Policy Working with the Pharmaceutical Industry or other Commercial Organisations

NHS
Tower Hamlets
Clinical Commissioning Group

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Executive Summary	• The aim of this policy is to clarify the arrangements for joint working with the pharmaceutical industry, ensuring any such arrangements are explicit, transparent, recorded, auditable, and audited • This document is intended as policy for NHS Tower Hamlets CCG (THCCG) and its staff who are considering industrial sponsorship, joint working and training arrangements with the pharmaceutical industry and other industry potentially supplying NHS with clinical support • This policy recognises that the primary purpose of NHS Tower Hamlets CCG is the commissioning of clinically effective safe publicly funded high quality health services to the local population in a cost effective fashion and is concerned with supporting this purpose.
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Document Author(s)	Allan Stein - Prescribing Adviser, NELCSU
Who has been consulted?	Tower Hamlets CCG Prescribing Delivery Board – 17.7.2013
Was an Equality Analysis required?	No
With what standards does this document demonstrate compliance?	• [1] Department of Health, 2008. Best practice guidance for joint working between the NHS and the pharmaceutical industry.

References and associated CCG documentation	• [2] ABPI, 2012. *Code of Practice for the Pharmaceutical Industry.* • [3]Department of Health, 2004. *Code of Conduct: Code of Accountability in the NHS*. 2nd Ed • [4]NHS Commissioning Board, October 2012. Standards of Business Conduct • [5]DoH/ABPI, August 2010 Moving beyond sponsorship: Interaction toolkit for joint working between the NHS and the pharmaceutical industry		
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Is this document fit for the public domain? Y / N	**Y**	**If No, why?**	

Contents

1 Purpose and scope

1.1 Purpose

This document is intended as policy for Tower Hamlets CCG (THCCG) and its staff who are considering industrial sponsorship, joint working and training arrangements with the pharmaceutical industry and other industry potentially supplying NHS with clinical support..

1.2 Scope

For the purposes of this policy, the term 'staff' refers to

THCCG executive directors; THCCG non-executive directors; THCCG employees (whether their remit is clinical or corporate); committee members; third parties acting on behalf of the THCCG under a contract; students and trainees (including apprentices); agency staff engaged by NHSE; and secondees.

It is also advisory guidance to NHS providers in Tower Hamlets who are membership practices of the CCG

for the purpose of this policy, joint working is defined as *situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner.* Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

2 Responsibilities

Area of working	Responsibility for Monitoring & Record Keeping
Rebate Scheme	Monitored by Commissioning Support Unit (CSU). Records kept by appropriate CCG officer
Sponsorship of educational meetings etc	Monitored by the Prescribing Delivery Board (PDB) or appropriate committee responsible for the workstream. Records kept by designated CSU member or designated representative from member practice.
Joint working arrangements	As above

3 Introduction

This policy recognises that the primary purpose of Tower Hamlets CCG NHS is the commissioning of clinically effective safe publicly funded high quality health services to the local population in a cost effective fashion and is concerned with supporting this purpose.

DH Guidance[i] encourages NHS organisation, other parties involved in commissioning health services and their staff, to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous.

4 Aims and Objectives

The aim of this policy is to clarify the arrangements for joint working with the pharmaceutical industry, ensuring any such arrangements are explicit, transparent, recorded, auditable, and audited:

To ensure any working relationships with the pharmaceutical or other relevant industry are appropriate and effective in relation to improving NHS services to the local community in the short and longer term

Inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical industry. Specifically, it aims to:

- assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business

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*.[ii]

5 Values

In line with the NHS Code of Conduct[iii] three public service values, accountability, probity and openness underpin the work of the NHS. These values should be respected in relation to the CCG, the NHS, the public, professional codes of conduct, the bribery Act 2012 and parliamentary scrutiny. Documentation related to decisions and interactions is required.

- *accountability – everything done by those who work in the NHS must be able to stand appropriate tests eg 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; and*
- *openness – there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public*

Where staff 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 in relation to individual and population needs and commissioning plans, including the JSNA and Health and Well-being Board plans.*
- *Consideration of potential short and long term outcomes*
- *Value for money*
- *Reasonable contact (time in negotiation and joint working with industry should not compromise work directly with the NHS)*
- *Responsibility*
- *Impartiality and honesty*
- *Truthfulness and fairness*.

6 Principles of Sponsorship, Joint Working, training and other arrangements.

Such arrangements must always be for the benefit of patients or of the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner. Arrangements should be of mutual benefit, the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined *before* entering into sponsorship or any joint working or training provision

Joint working initiatives, where undertaken must be explicit, registered within the CCG, and reviewed and audited regularly, at least annually. All arrangements and relating decisions etc. must be appropriately documented and audited by the committee responsible for the workstream at least annually.

The following principles will also apply to joint working

Public accountability for NHS provision is paramount:

- Staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant NHS guidance
- Contract negotiations will be negotiated in line with NHS values
- Confidentiality of information received in the course of duty must be respected and never used outside the scope of the specific project . Confidential information should not be shared with any third party without the explicit written agreement of all of the parties involved in the specified joint working arrangement. Joint working arrangements must be sanctioned at an appropriate corporate level, rather than proceeding at the behest of any individual.

- Any NHS body party to an agreement must ensure clinical and financial outcomes are robustly assessed through a process of risk assessment – which should be publicly reported on the CCG website and included in the annual report.
- A register of gifts and hospitality as well as conflicts of interest is maintained and reviewed within the organisation. These registers are refreshed in their totality on an annual basis and each meeting of the Governing Body or Committee of the Governing Body begins with members asked to declare any new interests.

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.

7 Approval of Joint Working Arrangements, sponsorship, joint training.

There needs to be a mechanism for the approval, recording, monitoring, and evaluation of any joint working arrangements through appropriate governance processes. With respect to any proposed initiative, the project lead should complete the Joint Working Framework (appendix 1) and Business Case Template (appendix 2), and submit to the Prescribing Delivery Board (PDB) or the appropriate governance committee. The project lead should fully engage with the Pharmaceutical Industry in ensuring all the information is transparent and accurate. The PDB will discuss and make recommendations for decision to the appropriate committee.

The joint working proposal should be considered using the Joint Working checklist/framework (Appendix 3). This checklist and joint working proposal should be submitted as an agenda item for consideration at the appropriate committee. Final decision may be made by the PDB or appropriate committee and escalated to the CCG Executive Board where appropriate.

Proposals and the outcome of assessment will be logged and documented with the appropriate governance committee in the respective organisations.

7.1 Exit Arrangements

Joint working agreements will be monitored according to agreed outcome measures.

Both parties can mutually agree to terminate the agreement at any time. Either party can terminate the arrangement providing one months notice is given. Termination can be immediate following a breach by either party.

8 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 and adhere to local and national guidelines.

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

NB Research applications with industrial support should be registered with and approved by the Research Ethics Committee

9 Declaration of Interest, Outside Work, Payments and Hospitality

9.1 Declaration of Interests

THCCG staff must declare any interest which may directly or indirectly give rise to an actual or potential conflict of interest or duty. This declaration is to ensure that any personal or business interest which may influence, or may be *perceived* to influence, their judgment, is known to THCCG eg any links with the pharmaceutical industry

9.1.1 Outside Work

Employees of THCCG (depending on the details of their contract as regards outside employment and private practice) are required to inform THCCG if they are engaged in or wish to engage in outside employment in addition to their work with THCCG. The purpose of this is to ensure that the THCCG is aware of any potential conflict of interest with their THCCG employment.

9.1.2 Payments and Hospitality

THCCG staff must at all times be seen to be fair, impartial and unbiased in their business relations. With the exception of items of little value (less than £25) such as diaries, calendars and small tokens of appreciation, all offers of gifts should be declined[4]. Any personal gift of cash or cash equivalents (e.g. tokens) must be declined, whatever its value. CSU staff should report all offers of unreasonably generous gifts to the Governance and Risk Manager

10 Sponsorship: Hospitality and meetings

It is recognised that pharmaceutical/commercial companies may want to support some events (e.g. practice/cluster meetings). It is expected that the pharmaceutical company sponsoring the meeting to be noted in any minutes for the meetings. 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 THCCG or CSU 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 be notified to the appropriate governance bodies for the respective organisations. 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 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 CCG or CSU contact 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

11 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).

11.1 Background

The London Primary Care Medicines Use and Procurement QIPP group has recommended schemes may be implemented if they were 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). 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[5].

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.

11.2 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, e.g., 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, e.g., 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 PCT's website
- Good practice principles for primary rebate schemes

The detailed content of primary care rebate schemes 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.

Issue	Good practice principles
	• 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 Management Committee/Area Prescribing Committee (or equivalent) 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

Issue	Good practice principles
Information and Transparency	• Primary care Organisations (PCTs and in the future 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 ePACT 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

12 Record keeping

Arrangements and templates to be agreed.

12.1 Audit and review:

The Governance officer of CCG will be responsible for entering the details of joint working with industry and sponsorship arrangements in a central register. The medicines management team will update the register as and when required.

Audit and impact assessment should be carried out annually; annual reports should be submitted to the CCG Audit Committee.

13 Reference and Additional Reading

[1] Department of Health, 2008. Best practice guidance for joint working between the NHS and the pharmaceutical industry.

[1] ABPI, 2012. *Code of Practice for the Pharmaceutical Industry.*

[1] Department of Health, 2004. *Code of Conduct: Code of Accountability in the NHS*. 2nd Ed

[4]NHS Commissioning Board, October 2012. Standards of Business Conduct

[5]DoH/ABPI, August 2010 Moving beyond sponsorship: Interaction toolkit for joint working between the NHS and the pharmaceutical industry

- [6]London Procurement Programme (LPP)rebate schemes
- http://www.lpp.nhs.uk/news_item.asp?fldID=45

14 Acknowledgements

Previous work by the following organisations was used to assist in the preparation of this document:

Tower Hamlets Primary Care Trust.

Policy on Sponsorship Arrangements Including Working with the Pharmaceutical Industry April 2003

Newham Clinical Commissioning Group

Guidance for Joint Working with the Pharmaceutical/Commercial Industry and Sponsorship 201

15 Appendix 1: Framework For joint working between The NHS pharmaceutical industry

I. JOINT WORKING PROJECT SUMMARY	
1. TITLE OF PROJECT	
2. SUMMARY OF INTENDED AIMS & OBJECTIVES	
3. SUMMARY OF EXPECTED OUTCOMES	
4. NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT	
5. NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION	
6. EXACT NATURE OF THE JOINT WORKING PROPOSAL	
7. START DATE	
8. FINISH DATE	
9. EXIT STRATEGY	
II. RESOURCES AND COSTS	
1. OVERALL COST OF THE JOINT WORKING PROJECT	
2. DIRECT AND INDIRECT RESOURCES / COST COMMITMENTS BY EACH PARTNER	
3. METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS	

4. INFORMATION ON COST EFFECTIVENESS (Has value for money been shown?)	
5. ARRANGEMENTS FOR LONGER TERM FUNDING IMPLICATIONS OF PROJECT (To be clear and unambiguous)	

III. GOVERNANCE ARRANGEMENTS	
1. PARTIES CONSULTED PRIOR TO INITIATING JOINT WORKING PROJECT AND HOW CONSULTATION WAS CONDUCTED	
2. METHOD FOR INFORMING PATIENTS OF THE JOINT WORKING PROJECT	
3. DECISION MAKING PROCESSES WITHIN THE JOINT WORKING PROJECT (To be open and transparent)	
4. OPERATIONAL AND MANAGEMENT ACCOUNTABILITIES (Include identified conflicts of interest)	
5. PILOTING ARRANGEMENTS (State if this project is a pilot)	
6. RELATIONSHIP TO EXISTING SYSTEMS OF CARE IN PRIMARY AND SECONDARY CARE SECTORS	
7. FOR CLINICAL SERVICES, PROFESSIONAL INDEMNITY AND LIABILITY ARRANGEMENTS	
8. WRITTEN AGREEMENT STATING OBLIGATIONS OF CONFIDENTIALITY, SECURITY STANDARDS AND LIMITS OF USE OF INFORMATION TO THE PURPOSES	

SPECIFIED	
IV. MONITORING AND EVALUATION	
1. MANAGEMENT ARRANGEMENTS	
2. LIST DESIGNATED RESPONSIBILITY AT EACH STAGE OF THE PROPOSAL	
3. METHOD OF EVALUATING PATIENT BENEFITS ON COMPLETION	
4. LEARNING OPPORTUNITIES FROM THIS PROJECT	
5. AUDIT ARRANGEMENTS	
6. METHOD FOR HIGHLIGHTING SIGNIFICANT PROBLEMS	

V. DATA AND PATIENT PROTECTION	
1. LIST INTERESTS OF PARTNERS IN RELATION TO THE JOINT WORKING PROPOSAL, AND WHERE THESE COINCIDE	
2. LIST POTENTIAL CONFLICTS OF INTEREST	
3. IDENTIFY "OWNERSHIP" OF THE DATA GENERATED BY THE PROJECT	
4. DESCRIBE ACCESS ARRANGEMENTS FOR THE DATA, AND FORMAT (Bearing in mind the requirements of the Data Protection Act and patient confidentiality of healthcare records)	

5. USE DATA WILL BE PUT TO	

VI. DECLARATION OF INTERESTS YES ☐ NO ☐

If Yes, qualify by inserting a tick in one box in column A and one in column B

A	**B**
Personal ☐	Specific ☐
Non-Personal ☐	Non Specific ☐

Signature _____ Date _____

Personal implies that you (or your spouse / partner) receive direct payment for services or hold shares in the relevant company concerned or a competitor.

Non-Personal implies that your unit benefits by receiving funding from the company.

Specific implies that you have undertaken work or given advice on other products made by the relevant manufacturer.

This system is based on that used by the Commission on Human Medicines and other national drug regulatory bodies.

16 Appendix 2: Business Case Template

Title:

Author:

For decision / discussion / noting (*delete as appropriate*)

Document Control

Issue	Issue Date	Version	Issued To

BUSINESS CASE FOR:	*Brief description of the project and its purpose: include the need for such an initiative, benefits to patients. Describe explicit aims and objectives of project*
CONTEXT, BACKGROUND AND SUPPORTING EVIDENCE :	*Include national policy context (e.g. NICE guidance, NSFs, national targets/standards, White Paper(s), national reports) description of local situation using local data, for example PCT performance indicators for the relevant clinical area such as admission rates, death rates. Refer to relevant local policies.* *Insert any clinical trial, pharmacoeconomic data or other supporting evidence*

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 measures 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 the 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 (e.g. local expert opinion, NHS independent reviews) 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 data will be used, (e.g. PACT data, hospital prescribing data, admission rates, death rates); what qualitative measures will be used (if any)*.
INITIAL RISK ASSESSMENT:	*Provide an assessment of the risks and benefits of the project.*

17 Appendix 3: Checklist

Issues to consider when working with Joint Working with the pharmaceutical industry

Question	Comments
1. Is the commercial organisation a legitimate registered company? Advice: check with Company's House	
2. Does the scheme have aims and objectives? 3. Are they written, and been signed by appropriate responsible officers for respected organisations?	
4. Are appropriate protocols and checks documented as part of the joint working process available? If no, please state what actions follow? NB: if protocols are not appropriate how are risks and issues identified and mitigated?	
Has due consideration been given to managing any related clinical or non-clinical accountability issues and is this appropriately documented?	
5. Are there any patient-related clinical responsibility or accountability issues to consider?	

Question	Comments
Advice: with regard to patient related information, ensure appropriate confidentiality and governance has been considered and documented. Where appropriate document in the Joint Working risk register.	
6. How will outcomes be measured or the scheme be audited? Has the process for tracking and monitoring progress and outcomes clearly defined and documented.	
7. Is there a clear exit stragey built into the process where appropriate and documented?	
8. What patient's interest/issues need to be considered? Has the appropriate steps been taken to ensure appropriate patient/issues been considered and that consent has been obtained and documented.	
9. Has the proposal need to be considered by the Reasearch & development Group / Ethic Committee where appropriate?	
10. Are actual and potential conflicts of interest clearly recorded and appropriate mitigation documented in the Joint Working arrangement for the NHS and the organisation? If yes, please state.	
11. Who owns the data and how will it be used? Does the document indicate the level of access of data, ownership of data and how it will be used by the respective parties with regards to patient confidentiality and data protection	

Question	Comments
Advice: clearly document what level information is available at what level, to whom and within what timescales.	
12. Are there any legal or ethical issues to consider?	
13. Does the scheme comply with all relevant law including the Bribery Act.	
14. Does the scheme meet the identified commissioning needs of the local population?	
15. Have any potential impact on other service areas been considered, mitigated against , worked through and documented. eg demand for lab tests, increased frequency of appointments.	
16. How will the scheme be managed and who is accountable for implementation and ensuring that that any impact on other services is appropriately managed and documented.	
17. Are there any associated costs eg start up costs, on-going costs, costs associated with impacts on other services and have these costs been documented?	