part-time, temporary and fixed term contract work, include:

- Employment with another NHS body
- Employment or carrying out duties with another organisation which might be in a position to supply goods/services to the CCG
- Directorship for GP federation; and
- Self-employment, including private practice, in a capacity which might conflict with the work of the CCG or might be in a position to supply goods/services to the CCG

The CCG requires that all individuals obtain prior permission to engage in secondary employment and reserves the right to refuse permission where it believes a conflict will arise which cannot be effectively managed. Consideration of the implications of secondary employment may be relevant when sponsorship or joint working agreements are proposed. In particular it is unacceptable for pharmacy advisers or other advisers, employees or consultants to the CCG on matters of procurement for themselves to be in receipt of payments from pharmaceutical or other industry suppliers.

4.2. Context and guidance

There is an obligation on NHS bodies to work together, and in collaboration with other agencies, to improve the health of the population they serve and the health services provided for that population.

Collaborative partnerships with industry can have a number of benefits in the context of this obligation. It is important to have a transparent approach to any sponsorship/joint working proposed to the CCG and for the CCG to consider fully the implications of a proposed sponsorship/joint working deal before entering into any arrangement. If any such partnership is to work, there must be trust and reasonable contact between the sponsoring company and the NHS. Such relationships, if properly managed, can be of mutual benefit to the organisations concerned. However it is essential that pharmaceutical companies or other suppliers cannot influence, or be perceived to influence, CCG decision making.

In all cases, the CCG and its employees must publicly declare sponsorship/joint working or any commercial relationship linked to the supply of goods or services and be held to account for it, even if a sponsored activity occurred in an employee's own time.

Whatever type of agreement is entered into, a clinician's judgement must always be based upon clinical evidence that the product is the best for their patients.

5. Compliance with the Policy and Protocol

All staff and individuals identified in the scope of the Policy must comply with the flow diagram and templates set out in the Appendices. All those within the scope must be conversant with the details of the Policy and ensure it is followed and enacted by themselves and any staff they manage, including any third parties or contracted staff.

5.1. Luton CCG Sponsorship/Joint Working Protocol

Before entering into any sponsorship agreement the CCG will:

- Satisfy itself, with reference to information available, that there are no potential irregularities that may affect a company's ability to meet the conditions of the agreement or impact on it in any way, for example checking financial standing by referring to company accounts.

- Assess the costs and benefits in relation to alternative options where applicable, and to ensure that the decision-making process is transparent and defensible.

- Ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with; no information should be supplied to a company for their commercial gain. As a general rule, information which is not in the public domain should not normally be supplied.

- Determine how clinical and financial outcomes will be monitored.

Ensure that the sponsorship/joint working agreement has break clauses built in to enable the CCG to terminate the agreement if it becomes clear that it is not providing expected value for money and/or clinical outcomes.

Make clear that acceptance of commercial sponsorship will not in any way compromise commissioning decisions of the CCG or be dependent on the purchase or supply of goods and services. Sponsors should not have any influence over the content of an event, meeting, seminar, publication or training event. Sponsorship arrangements do not imply that the CCG endorse individual companies or their products.

5.2. The CCG will apply the following principles:

- Purchasing decisions, including those concerning pharmaceutical and appliances, will always be taken on the basis of best clinical practice and value for money. Such decisions will take into account their impact on other parts of the health care system, for example, products dispensed in hospital which are likely to be required by patients regularly at home.
- When making purchasing decisions on products which originate from NHS intellectual property, ethical standards will ensure that the standard is based on best clinical practice and not on whether royalties will accrue to an NHS body.
- Arrangements whereby sponsorship/joint working is linked to the purchase of particular products, or to supply from particular source, will not be allowed, unless as a result of a transparent tender for a defined package of goods and services.
- Patient information attracts a legal duty of confidentiality and is treated as particularly sensitive under Data Protection legislation. Professional codes of conduct also include clear confidentiality requirements. The CCG will assure itself taking advice when necessary, that sponsorship/joint working arrangements are both lawful and meet appropriate standards.
- Where a sponsorship/joint working arrangement permitting access to patient information appears to be legally and ethically sound (for example, where the pharmaceutical company is to carry out or support NHS functions, where patients have explicitly consented), a contract will be drawn up which draws attention to obligations of confidentiality, specifies security standards that should be applied, limits use of the information to purposes specified in the contract and makes it clear that the contract will be terminated if the conditions are not met. This must comply with the current legal position concerning sharing of Patient Identifiable Data (PID). Guidance must be sought from the CCG's Senior Information Risk Officer.
- Where the major incentive to entering into a sponsorship/joint working arrangement is the generation of income rather than other benefits, then the scheme should be properly governed by income generation principles rather than sponsorship arrangements. Such schemes should be managed in accordance with income generation requirements, i.e. they must not interfere with the duties or obligations of the CCG. A memorandum trading account should be kept for all income generation schemes and the Finance Department must be involved in making and conducting the agreement.

- Sponsorship/joint working arrangements involving the CCG will be at a corporate, rather than individual level, even if the activities concerned are to take place in an employee's own time.
- If publications are sponsored by a commercial organisation, that organisation should have no influence over the content of the publication. The company logo can be displayed on the publication, but no further advertising or promotional information should be displayed. The publication should contain a disclaimer which states that sponsorship of the publication does not imply that the CCG endorses any of the company's products or services.
- All CCG employees should discuss the implications, with their manager, before accepting an invitation to speak at a meeting organised by a pharmaceutical or other company. The company should have no influence over the content of any presentation made by the CCG employee. It should be made clear that the employee's presence does not imply that the CCG endorses any of the company's products or services. This also applies to interviews with CCG employees given live or published.
- The CCG will ensure that all sponsorship/joint working deals are documented through the use of a register held by the Assistant Director, Operations, which can be audited as appropriate. In order to demonstrate openness, the Register will be available on request to the public.
- In order to provide a robust framework to support successful implementation of this policy any proposals for sponsorship/joint working by the Pharmaceutical Industry, whether direct or indirect through an intermediary, should be reviewed and commented on by the Luton CCG Primary Care Prescribing Committee. The proposal and comments from the Prescribing Committee will then be considered and receive approval or non-approval from the Clinical Commissioning Committee. This process is encapsulated in the Pharmaceutical Industry Sponsorship/Joint Working Proposal Process Flow Diagram (Appendix B).
- Checklists 1&2 (Appendices C & D) should be populated by the appropriate lead usually the strategic implementation lead or work stream lead and submitted to the Medicines Optimisation Coordinator. The proposal is then considered at the CCG Prescribing Committee. The Prescribing Committee issue a recommendation on the proposal. The recommendation and the populated checklists are then considered by the Luton CCG's Clinical Commissioning Committee (CCC) for final approval.
- Point of contact for Pharmaceutical industry to Luton CCG: lutonccg.prescribing@nhs.net

6. Protocol for meeting with Pharmaceutical Company or other Industry Representatives

Healthcare professionals are not obliged to see a pharmaceutical or other industry sales representative and should never be afraid to decline a visit if they do not feel it is appropriate. However, information provided by the representative can be useful to gain an understanding of messages that may be being shared with GPs and prescribers. Pharmaceutical companies may have additional prescribing information that may prove useful to the local community. They also are able

to share certain details of new products prior to launch to allow forecasting impact within the CCG. They can also provide useful trial data and possibly resources.

Before agreeing to meet it is good practice to ask or consider the following:

- Ask the pharmaceutical sales representative which product they would like to discuss
- Assess how the product fits with local priorities
- Prepare for the meeting by researching the product
- Request further information from the representative if you need clarification or additional resources
- Defer making the appointment, if time is needed for reflection, to make further enquiries before making an informed decision.

Some questions you should ask or clarify in advance with the MO team:

- Is this product within my scope of expertise?
- How is this product more effective than the current product in use?
- How does the price compare with similar products?
- Do you have any details of other people to contact to obtain further information? (e.g. tissue viability nurse).

The proforma (Appendix F) is intended to be sent to all pharmaceutical representatives via MOT PA/Co-ordinator prior to arranging meetings. This will allow a standard, equitable response to meeting requests across the team. The requests from companies will be collated and forwarded to the most appropriate clinician in the team, who will complete the 'office use only' section and return to the PA/Co-ordinator. If further information is required this should be made clear on the form so that the PA/Co-ordinator can request it. The PA/Co-ordinator will arrange the meetings or phone calls, or request further information as required. The proforma will be updated as to the actions taken. Outcomes following the meeting should be relayed to the PA/Co-ordinator, and the proforma updated. A database will be created to record details of requests for meetings and meetings held. This will facilitate managing multiple requests from the same company or requests to meet different people within the team.

7. Primary Care Rebate Schemes

In recent years the number of rebates offered within primary care has increased. These rebate schemes are predominantly offered by medicines manufacturers as a way of reducing the effective price of a medicine to a CCG without affecting the list price. Companies may be reluctant to change the list price which is used as a reference for medicines pricing in other countries.

In order to provide assurance Luton CCG seeks external independent review of schemes. In 2012, the PrescQIPP NHS Programme established the Pharmaceutical Industry Scheme Governance Review Board, offering governance on behalf of PCTs. This has developed to be the largest governance provider on behalf of CCGs in England, Health and Social Care Board Northern Ireland and the Health Boards of Wales.

The Pharmaceutical Industry Scheme Governance Review Board has been created by PrescQIPP in response to requests by CCGs to provide guidance as to the acceptability of Primary Care Rebate Schemes being offered to the NHS by the pharmaceutical industry. As a subscriber to PresQIPP Luton CCG has access to this guidance.

The Review Board's role in the governance process will be to comprehensively assess these schemes, outlining issues, and inappropriate Schemes.

Schemes offered by the pharmaceutical company will be considered by the Luton Primary Care Prescribing Committee with reference to the Review Board assessment. Schemes not assessed by the Review Board will not be considered by the Luton CCG without taking legal advice.
The Head of Medicines Optimisation will sign the rebate schemes on behalf of the CCG for schemes approved by the Prescribing Committee and authorised by the Audit and Risk Management Committee*. The Medicines optimisation team will monitor on an on-going basis and liaise with finance team to manage financial elements including invoicing arrangements.

Appendix A: The 7 Principles of Public Life (The Nolan Principles)

The Seven Principles of Public Life, known as the Nolan Principles, were defined by the Committee for Standards in Public Life . They are:

Selflessness Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends.

Integrity Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

Objectivity In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

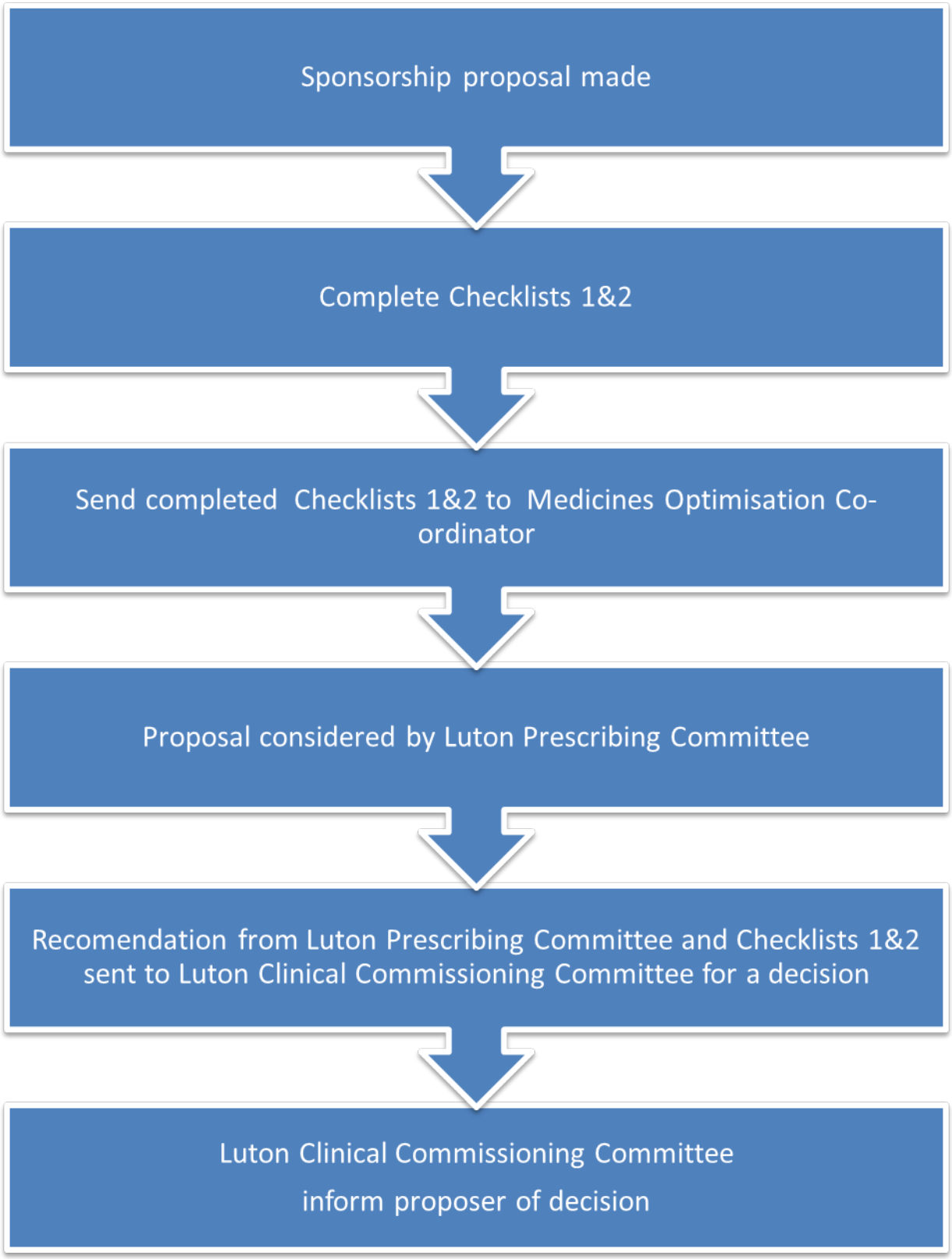
Openness Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands it.

Honesty Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership Holders of public office should promote and support these principles by leadership and example

Appendix B: Pharmaceutical Industry Sponsorship/Joint Working Proposal

Pharmaceutical Industry Sponsorship/Joint Working Proposal
PROCESS FLOW DIAGRAM



Appendix C: Pharmaceutical/Industry Sponsorship Joint Working Checklist

To be completed by the CCG lead for the particular proposal + the pharmaceutical/industry company representative

Contact Details NHS	• Organisation: • Name (lead for proposal): • Contact email: • Contact number:
Contact Details Pharma/Industry	• Organisation: • Name: • Contact email: • Contact number:
Sponsorship/Joint Working Proposal	• Type of Sponsorship/Event • Amount of Funding • No of Practices involved • Benefits to NHS & Patients (include clinical & financial outcomes) • Benefits to Company • Duration of sponsorship/joint working (clarity on how and when sponsorship/joint working ceases) • Are there any potential irregularities that might affect the Pharma company ability to meet the conditions of the agreement • Summary of Sponsorship
Any further Information	
Signatures & Designation	• Luton CCG Lead for Proposal signature: • Designation of above: • Pharma Representative signature: • Designation of above:

Appendix D: Pharmaceutical/Industry Joint Working Sponsorship Checklist 2

To be completed by the CCG lead for the particular proposal

Proposal	• Can the aims and objectives in the proposal be realised within the CCG? • If Yes to above - what are the reasons for working with the pharmaceutical/ industry? • If No to above - what are the reasons for working with the pharmaceutical /industry? • Is the proposal consistent with the commissioning priorities of the CCG? • Is there a similar service available from another source? • Are the skills, competencies, professional status and qualifications of the named individuals who will be directly involved in the proposed sponsorship programme of a sufficient level to achieve the aims and objectives effectively, efficiently, reliably and safely?
Information Governance	• Are IG requirements met, is the proposal lawful and does the proposal meet ethical and IG standards?
Evidence **(where the sponsorship involves the use of a device, appliance or drug)**	• Does the proposal include the use of a pharmaceutical product either directly or indirectly? • If yes to above- what is the pharmaceutical product? • Is the pharmaceutical product supported by evidence? • If yes to above- what is the quality of the evidence? • Does there need to be a tendering process?
Presentations at events	• Will the pharmaceutical company be presenting at an event? • If yes to above - is there an agreement that the CCG will see and agree the presentation before?

Appendix E: NHS Luton CCG Committees' Recommendation and Approval Form

Luton CCG Prescribing Committee

Outcome	
Proposal:	
Date of Committee:	
Recommendation:	

Luton CCG Clinical Commissioning Committee

Outcome	
Proposal:	
Date of Committee Meeting:	
Approved/Not approved	
State if any additional information required	

Appendix F: Pharmaceutical or other Industry Meeting Request Form

- Each meeting will last for 30 minutes unless pre-arranged for longer
- The meeting will be with the team member who leads in the therapy area
- Completion of this proforma does not guarantee a meeting
- Meeting requests will be prioritised based on CCG priorities
- Horizon scanning of products likely to have volume or cost impact will also be prioritised
- Only one product/issue will be discussed per meeting.

Your name:	
Company name:	
Contact telephone and email:	
Have you seen a member of the MOT before?	
Have you seen other members of CCG staff relating to this product/service?	
Have you or representatives met or visited GP practices regarding this issue?	
What is the nature of your request?	
Is your visit regarding a new service or product?	
If yes, what is the service offer or product's name?	
Does your product or service have a cost implication to NHS Luton CCG and if so how much?	
How can your product benefit the patients of Luton?	

Any additional comments? Please feel free to add further evidence	
Will you be bringing a colleague with you? Please give name and role.	

Office use only	
MO team advice sought/ given	
Need to meet in person	
Need telephone call	
Written communication needed	
Further information required	
No action needed	
Other	

Review and Amendment Log

Version	Date	Author	Revision Description
1.0 Final Draft	15 October 2013	Head of Medicines Optimisation	New stand-alone policy
1.1	22 October 2013	Head of Medicines Optimisation	Amendments following LCCG Board discussion.
1.2	1 June 2016	Chief Officer	Revised in line with new statutory guidance 'Managing Conflicts of Interest – Statutory Guidance for CCGs' published as an update April 2016, NHS England
1.2	24 June 2016		Update following review by Prescribing Committee
1.2	01 August 2016		Update following receipt of final statutory guidance
2	22 August 2016	Assistant Director	Reformat at version 2 ready for ratification

Version	Date	Approved by:
1	**22nd October 2013**	**LCCG Board**
2	**6th October 2015**	