NHS
Waltham Forest
Clinical Commissioning Group

Working with Industry policy

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30.10.2017	3	Updated references and minor amendments		WF CCG Medicines Optimisation Team
05.10.2015	2	1)A complete review of the policy and the addition of guidance relating to pharmaceutical samples 2) Amendment to page 5 relating to the difference between joint working and sponsorship	Incorporates guidance around sample	NELCSU Medicines Management, Waltham Forest
20.8.2013	1			NELCSU Medicines Management, Waltham Forest

Document approval

Date	Version	Revision	Role of approver	Approver
08.11.2017	3			Medicines Optimisation Committee
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Contents

1. Introduction

DH Guidance[1] encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical/commercial 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 NHS document „"*Commercial Sponsorship - Ethical Standards in the NHS* "[1] requires development of local arrangements in relation to commercial sponsorship within a national framework. This document recognises that there can be mutual benefit in sponsorship arrangements with organisations external to the NHS, but only if they are agreed within a framework with the necessary safeguards and checks.

This policy is underpinned by, and should be read in conjunction with, the documents listed in the references.

2. Definition of Joint Working

Joint working is a relatively new concept and differs from the traditional practice of sponsorship. The DH "*Best Practice Guidance on Joint Working between the NHS and the Pharmaceutical Industry"*[2] 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 is distinctly different from **sponsorship.** In sponsorship arrangements pharmaceutical companies simply provide funds for a specific event or work programme.

3. Scope

This document is intended as policy for:

- All staff in Waltham Forest who work for/on the behalf of Waltham Forest Clinical Commissioning Group (WF CCG) including independent contractors and locum practitioners and involved in joint working with the pharmaceutical industry and sponsorship by the pharmaceutical industry including independent contractors, locum practitioners, and others working under NHS terms and conditions for remuneration.

All collaborative projects with a pharmaceutical/commercial industry should be considered as "Joint Working", and requires approval by Medicines Optimisation Committee (MOC). Sponsorship is the only exception, and should be recorded using the appropriate notification form.

4. Aims and Objectives

The aim of this policy is to:

- Assist Waltham Forest healthcare professionals and managers to achieve organisational 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 or sponsorship 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

5. Values

In line with the *NHS Code of Conduct*[3] 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
- **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
- **Openness** – there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public

Where staffs enter into any joint working 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.

6. Principles of Joint Working

Joint working must be for the benefit of patients or the NHS and preserve patient care. Any joint working between the NHS organisations /service providers and the pharmaceutical/commercial industry should be conducted in an open and transparent manner. Arrangements should be of mutual benefit,

the principal beneficiary being the patient. The duration 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:

- Joint working arrangements should take place at a corporate, rather than an individual, level
- 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
- Clinical and financial outcomes will be assessed through a process of risk assessment
- Mechanisms 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.

A “Joint Working” project may comprise a number of activities including, but not limited to, the following:

- staff training & development
- staff and/or patient education
- economic analysis
- nurse services
- facilitation of pathway redesign
- support for guideline implementation
- funding of project staff requirements (e.g. provision of administrative, clinical, analytical health economic and/or management resources by either party)
- secondments
- audit

Joint working differs from sponsorship, as sponsorship is where pharmaceutical companies simply provide funds for a specific event or work programme. For the purpose of this guidance, sponsorship is defined as funding to the NHS from an external source for any expenditure item include the following:

- The salary or costs of staff
- Costs of NHS research
- Training
- Equipment
- Any hidden or recurrent costs cost for maintenance should be disclosed to the CCG
- Costs associated with meetings
- Gifts
- Hospitality including the provision of meals
- Hotel and transport costs (including trips abroad)
- Provision of free services (speakers)
- Provision of free discounted producted of any description
- Provision of free stationery bearing commericial advertising

Staff are reminded that at all times they have a responsibility to comply with their own professional codes of conduct, and that representatives of the pharmaceutical industry must comply with the *ABPI Code of Practice for the Pharmaceutical Industry*.[2]

Sponsorship should only be accepted on behalf of WF CCG from the pharmaceutical industry to support initiatives that are in line with its strategic priorities. These include:

- Joint initiatives must promote evidence-based practice and support only those drugs that have an acceptable evidence-base.
- Any learning or products (protocols, guidelines etc.), developed through sponsored projects will be shared with other NHS organisations.
- The WF CCG will consider supporting the dissemination of the learning from the set projects but retains the right of approval of associated literature and material.
- If the joint projects between the WF CCG and the pharmaceutical industry concern research projects, the WF CCG will follow best research practice in consultation with the Local Research Ethics Committee and follow-on arrangements for affected patients and the service must be fully assessed before entering into any research projects.

7. Confidentiality and Data protection

NHS data is confidential, and may also be copyright, therefore may not be shared with pharmaceutical/commercial companies. Any joint working agreement should comply with the legal and ethical requirements for the protection and use of patient information and other NHS information should be in line with information governance principles.

- Reports or information from the work should not be used or published elsewhere without explicit permission from the NHS organisation/service provider concerned.

8. Approval of Joint Working Arrangements

There needs to be a mechanism for the approval, recording, monitoring, and evaluation of any joint working arrangements. With respect to any proposed initiative, the project lead should complete the Joint Working Framework (appendix 1) and business proposal (appendix 3), and submit to MOC. The project lead should fully engage with the Pharmaceutical Industry in ensuring all the information is transparent and accurate. The MOC will discuss and make recommendations.

The joint working proposal should be considered by the MOC using the Joint Working with the pharmaceutical industry –checklist/framework (Appendix 2). This checklist and joint working proposal should be submitted as part of agenda for members to consider at the MOC. Final decision may be made by the MOC or decision escalated to the Waltham Forest Executive Board.

Proposals and the outcome of assessment will be logged and documented. Where appropriate, proposals should be accompanied by an action plan that sets out what should be done by whom and by when.

Joint working agreements will be monitored according to agreed outcome measures. Either party can terminate the arrangement if these outcome measures are not achieved, providing at least one month notice.

9. Sponsorship: Hospitality and meetings

It is recognised that pharmaceutical/commercial companies support some events (e.g. practice/cluster meetings). It is expected that the pharmaceutical/commercial company sponsoring the meeting to be noted in any minutes for the meetings and any participants in the meeting to declare any interests which should be documented in the minutes. It is the meeting organiser's responsibility to hold a list of declared Interests and keep it up to date.

Sponsorship should not influence purchasing decisions and it must be clear that sponsorship does not imply WF CCG endorsement of any product or company. There should be no promotion of products apart from that agreed in writing in advance prior to the meeting, which should be submitted to the chair of the meeting within 5 working days.

Companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings. Hospitality must be secondary to the purpose of the meeting and the level of hospitality should be appropriate. Where training is sponsored by external sources, the fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Sponsorship for training should also be notified. Sponsorship for training is accepted on the understanding that:

- The course organiser retains overall control of the event
- The sponsor does not have the right to present teaching material
- Where the organiser considers additional value may be gained from presentation by the sponsor, the content of the material is agreed in advance of the meeting.
- The course organiser will assess any educational content provided by the sponsor and refer on to the Medicines Management Team or MOC for advice where appropriate.
- Where course material is provided by the pharmaceutical company, that there is no promotion of specific products (the name of the company supporting the training event is acceptable)
- The sponsor does not use WF CCG or any contact working on the behalf of the WF CCG or project lead to promote products outside the meeting
- Promotional material or products should be located outside the main meeting room where practical
- Attendance of the meeting by the sponsor is at the discretion of the course organiser

Record keeping

It is the responsibility of individuals to inform the MOC of any sponsorship where funds are received or costs are met by a sponsor. Sponsorship form should be completed (Appendix 4) and submitted to the MOC.

Once sponsorship has been approved, agreement form (Appendix 5) should be completed.

10. Sponsorship: Gifts, Conflicts of Interest and Payments

Principles outlined in the current ABPI Code of Conduct for Pharmaceutical Industry, 2016[3] should be followed:

Gifts

- No gift, benefit in kind or pecuniary advantage is permitted, be offered or given to members of the health professions or to administrative staff as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine,
- Health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme. The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them.
- Health professionals and appropriate administrative staff attending scientific meetings and conferences, promotional meetings and other such meetings may be provided with inexpensive notebooks, pens and pencils for use at such meetings. They must not bear the name of any medicine or any information about medicines but may bear the name of the company providing them.

Sponsorship

Whilst there is no national guidance stipulating financial limits on sponsorships, the following is proposed:

- All sponsorship must be agreed by the MOC. Details should be completed on a register held by the MOC and reported to WF CCG Quality and Clinical Governance Director.
- Proposals pertaining to medicines should be forwarded to MOC first for consideration.

Conflicts of Interest

All staff working for WF CCG or on their behalf must declare links with the pharmaceutical industry. The information should be made widely available so that any conflicts of interest can be avoided.

It is important that individuals who have benefitted from personal sponsorship are not involved in formulary decision making or procurement decisions where those companies are involved.

Payments for Outside Work

NHS employees are advised not to engage in outside employment which may conflict with their NHS work, or be detrimental to it. They are advised to tell their NHS employing authority if they think they

may be risking a conflict of interest in this area: the NHS employer will be responsible for judging whether the interests of patients could be harmed.

Code of Conduct for WF CCG staff and staff working on the behalf of the CCG

- Act impartially on all areas of work.
- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking exert influence to obtain preferential consideration. All such gifts should be declined or returned and benefits, hospitality and sponsorship refused.
- Declare and register gifts worth £25 or more in line with WF CCG Gifts, Hospitality and Sponsorship Policy.
- Declare and record financial or personal interest (e.g. company shares, research grant) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations.
- Make it a matter of policy that offers of sponsorship that could possibly breach the code be reported to the highest level (i.e. respective Boards for WF CCG).
- Should not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others
- Be aware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality
- Refuse to practise under any conditions which compromise professional independence or judgement, nor impose such conditions on other professionals

11. Samples

Samples should not be routinely accepted. Where there is an identified need e.g. placebo inhalers, then a formal request should be made to the MOC (or equivalent) explaining the reason (Appendix 7). *Samples of medicinal products should not be accepted under any circumstance.*

No more than four samples of a particular medicine may be provided to an individual health professional during the course of a year.

A sample of a medicine must be no larger than the smallest presentation of the medicine on the market in the UK.

Samples of a product may be provided only to a health professional qualified to prescribe that product.They must not be provided to other relevant decision makers.

12. Rebate Schemes

Primary Care Rebate Schemes (PCRS) are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s).

Background

The London Primary Care Medicines Use and Procurement QIPP group and PrescQIPP group have recommended schemes should only be implemented if they are not in breach of UK legislation and that they offered genuine benefits to the NHS and to patients.

Legal advice sought by the London Procurement Partnership (LPP) concluded that primary care rebate schemes are not unlawful and are within the powers of NHS organisations, provided they meet certain requirements. Commissioners should refer to the detailed legal advice for further information (available from LPP and PrescQIPP). Whilst this legal advice may be shared within the NHS, it should be noted that this legal advice is addressed to the LPP. If individual organisations identify any points that require further clarification, then they may need to seek their own further legal advice[4].

Following legal advice and consultation with stakeholders, a set of principles of good practice for primary care organisations to use to facilitate robust scrutiny and identification, adoption and implementation of primary care rebate schemes have been developed.

Principles of good practice

- It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS.
- Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population.
- It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision making processes or formulary development. This is in line with the DH document (gateway reference 14802) on *Strategies to Achieve Cost-Effective Prescribing (October 2010)*. This states that the following principles should underpin local strategies:
    - The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, eg, from the National Institute for Health and Clinical Excellence (NICE) or other authoritative sources;
    - Health professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, eg, patients whose clinical history suggests they need a particular treatment should continue to receive it;
    - The individual patient (and their guardian or carer where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;

- Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;
- Schemes should be reviewed whenever relevant NICE or alternative guidance are updated.
- Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the WF CCG's website.

Good practice principles for Primary Rebate Schemes

The detailed content of PCRS offered to Primary Care Organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. Although these Good Practice Principles can help CCGs assess these schemes, the CCGs will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the DH's controls on pricing made under the 2006 Act, the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness (see legal advice for more details).

Issue	Good practice principles
Product related	• Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by established local decision-making processes. The clinical decision should inform the financial/procurement decision and not vice versa. • Health professionals should always base their prescribing decisions primarily on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration. • Any medicine considered under a PCRS must be licensed in the UK. Where there is more than one licensed indication for a medicine, a scheme should not be linked to a particular indication for use. • Rebate schemes promoting unlicensed or off label uses must not be entered into. All recommendations for use of a medicine within a PCRS must be consistent with the Marketing Authorisation of the medicine in question i.e. the PCRS should only advocate the use of the drug in line with the data sheet for the drug in question.
Rebate scheme related	• Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate. • Rebate schemes should be approved through robust local governance processes that include Medicines Optimisation Committee/Joint Prescribing Committee approval, involving both primary and secondary care and Director level approval. • The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement. • Primary Care Rebate Schemes should be agreed at a statutory organisational level,

	they should not be agreed at GP practice level. • Schemes encouraging exclusive use of a particular drug should be avoided. • Rebate schemes are not appropriate for medicines in Category M and some medicines in Category C of the Drug Tariff, because of the potential wider impact on community pharmacy reimbursement • Ideally the PCRS should not be directly linked to requirements to increase market share or volume of prescribing. • A volume based scheme should only be agreed if clinically appropriate. However, the administrative burden of monitoring such a scheme should be carefully considered. • Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure (i) that the terms of the scheme are clear and (ii) to maximise the legal protection. All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties. • PCRS agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a sensible notice period e.g. three or six months. • The need for exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances
Information and Transparency	• CCGs should make public (for example on their website) the existence of any PCRS they have agreed to. • Primary care organisations should not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These PCRS should all be considered using the same criteria. • There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from E-pact data. • PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised. • Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share. • Freedom of Information – As a general principle information relating to rebate schemes is likely to be releasable, these issues should be discussed with the manufacturer before a commissioner enters into any agreement with them. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract. See legal advice for more details. • Discounts and details of any PCRS offered should be allowed to be shared within the NHS. This should be agreed as part of the PCRS contract

13. References

1. Department of Health – Commercial Sponsorship – Ethical Standards in the NHS, Nov 2000
2. Department of Health – Best Practice Guidance on Joint Working between the NHS and the Pharmaceutical Industry, 2008
   http://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/dh_082569.pdf
3. ABPI Code of Conduct for the Pharmaceutical Industry 2012
   http://pmcpa.org.uk/files/ABPI%20Code%202012.pdf
4. London Procurement Programme – rebate schemes
   http://www.lpp.nhs.uk/news_item.asp?fldID=45

14. Further reading

- Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry, Department of Health/ABPI (March 2008)

- Best practice guidance for joint working between the NHS and the pharmaceutical industry, Department of Health (February 2008)

- A Common Understanding: Guidance on Joint Working between NHS Scotland and the Pharmaceutical Industry (2003)

- Guidance for Partnership Working between NHS Organisations, Primary Care Contractors, the Pharmaceutical Industry and the Allied Commercial Sector in Wales (2004)

- ABPI Code of Practice for the Pharmaceutical Industry (2016)

- Strategies to Achieve Cost-Effective Prescribing (October 2010)

- Guidance on collaboration between healthcare professionals and the pharmaceutical industry
  http://www.rcplondon.ac.uk/sites/default/files/guidance-on-collaboration_0.pdf

- Department of Health/ABPI – Joint working toolkit “Moving Beyond Sponsorship” Gateway ref: 14600
  http://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf

- New ABPI working tool
  http://www.abpi.org.uk/our-work/news/2012/Pages/140512.aspx

- Moving beyond sponsorship – Joint working between the NHS and Pharmaceutical Industry

http://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf

- NHS Waltham Forest CCG Gifts and Hospitalities
  http://www.walthamforestccg.nhs.uk/downloads/aboutus/How-we-commission/Conflict/NHS_WF_CCG_Register_Gifts_hospitality_sponsorship_2016-17.pdf

- NHS Waltham Forest CCG Standards of Business Conduct and Managing Conflicts of Interest Policy
  http://www.walthamforestccg.nhs.uk/downloads/aboutus/publications/policies/Waltham%20Forest%20CCG%20Standards%20of%20Business%20Conduct%20and%20Managing%20Conflicts%20of%20Interest%20Policy.pdf

- NHS Waltham Forest CCG Anti-Bribery and Fraud Policy

  http://www.walthamforestccg.nhs.uk/downloads/aboutus/publications/policies/NHS-Waltham-Forest-CCG-Anti-fraud-policy-December-2015.pdf

15. Acknowledgements

Previous work was adapted from the following in development of the policy:

Homerton University Hospital and City and Hackney Clinical Commissioning Group, June 2012
Barts Health NHS Trust Commercial representatives and sponsorship policy, March 2012
Policy on working with the Pharmaceutical Industry, NHS North Somerset, July 2012
Policy and Guidance for Joint Working and commercial Sponsorship with the Pharmaceutical Industry, Harrogate and Rural District Clinical Commissioning Group, December 2013

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Appendix 1: Framework for Joint working between the NHS and Pharmaceutical Industry

The form should be completed and submitted to the Medicines Optimisation Committee (MOC).

FRAMEWORK FOR JOINT WORKING with commercial/pharmaceutical industry

JOINT WORKING PROJECT SUMMARY	
1. Names of the partner organisations involved in the joint working proposal	
2. Title of project	
3. Summary of intended aims and objectives	
4. Summary of expected outcomes	
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	
10. If product is already included on local formulary, please state:	
11. Contingency arrangements agreement to cover unforeseen circumstances (e.g. updated clinical guidance, changes to summary of product characteristics, where appropriate)	
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 funding implications of project (to be clear and unambiguous)	
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	

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	
DATA AND PATIENT PROTECTION	
1. List interests of partners in relation to the joint working proposal,	
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. How data is collated and used?	

DECLARATION OF INTERESTS YES ☐ NO ☐

Provide a brief summary of the interest

Signature: _____ Date: _____

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Appendix 2: Joint Working with the pharmaceutical/commercial industry – issues to consider checklist

Question	Comments
1. Is the commercial organisation a legitimate registered company?	
2. Does the scheme have aims and objectives? Are they written, and been signed by a responsible officer?	
3. Are protocols available? If no, please state what actions follow?	
4. Are the clinical aspects of the scheme of sufficiently high quality? E.g. in line with local /national guidelines, and best evidence	
5. Are there any patient-related clinical responsibility or accountability issues to consider?	
6. How will outcomes be measured or the scheme be audited?	
7. What patient's interest/issues need to be considered?	
8. Are there any potential conflicts of interest for the NHS and the organisation? If yes, please state.	
9. Who owns the data and how will it be used?	

10. What are the legal issues to consider?	
11. Does the scheme comply with the law?	
12. How does the scheme fit in with existing NHS services?	
13. List any implications for other aspects of healthcare? e.g. create demand for lab tests	
14. How will the scheme be managed and who is accountable for the scheme?	
15. Will there be any recurrent costs to pick up, and who will be responsible for these? If yes, what are they?	

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Appendix 3: Business Case Template

Title:
Author:
For decision/discussion/noting (delete as appropriate)

Document Control

Issue	Issue Date	Version	Issued To

Business case for:	
Context, Background and supporting evidence	*Brief description of the project and its purpose; include the need for such as initiative, benefits to patients. Describe explicit aims and objectives of project.*
Recommended approach	*Brief summary of recommended approach to the project: outline approach, contributions of each party, expertise required and how deployed.*

Rationale	*The basic reasons for project in the context of patient benefit, strategic objectives of organisation. Include supporting evidence such as clinical trial evidence and pharmacoeconomic data where possible.*
Options	*What options are there for addressing this issue? What are the costs and benefits for each option? Why is joint working the preferred option?*
Outcomes and success criteria	*Describe the expected and desired outcomes, and the measure to be used to assess by which success will be measured. Include criteria for the project itself and for the process of joint working.*
Timescales	*Indicate the expected length of project*
Service impact of the proposal	*Implications for staff training, purchase of equipment, monitoring of patients etc. Include both primary and secondary care implications*

Resources required and sources	*Indicate resources required (people, equipment, expertise, finance, communication channels, IT) and where these will come from. Outline which NHS/company budget(s) might be appropriate source of funding.*
Stakeholder opinion and support	*Include current knowledge of stakeholder opinion and support and plans to generate further support*
Patient views	*Include opinions from relevant local patient groups, and any assessments of patient views in this area*
Evaluation and audit; how success will be measured	*Describe evaluation and audit methods: what quantitative date will be used; what qualitative measures will be used if any*
Initial risk assessment	*Provide an assessment of the risks and benefits of the project*

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Appendix 4: Sponsorship application form

Name of applicant……

Position/ directorate……..

Name of sponsoring organisation…….

Sponsor contact name…… Date……..

Please summarise the purpose of the meeting / conference / joint work?

What is the proposed contribution by the sponsoring organisation?

Please answer the following questions:

Question	**Yes/No**
Is the proposed service consistent with the guidance detailed in "Corporate Policy and guidance for joint working with the pharmaceutical/commercial industry and sponsorship"	
Is the proposed sponsorship of an appropriate level for the purpose?	
Is the CCG, or CSU on behalf of 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?	
Is the CCG or CSU on behalf of CCG satisfied that the offer is independent of purchasing or prescribing decisions?	
Can it be confirmed that there is no current conflict of interest for any parties in relation to the service offered?	
Are you satisfied that all materials and information supplies are valid, evidence-based,	

balanced and non-promotional?	
Have you reached an agreement with all members of your team involved that the service is appropriate?	
If patients are involved have arrangements been made to ensure the patients are aware of the service where appropriate?	

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.

Signature of applicant…… Date……..

Name of applicant:……

Action to be taken:……

Signature of recipient of application…… Date……

Designation of recipient of application ……

On completion, please submit to secretary for Medicines Optimisation Committee, Waltham Forest.

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Appendix 5: Agreement form for pharmaceutical/commercial sponsorship

On completion, please submit to secretory for Medicines Optimisation Committee, Waltham Forest.

Dear……. (Name of contact and company)

Thank you for agreeing to sponsor / support (please outline details of event):
……
……
……
……
……
……
……
On……. Proposed dates

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Appendix 6: Proforma for seeing pharmaceutical representatives

	Please complete
Your name	
Company Name	
Contact Tel	
Contact E-mail	
What is the nature of your meeting? i.e. content of meeting	
Have you met or visited any of the local GP's regarding this issue? Please provide details.	
How will your service impact on the NHS or CCGs?	
Any additional comments *(maximum 50 words or feel free to add additional evidence to your e-mail*.	
Will you be bringing a colleague with you? If yes, provide details	

FOR OFFICE USE ONLY		
Head of Medicines Management		Comments
Face to face	Yes / No	
Teleconference / call	Yes / No	
Written communication required	Yes / No	
No further action	Yes / No	

PLEASE NOTE THAT COMPLETING THIS PRO-FORMA DOES NOT GUARANTEE YOUR MEETING

NHS
Waltham Forest
Clinical Commissioning Group

Appendix 7: Proforma for receiving pharmaceutical samples

The form should be completed and submitted to the Medicines Optimisation Committee (MOC).

Application for approval of samples	
1. Date of request:	
2. Name of the person submitting application:	
3. Role of the applicant:	
4. Name of the pharmaceutical sample	
5. Name of pharmaceutical company who is providing the sample:	
6. Quantity of sample requested	
7. Exact nature for the request of the sample	
8. Outcome (approved/not approved)	
9. Approved by (name in block capitals)	
10. Date approved:	