Walsall Clinical Commissioning Group

Policy for Commercial Sponsorship and Joint Working with Pharmaceutical Industry

The NHS Walsall CCG Safety Quality and Performance committee SQP Approved this on:

Date: ……

Signed: ……
Chair of the committee

Signed: ……
Designated Strategic Lead

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The footer must give the file name and pathway of the master version of the policy, page of page number and the title of the policy

Document reference information

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Monitoring Compliance and Effectiveness	Monitoring and updates through the medicines management team
References	All procedural documents must include an accurate list of references used when compiling a document – page 17

The topics covered in the grey shaded area above can be kept in this table but if the narrative for them is lengthy then it is best if they are put into the main body of the document.

CONTRIBUTION LIST

Key roles involved in developing the document

Designation
Head of Medicines Management and Primary Care
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Circulated to the following for consultation

Committee/Group	Designation
Medicines Management Committee	
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Version Control Summary

Significant or Substantive Changes from Previous Version
A new version number will be allocated for every review even if the review brought about no changes. This will ensure that the process of reviewing the document has been tracked. The comments on changes should summarise the main areas/reasons for change.

When a document is reviewed the changes should using the tracking tool in order to clearly show areas of change for the consultation process.

Version	Date	Comments on Changes	Role
V1.0	July 13		

A contents page must be included for documents where the main body of the document is over 3 pages long.

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1. INTRODUCTION

The New NHS: Modern and Dependable places an obligation on Primary Care Trusts (PCTs) to work together and in collaboration with other agencies to improve the health of the population served. Commercial companies, especially manufacturers of drugs, dietetic products and dressings increasingly seek to work in collaboration with NHS service providers. The move towards a primary care-led National Health Service, the new GMS contract and an increasing range of health professionals being given prescribing rights also mean that more individuals can expect to be approached by representatives of the pharmaceutical industry.

All NHS staff have a duty to ensure that all their dealings adhere to the public service values of accountability, probity and transparency. This policy aims to ensure that all staff respond consistently to approaches from the Pharmaceutical Industry and that the interests of patients are maintained whilst utilising public funds to the best advantage and ensuring value for money.

This policy applies to all directly-employed CCG staff as well as self employed sessional staff for example practice support pharmacists. This also includes independent contractors and locum practitioners, GP Localities., PMS, NHS-Direct, Walk-in centres.

Values

In line with the NHS Code of Conduct (reference) 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; agreements should include arrangements for monitoring and evaluation.*

• ***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*

2. DEFINITION OF COMMERCIAL SPONSORSHIP

Commercial sponsorship can be defined as NHS funding from an external source to **include** funding of all or part of the cost of:

- Staff
- NHS research
- Training and staff development
- Pharmaceuticals (Medicines and products including dressings & dietetic products)
- Equipment
- Servicing / calibration of equipment
- Meeting rooms
- Costs associated with meetings
- Meals
- Gifts
- Hospitality
- Hotel and transport costs (including trips abroad)
- Provision of free services (eg speakers)
- Buildings or premises

Sponsorship can't be used for the funding or hospitality of CCG commissioning meetings.

3. GENERAL PRINCIPLES

3.1 Code of Practice

This guidance is in addition to personal and professional standards required by professional Codes of Conduct such as those issued by GMC, RPSGB, GDC, RCN, NMC etc.

CCG Trust Staff and Independent Contractors and their staff (GP practices, community pharmacies, dentists and opticians) working within Walsall CCG are expected to:

- Act impartially in all their work
- Declare and register gifts, benefits or sponsorship of any kind, which have been accepted. The register, which can be audited as appropriate, must be available to the public. The gift as a low value promotional aid is one that has cost the donor company no more than £10, excluding VAT. *(PMCPA Quick Guide to the code for health professionals)* ***See appendix 4*** *– register of gifts and hospitality page 23.*

Modest hospitality provided it is normal and reasonable in the circumstances, e.g. lunches in the course of working visits, may be acceptable, though it should be similar to the scale of hospitality which the NHS as an employer would be likely to offer.

Hospitality should only be provided within the CCG when meetings involve senior officers from external organisations. Internal meetings should not be provided with hospitality.

- Refuse gifts, benefits, hospitality or sponsorship of any kind that might reasonably be seen to compromise their personal and/or professional judgement or integrity. All such gifts should be returned and hospitality refused. Unacceptable gifts also include those for use at home. Records of gifts, benefits or sponsorship refused would be regarded as good practice. All cash gifts must be refused. Declare and record any financial or personal interest (e.g. company shares, research grant) in any pharmaceutical company or 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.
- Report any offers of sponsorship that could possibly breach the ABPI Code of Conduct to the CCG Board via the Medicines Management Committee.
- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others
- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services.
- Beware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality.
- Ensure that sponsorship does not imply endorsement of any product or company
- Neither agree to practice under any conditions that compromise professional independence/judgement, nor impose such conditions on other professionals.

3.2 Patient Interest

The interests of patients, individually and collectively are paramount, and should have been taken into account

3.3 Openness & Ethical Issues

Any agreement entered into should be open and transparent, with agreed aims and objectives

Conflicts of interest should be identified and resolved prior to entering into any agreement

3.4 Patient and data confidentiality

Any agreement should comply with legal and ethical requirements for the protection and use of patient information, and other NHS information. Where people external to the NHS are accessing patient information without the patient's consent this is a breach of confidentiality & may not be in the best interests of patients.

Under Caldicott Guardian regulations identifiable data (i.e. data where the identity of the patient can be ascertained) can only be released if all of the following criteria are fulfilled:

- the patient has given explicit consent
- the information is required for a valid purpose
- the users of the information handle & store it to protect confidentiality & will not release it to a third party.

(Where non-identifiable data are released patient consent is not required.)

3.5 Legal Issues

The intended agreement must be lawful

3.6 Accountability

The NHS parties should be accountable for any agreement, and agreements should include arrangements for monitoring and evaluation
Schemes should be agreed at a corporate rather than at an individual level

3.7 Financial Issues

Agreements should represent good value for money for the NHS, including being compatible with national arrangements for the prescribing and dispensing of medicines, and with the CCG Standing Financial Instructions
Schemes must not be linked to the purchase or supply of particular products

3.8 Fairness

No one organisation should be given preferential treatment, or competitive advantage
Schemes that provide access to sensitive or confidential information that would give an advantage to a pharmaceutical company over their competitors must be avoided
The usual tendering procedure must be followed where appropriate.

3.9 Probity

Where financial payment forms part of an agreement between a NHS organisation and the pharmaceutical industry (e.g. payment for clinical research studies), audit arrangements should be detailed within the agreement and should be such that probity is ensured

4. JOINT WORKING

4.1 Principles of Joint Working

In joint working, goals are agreed jointly by the NHS organisation and company, in the interest of patients, and shared throughout
the project. In an open and transparent manner.

Joint working can be considered an opportunity but must be for the benefit of patients or of the NHS and preserve patient care. A joint working agreement is drawn up and management arrangements conducted with participation from both parties

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 CCG supports the Department of Health Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry defines **joint working** as *situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner.* Joint working differs from **sponsorship**, where pharmaceutical companies simply provide funds for specific event or work programme.

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.

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 extant NHS guidance
- Joint working will be conducted in an ethical, open and transparent manner
- 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 a corporate, rather than an individual, level
- Clinical and financial outcomes will be assessed through a process of risk assessment
- In the interests of transparency, the overall arrangements must be made public, although parties should consider which parts of the Joint Working arrangements are commercially sensitive

4.2 Benefits of Joint working

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.

The criteria should be set against:

- Meet patient and NHS needs
- Be most accessible
- Provide sustainable clinical benefits
- Be highly cost effective

4.3 Examples of Joint working

A joint working Project may comprise of a number of activities including, but not limited to, the following:

- Staff training
- Staff and/or patient education
- Nurse services
- Facilitation of pathway redesign
- Support for guideline implementation
- Funding of project staff requirements such as administrative, clinical staff

- Secondments
- Audits

4.4 Governance of Joint working

Any joint working between the Pharmaceutical Industry and the NHS must be conducted in an open and transparent manner. This will include entering into appropriate Joint Working agreements, establishing steering groups and consulting with relevant stakeholders about each particular project.

The discussions and agreements should take place at an appropriate organisational level within the NHS, such as the SQP / IOB Board, or Trust health Board and the pharmaceutical company's senior manager or director level.

4.5 Measuring Joint working

The outcome of every Joint Working project should be measured. Depending on the project, a set of baseline measurements should be established at the outset of the project to track and measure the success of the project aims in particular patient outcomes.

- Measurement should be shared between the NHS and the pharmaceutical company as appropriate
- For longer term projects (>1 year) patient outcomes should be analysed at least every 6 months as a minimum to ensure that anticipated patient benefits are being delivered
- Measurement should be conducted at a suitable level within the company to avoid the impression that local sales personnel are unduly influencing a Joint Working project
- If measures relate to changes in the use of one or more medicine(s) in accordance with appropriate local/national guidance, then the change can be used to estimate the potential benefit to patients and the NHS

There are examples of how the outcomes/successes of Joint Working projects maybe measured in the ABPI document – *guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients – March 2009*

4.6 Joint working Agreements

Every Joint Working project should have a formal, written document in place setting out what each party has agreed before the project begins. The precise nature of such documents will be determined by the particular project and the parties involved. Templates for written agreements and business cases can be accessed via the toolkit – moving beyond sponsorship available on the DoH website .

Any agreement should clearly state the following:

- The name of the Joint Working project, the parties to the agreement and the date and the term of the agreement

- The expected benefits to patient, the NHS and the pharmaceutical company. Patient benefits should always be stated first and patient outcomes should be measured
- An outline of the financial arrangements
- The agreement should clearly indicate the roles and responsibilities of the NHS and the pharmaceutical company. How successes will be measured, when and by whom. This should include aspects of training, support for service redesign and business planning.
- There should be specific procedures for dealing with Freedom of Information Act requests
- The agreement should include arrangements to cover unforeseen circumstances such as changes to summarises of products characteristics and updated clinical guidance.
- Companies must make public an executive summary of their Joint Working agreements.

4.7 Disengagement / Exit Criteria

Clearly defined, mutually agreed exit criteria must be written into Joint Working agreements at the outset.
Clear and defined end points in relation to timings, resources and budget commitments and outcomes will facilitate disengagement / exit from a project.

During the course of the Joint Working project, if either party fails to deliver on it commitments the other party is free to exit or renegotiate and take reasonable steps to recoup its investment. This should be defined fully at the outset.

Either party should be free to exit an agreement if it is highlighted that patients are not benefiting from the project and must do so if the project is detrimental to patients.

Joint Working agreements should not be terminated by a pharmaceutical company solely on the grounds of a negative return of investment or a decline in their medication items.

4.8 Commercial and confidence Issues

Joint Working projects may in some cases involve more than one pharmaceutical company so competition and commercial issues may arise. Each company will and should seek its own advice to ensure that it complies with competition law and enters appropriate confidential agreements.

They should provide written agendas for meetings and detailed minutes of meetings that have already been held.
The terms of reference of a Joint Working steering group should be discussed and fully agreed by the pharmaceutical company(s) and the NHS Trust taking part in the project.

5. HOSPITALITY AND MEETINGS

Obligations relating to the provision of inducements and hospitality are placed on the pharmaceutical industry and health professionals by the Medicines (Advertising) Regulations. These are self regulated by the PMCPA through the ABPI.

- Industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have been incurred.

- The level of hospitality offered must be in proportion to the occasion, not exceeding that which recipients would normally pay for themselves or expect to be reciprocated by the NHS.

- Where initiatives are in areas where more than one company has an interest, any support should involve more than one sponsor.

- Where CCG meetings & events are sponsored by the pharmaceutical industry this fact must be disclosed in the papers relating to the meeting and in any published proceedings.

- The CCG reserves the right to exclude industry representatives from the content of the meeting.

- Any stand used by the industry to promote products is to be outside any meeting room where practical

- Any promotional activity by the sponsor must be consistent with the Walsall formulary or any local clinical management guidelines

- Payments may not be made to doctors or groups of doctors, or GP Practices, either directly or indirectly, for rental of rooms to be used for meetings

- A decision to attend meetings organised or sponsored by the pharmaceutical industry, in the UK should be based on the programme and not the associated hospitality or venue. Meeting held outside the UK must have good supporting reasons for being held abroad. Cost saving is, in itself, not seen as sufficient justification for an oversees meeting.

- The meeting must have a clear educational content & hospitality must be secondary to the purpose of the meeting.

- Sponsorship of or attendance by company representatives at CCG commissioning meetings **is NOT allowed**; meetings must primarily educational or for professional development in nature. It is not acceptable for a representative to make a short presentation in an attempt to comply with his requirement.

- Meals and drinks must be secondary to the purpose of the meeting and not out of proportion.

- Hospitality must not extend to a spouse, partner or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant in their own right.

- Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense. Their entire costs are the responsibility of those they accompany.

6. INDIVIDUAL MEETINGS WITH REPRESENTATIVES

Staff must not ask for, or accept fees or material gifts for agreeing to meet with representatives of the pharmaceutical industry.

Ideally, meetings should be pre-booked, with the purpose of the meeting, expected time required and names of those attending stated beforehand. Any materials to be discussed should be sent to the health professional/s before the appointment if possible.

7. PROVISION OF SAMPLES

Samples of pharmaceutical products including medicines, dressings, dietetic products, should ideally not be accepted. Representatives of the Pharmaceutical Industry should not be permitted to leave samples in General Practice surgeries, clinics or health centres.

In some cases a small supply of a medicine is provided to a healthcare professional so that they may familiarise themselves with it and acquire experience of dealing with it.

No more than ten samples of a particular medicine maybe provided to an individual during the course of a year. However samples may not be provided of any product which has been on the market for more than ten years. Samples may only be supplied in response to written requests that have been signed and dated and the company must keep records of this for at least one year.

This does not cover starter packs. These are designed to be used when there maybe a delay in initiating treatments and is limited to analgesics, antibiotics and such like. The quantity of medicine in this case has to be modest.

8. TRAINING

Employers should be careful to ensure that staff are not pressurised by sponsors of training, to alter their own activity in accordance with the sponsor's wishes, when this is not backed up by the appropriate clinical evidence or national guidance.

Participants should ensure that any suggested change in practice is supported by appropriate evidence, and that they are not unduly influenced by the sponsors.

Pharmaceutical company sponsorship for professional training should only be accepted if it can be assured that such training is in line with CCG/ practice and national policy and has been identified through a training needs assessment.

9. SPONSORSHIP OF HEALTH-PROFESSIONAL POSTS

The post-holder must be informed that the post is subject to sponsorship and the name of the sponsor.

Request for information by the sponsor must be made directly to the CCG and not to the post-holder. Responsibility for collation and disclosure must not involve the post-holder.

Sponsorship should not be accepted if it would require a health-professional to recommend the sponsor's product in preference to other clinically appropriate products, or if it requires the patients to use a particular service. Health-professionals should not withhold information about other products.

10. PURCHASING DECISIONS

Purchasing decisions, including those concerning pharmaceuticals and appliances, should always be taken on the basis of best clinical practice and value for money. Such decisions should 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 must ensure that the standard is based on the best clinical practice and not on whether royalties will accrue to an NHS body.

If there is competition in the market place, a tendering process shall be undertaken as defined by the standing, financial instructions of the PCT.

11. CLINICAL GUIDELINES AND FORMULARIES

Help from a pharmaceutical company in preparing the contents of a formulary or clinical guidelines should be declared. All relevant manufacturers should be approached for funding of printing costs. Industry logos or company names should not appear on printed documents.

Clinical aspects must always be under local control. The development of guidelines or protocols will be through a local group, although they may decide to use or adapt information produced elsewhere.

This applies to locally CCG and practice developed guidelines and formularies as well as those developed jointly between primary and secondary care.

12. RESEARCH AND DEVELOPMENT (see Appendix 1 for additional detail)

All research protocols (commercial and non-commercial) must be approved by the Local Research Ethics Committee.

Health professionals involved in sponsored research should have no financial interest in this, nor should patients under their care. They should not advertise the availability of their own or colleagues' patients for use as research subjects (RCP guidance). Results of sponsored studies may be published in a journal of the health professional's choice but should acknowledge the support of the sponsoring healthcare company. The company should not seek to influence the results of the study.

Medical staff should follow the guidance (Research: The role and responsibilities of doctors) recently issued by the General Medical Council.

13. CHARITABLE FUNDING

Trustees should take steps to remove any non-charitable items within charitable trust fund accounts. Examples include drug trials undertaken directly by a consultant and supported by funding from non-official sources (i.e. not part of the R&D programme managed by the provider). Not all consultant drug trials are non-charitable (see NHS Charitable Funds: A Guide", published by the Charity Commission), but, where they do not have charitable status, they should be removed from the charitable trust fund accounts. If the drug trial contract is made between industry and the CCG, then the transaction should be recorded as a normal income generation scheme. In other cases, the CCG should consider other options including the transfer of responsibility back to the consultant concerned.

14. IMPLEMENTATION OF THE POLICY

14.1 DETAILS OF COMMERCIAL SPONSORSHIP

Declarations
All CCG employed Staff, those working under a service level agreement and Independent Contractors and their staff (GP practices, community pharmacies, dentists and opticians) working within Walsall CCG, have a duty to ensure that all their and the practices should maintain details in order that they may declare commercial sponsorship by all staff directly employed by the CCG or other CCGs working in the CCG area, partners & staff employed by the practice. The form to be used in this process is located on pages 16 and 17 (Appendix 2) of this policy.

A copy of completed form should be forwarded to the Medicines Management Team –, Jubilee House, Bloxwich Lane, Walsall.

A copy should be kept within the practice / base for audit purposes.

An electronic data base will be kept of all declarations and details. This will be made available if required to the medicines management committee, Board meetings and on the tPCT Intranet.

14.2 PROCEDURE FOR SPONSORSHIP REQUESTS within the CCG

A proposal form and agreement **(attached-Appendix 2 (page 20 and 21) and available on the CCG Intranet)** should be completed for each request for commercial sponsorship within directly managed services of the CCG. **A copy of completed form should be forwarded to the Head of Medicines Management and Primary Care Walsall CCG, Jubilee House, Bloxwich Lane, Walsall.**

All applications will be considered by an approval panel. This panel will consist of representation from the medicines management team, CCG governance lead and CCG clinical lead.

A copy should be kept within the practice / base for audit purposes.

Any breach of the policy will be forwarded to the CCG Safety and Quality Performance (SQP).

14.3 CONTRACTS FOR MAJOR COLLABORATIVE PROJECTS

For major collaborative projects, written contracts should be in place. **Refer to section 4 – Joint Working Information**. Any contract must draw attention to the obligations of confidentiality and specify security standards that should be applied. The contract must also limit the use of the information to the purpose specified in the contract, and make it clear that the contract will be terminated if these conditions are not met.

The contract should make clear that funding will only be accepted when a detailed written agreement has been accepted and signed by both sides. This would include:

- Contact names on both sides
- Expected outcomes and outputs
- Monitoring and enforcement of the agreement and provision of progress reports
- An opt-out clause for both parties
- Procurement of legal advice maybe necessary for major projects
- All joint working should be discussed within the CCG management team

15. REFERENCES & FURTHER INFORMATION

- Department of Health. The new NHS: Modern and dependable. Cm 3807. London: Stationery Office; 1997
- Commercial Sponsorship: Ethical standards for the NHS (2000)
- The Medicines (Advertising) Regulations 1994(SI 1994 No 1932).
- General Medical Council. Research: The role and responsibilities of doctors. The Council: 2002
- Royal Pharmaceutical Society's Guidance for Pharmacists (on working with the pharmaceutical industry); 2000
- Association of the British Pharmaceutical Industry. Code of Practice for the Pharmaceutical Industry. London: The Association; 2003
- The Surgical Dressing Manufacturers Association (SDMA). Code of Practice. January 2000
- Prescription Medicines Code of Practice Authority (PMCPA) – ABPI; 1993
- Nursing and Midwifery Council. Code of professional conduct. Protecting the public through professional standards. London: The Council; 2002
- The protection and use of patient information. HSG(96)18. Leeds: NHS Executive; 1996.
- Corporate governance in the NHS: code of conduct; code of accountability. London: Department of Health; 1994
- NHS Charitable Funds: A Guide – published by the Charity Commission
- Report from the Royal College of Physicians (RCP) "The relationship between physicians and the biomedical industries", Bennett J & Collins J, *Clinical Medicine* 2002 2:320-322.
- BMJ issue 7400: "Time to untangle doctors from drug companies" various articles (May 2003).
- **http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840**
- ABPI document – Joint Working – A quick start Reference Guide for NHS and Pharmaceutical Industry Partners – May 2012 http://www.abpi.org.uk/our-work/library/guidelines/Pages/joint-working-handbook.aspx
- PMCPA – Quick guide to the code for health care professionals
- ABPI guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-guidance.aspx March 2009
- Moving beyond sponsorship Joint working with the NHS and the Pharmaceutical industry **http://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf**

Acknowledgement is made to the following PCTs for access to their current or draft Commercial Sponsorship Policies:

- Dudley CCG
- East Kent Coastal and Canterbury & Coastal PCTs
- Heart of Birmingham Teaching PCT
- Sandwell PCT

- Staffordshire Moorlands PCT
- Wolverhampton City PCT
- City & Hackney PCT
- Westminster PCT

Appendix 1 – RESEARCH AND DEVELOPMENT

(1) Exceptionally, in the case of non-commercial research and development (R&D) originated or hosted by NHS providers, commercial sponsorship may be linked to the purchase of particular products, or to supply from particular sources. This should be in accordance with the guidance at paragraph 28 of HSG(97)32 *Responsibilities for meeting Patient Care Costs Associated with Research and Development in the NHS.1* Where there is industry collaboration in such studies, companies may alternatively make a contribution towards the study's costs, rather than supply of product.

(2) Any funding for research purposes should be transparent. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, the CCG will wish to consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended.

(3) Separate Guidelines exist for pharmaceutical company Sponsored Safety Assessment of Market Medicines (SAMM) which remain in force.

(4) Where R&D is primarily for commercial purposes, NHS providers are expected to recover the full cost from the commercial company on whose behalf it is carried out. (HSG(97)32, paragraph 7). An industry-sponsored trial should not commence until an indemnity agreement is in place; see the guidelines in HSC(96)48 *NHS Indemnity, Arrangements for Clinical Negligence Claims in the NHS* . A standard form of indemnity agreement, agreed with ABPI, can be found at Annex B of that guidance.

(5) The NHS should benefit from commercial exploitation of intellectual property derived from R&D that the NHS has funded, or for which it has been funded, even where the intellectual property itself is owned by people outside the NHS. The CCG shall ensure that an agreement to this effect is included in any contracts concerning R&D. The guidelines in HSC 1998/106 *Policy Framework for the Management of Intellectual Property within the NHS from R&D* should be followed.

1 - Paragraph 28 of HSG(97)32 states: At present, industry frequently contributes to the costs of pharmaceuticals (and other products), which are the subject on non-commercial R&D in the NHS. Although, by definition such items constitute Treatment Costs, the NHS will continue, under the Partnership Arrangements, to look to researchers and non-commercial research funders to secure such contributions before approaching the NHS for support.

Appendix 2

Proposal & Agreement for Commercial Sponsorship

This form should be completed for each request for commercial sponsorship within directly managed services of the CCG.

A copy of completed form should be forwarded to the Head of Medicines Management and Primary Care at Walsall CCG, Jubilee House, Bloxwich Lane, Walsall.

A copy should be kept within the practice / base for audit purposes.

Any breach of the policy will be forwarded to the CCG Safety and Quality Performance Committee (SQP).

1. Name and contact details of the person applying for sponsorship	
2. Name and contact details of the sponsoring pharmaceutical company/ies	
3. Project / meeting/ training event title	
4. Project aims and objectives (training event learning outcomes)	
5. Training event programme	
6. Description of how funding is to be used and other sources of funding/resources	
7. Project applications only :-	**ONLY COMPLETE DETAILS BELOW IF PROJECT APPLICATIONS – FULL DETAILS REQUIRED**
• *Description of how the project will be conducted*	
• *Outline of any issues of patient confidentiality*	
• *List of clinical responsibility and accountability*	
• *List of outcomes to be measured*	
• *List of potential conflicts of interest*	
• *Outline how the data will be used and by whom*	
• *Explanation how the project fits in with the CCG commissioning priorities*	
• *Identification of any knock-on implications for health care (e.g. demand for lab tests)*	
• *List of persons accountable for the project*	
• *List of persons involved in managing the project*	
• *Identification of recurrent costs from the project and who will be*	

responsible for these.	
• Outline of the Intellectual Property arrangements have been discussed and agreed.	

Agreement for Sponsorship

1. *(The company)* may only be involved (*to the extent defined in this agreement*) consistent with the CCG principles for working with the pharmaceutical industry
2. *(The Company) agree to be compliant with the CCG information governance policy and procedure.*
3. Any reports resulting from the audit work will acknowledge *(the company's)* contribution
4. Such reports will be used for the purposes described above. *(the company)* cannot use the report or information from this work without explicit permission from Walsall CCG.
5. Where a training event organiser considers additional value may be gained from a presentation by (*the company*), that the content of the material is agreed in advance of the meeting
6. (*The company*) agree not to use Walsall CCG contact to promote products outside any training event
7. The organiser retains overall control of the event
8. (*The company*) does not have a right to present teaching material
9. Any stand (*the company*) uses to promote products is to be outside any meeting room where practical
10. Attendance at a training event by (*the company*) is at the discretion of Walsall CCG.
11. Where course material is provided by (*the company*), that there is no promotion of specific products (the name of the company supporting the training event is acceptable)
12. Names, Designation and Signatures:

Name…….

Title ……

Signature……..Date: ……
On behalf of Walsall CCG

Name …….

Title……

Signature…….. Date: ……
On behalf of Pharmaceutical/Commercial Organisation

Appendix 3

DECLARATIONS OF INTEREST FORM

Name:	
Job Title:	

Have you, or anyone in your family, any financial or other interest in any pharmaceutical manufacturer or supplier that may constitute a real, potential or apparent conflict of interest	**Yes**	**No**

Employment/involvement with a pharmaceutical company or other provider organization	**Have you had, during the past 4 years, any employment or other professional relationship with any organization that is a pharmaceutical supplier or that supplies other goods or services to the Walsall Healthcare Economy (e.g. CCG, Acute Trust, Community Services or Mental health Trust Nil Returns must be submitted.**
Direct employment – current or previous	
Appointments (voluntary or otherwise) e.g. trusteeships, directorships, positions of office including community pharmacies	
Membership of any professional bodies, special interest groups or mutual support organizations	
Other fee-paid work including speaking, chairmanship or advisory groups	
Shareholdings / Investments in pharmaceutical or provider companies	
Gifts or hospitality offered (accepted or not) except that allowed under the ABPI Code of Practice	
Any other conflicts that are not covered by the above	

To the best of my knowledge, the above information is complete and correct.
I undertake to update as necessary and to review the accuracy on at least an annual basis. I will declare any conflict of interest which arises at a meeting including any that I have not previously declared on this form.

Signature:	
Date:	

Walsall Clinical Commissioning Group

Walsall Clinical Commissioning Group

Appendix 4

REGISTER OF GIFTS AND HOSPITALITY

Ref No	Details of Hospitality and/or Gift(s)	Date	Recipient and Job Title	Sponsor	Estimated value of sponsorship	Accepted/Rejected
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

You must register all gifts over £10 and hospitality over £25 on this form and return to the Administrator to the Governing Body. Serena.Causer@walsall.nhs.uk please copy in your Strategic Lead

All cash gifts must be refused.

Gifts up to the value of £10.00 may be accepted providing they are not seen as compromising the integrity of individuals or the CCG

Appendix 5

Summary of the Policy for Commercial Sponsorship & Working with the Pharmaceutical Industry

All CCG Staff (including Community staff) and Independent Contractors and their staff (GP practices, community pharmacies, dentists and opticians) working within the Walsall area, have a duty to ensure that all their dealings adhere to the public service values of accountability, probity and transparency. This policy aims to ensure that all staff respond consistently to approaches from the Pharmaceutical Industry and that the interests of patients are maintained whilst utilising public funds to the best advantage and ensuring value for money.

- Before entering into any arrangements with a commercial sponsor, consider exactly what is being offered and what will be the potential benefits for patients & for the organisation.

- Do not rely on information provided by the Pharmaceutical Industry as your sole source of evidence. The Medicines Management Team, which includes the Head of Medicines Management, Prescribing Advisors and Practice Pharmacists have access to independent sources of evaluated information and can provide advice & support.

- Ensure that the proposed outcomes from any Joint Working project are clear & outcomes can be fully evaluated

- Refuse sponsorship of any kind that might reasonably be seen to compromise professional judgement or integrity. Always ask the question "Are you willing to have these arrangements generally known"

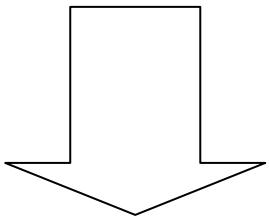
- Ensure that any access to patient information is in accordance with the Data Protection Act. Remember that any searches on practice computers relating to prescribing also allow access to other patient data. Where people external to the NHS are accessing patient information without the patient's consent this is a breach of confidentiality & may not be in the best interests of patients.

- Ensure all details of commercial sponsorship and support from the Pharmaceutical Industry is maintained so that it may be declared if needs be to the Medicines Management Committee within the CCG.

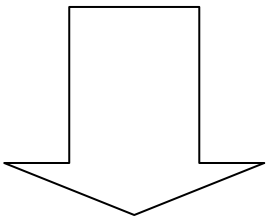
- All sponsorship requests within directly managed services of the CCG should be forwarded to the Head of Medicines Management and Primary Care & will be reviewed and discussed by the appropriate review panel and feedback to the Medicines Management Committee. A regular report will be presented to SQP detailing the benefits and outcomes following any joint working activity.
- **Appendix 6**

Summary of sponsorship process

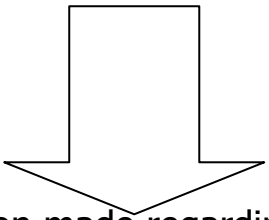
Application of proposal and agreement of commercial sponsorship completed



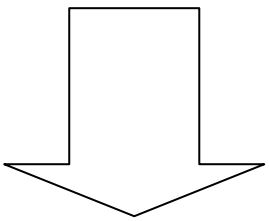
Application sent to Head of Medicines Management and Primary Care



Application considered by panel consisting of representation from medicines management, CCG governance lead and CCG clinical lead



Feedback on the decision made regarding the application



Applicant given the opportunity to amend the application form following the decision made. This may include e.g. further clarity regarding outcomes