CENTRE FOR PHARMACY POSTGRADUATE EDUCATION

Policy and guidance for joint working with the pharmaceutical industry and principles for sponsorship for collaborative working from the pharmaceutical industry

Template based on the Department of Health's *Best practice guidance on joint working between the NHS and the pharmaceutical industry and other commercial organisations* (February 2008).

Version:	6
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CENTRE FOR PHARMACY POSTGRADUATE EDUCATION

Contents

NHS Health Education England

MANCHESTER 1824 The University of Manchester

Scope

This document is intended as policy for the Centre for Pharmacy Postgraduate Education (CPPE) and its staff who are involved in joint working with the pharmaceutical industry.

For the purposes of this policy, the term 'staff' refers to all employees and contractors who are engaged to undertake duties on behalf of CPPE.

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 educational 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. This policy also covers 'sponsorship' or 'collaborative support', which for the purpose of this policy is defined as situations where, for the benefit of patients, pharmaceutical companies are prepared to support educational meetings in an open and transparent manner.

Introduction

Department of Health (DH) guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry where the benefits that this could bring to patient care and the difference it can make to their health and wellbeing are clearly advantageous.[1] CPPE is funded to provide postgraduate education to pharmacy professionals providing NHS services and has had agreement that it may work with the pharmaceutical industry. Joint working requires all partners to be involved from the beginning to develop a framework with demonstrable outcomes and return on investment from the initiative.

Aims and objectives

The aim of this policy is to:

- assist CPPE to achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry
- inform and advise staff of their main responsibilities when entering into joint working arrangements or sponsorship agreements with the pharmaceutical industry. Specifically, it aims to:
    - assist CPPE staff in maintaining appropriate ethical standards in the conduct of CPPE business
    - highlight that CPPE staff are accountable for achieving the best possible educational outcomes within the resources available.

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 Association of the British Pharmaceutical Industry (ABPI) *Code of practice for the pharmaceutical industry*.[2]

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 CPPE 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
- value for money
- reasonable contact
- responsibility
- impartiality and honesty
- truthfulness and fairness.

Principles of joint working

Joint working must be for the benefit of patients or of CPPE 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 contribution of funding or capacity from both parties, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

The following principles will also apply to joint working:

- staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described
- contract negotiations will be conducted 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 determined through a process of risk assessment.

CPPE has a mechanism in place for recording and monitoring, and evaluating any joint working arrangements. This consists of:

- completion of the CPPE framework (Appendix 2) in the first instance to gain approval
- establishment of a joint project group who will retain overall accountability and agree outcomes and deliverables
- programme of activity detailing deliverable milestones to be produced
- management structures and governance arrangements
- appointment of project manager to manage budget and oversee project plan
- development of a business case identifying resources required. The contribution of funding or capacity from both parties to be agreed
- more complex initiatives to receive CPPE IPR sub group approval
- regular monitoring and evaluation to be carried out.

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.

Principles of sponsorship for collaborative working

Where the principles of joint working are not possible to follow, eg, when CPPE programmes are already developed or the benefits to patient care and the return on investment are not easily measurable, pharmaceutical companies may be prepared to work collaboratively with CPPE by sponsoring educational events. This should be carried out in an open and transparent manner.

The following principles would apply:

- collaborative working (sponsorship opportunities) would be available to all pharmaceutical companies
- completion of the CPPE framework (Appendix 1) in the first instance to gain approval
- each company will agree its own model of support with CPPE
- the companies will be reassured about the content of the events before agreeing to sponsorship, eg, by attending a similar event
- CPPE will ensure that workshop content is regularly updated
- CPPE will ensure that tutors are regularly revalidated
- CPPE will hold the workshops in venues that are deemed appropriate, eg, not golf clubs or country clubs
- the hospitality and subsistence at the CPPE workshops will be proportionate to the occasion
- the events will be open to all pharmacy professionals providing NHS services and in some cases other healthcare professionals
- the events will be advertised by CPPE showing clearly that they are supported by the pharmaceutical industry with this wording: '*Pharmaceutical companies may have provided financial support for the cost of the venues and subsistence, the trainers and materials used, but have had had no influence or input into the content of the meetings or materials*'
- CPPE will agree with the companies the amount of support required which could extend to hire of a venue and refreshments and the provision of equipment to be used in the training

- local arrangements would be made for the flow of funding, eg, invoicing by CPPE or companies paying the venue directly
- the names of the attendees will be made available to the companies sponsoring the event.

Confidentiality and data protection

It is the policy of CPPE that all processing of personal data by, or on behalf of CPPE will be in accordance with the requirements, as currently understood, of:

- the Data Protection Act 1998 and any subsequent amendments and statutory instruments, which may be approved by Parliament
- the Data Protection Registration of the University of Manchester currently operative
- work within requirements set out in the University of Manchester Information Governance Policy.

Conflicts of interest, payments and hospitality

University of Manchester staff are required to declare and record financial or personal interests (eg, company shares, research grants, consultancies) 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. Nor should they misuse their official position or information acquired in the course of their official duties to further the private interests of themselves or others.

Staff and Governing Body members are reminded of the requirement to acquaint themselves with the University of Manchester Integrity Policy and the registration of interests form (Appendix 3).

Approval of joint working or sponsorship arrangements

Submission of the CPPE framework (Appendices 1 or 2) in the first instance to gain approval of the joint working or sponsorship arrangements.

Approval of the director of CPPE will be required if there are financial implications to CPPE. However, larger more complex initiatives will require CPPE IPR subgroup level approval.

References and additional reading

1. Department of Health. *Best practice guidance on joint working between the NHS and the pharmaceutical industry and other commercial organisations*. Crown Copyright. 2008.

2. Association of the British Pharmaceutical Industry. *The Code of practice for the pharmaceutical industry*. ABPI. 2014.

3. Department of Health. *Code of conduct: code of accountability in the NHS*. Second edition. 2004.

4. Business Services Authority. *Standards of business conduct for NHS staff*. NHS circular HSG(93)5. Issue 3. 2010.

5. University of Manchester. *Integrity Policy*. **www.policy.manchester.ac.uk/resources/civil-servant/ethics/integrity**

Appendix 1
Framework for sponsorship to support collaborative working between CPPE and the pharmaceutical industry

I.	COLLABORATIVE WORKING PROJECT SUMMARY
1. TITLE OF PROJECT	
2. SUMMARY OF INTENDED AIMS & OBJECTIVES	
3. SUMMARY OF EXPECTED OUTCOMES	
4. NAMES OF THE ORGANISATIONS INVOLVED IN THE COLLABORATIVE WORKING ARRANGEMENT	
5. NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION	
6. EXACT NATURE OF THE COLLABORATIVE WORKING PROPOSAL	
7. START DATE	
8. FINISH DATE	
9. EXIT STRATEGY	

II. RESOURCES AND COSTS	
1. OVERALL COST OF THE COLLABORATIVE 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 (can/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 COLLABORATIVE WORKING PROJECT AND HOW CONSULTATION WAS CONDUCTED	

2. DECISION MAKING PROCESSES WITHIN THE COLLABORATIVE WORKING PROJECT (To be open and transparent)	
3. OPERATIONAL AND MANAGEMENT ACCOUNTABILITIES (Include identified conflicts of interest)	
4. PILOTING ARRANGEMENTS (State if this project is a pilot)	
5. PROFESSIONAL INDEMNITY AND LIABILITY ARRANGEMENTS	
6. 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 COLLABORATIVE 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 ◉

<u>If yes</u>, 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 _____

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.

Appendix 2
Framework for joint working between CPPE and the 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	
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	
5.	USE DATA WILL BE PUT TO	

VI. DECLARATION OF INTERESTS YES ☐ NO ☐

<u>If yes</u>, 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 _____

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

THE UNIVERSITY OF MANCHESTER

Manchester Pharmacy School

REGISTER OF INTERESTS (2014), GIFTS AND HOSPITALITY

All members of staff in the School are asked to complete this form in. The information provided will be compiled by the School into a single Register and this document will be referred to staff annually for amendment. Staff are asked to notify the Head of School, or Head of School Administration, of substantive changes in their Registration whenever these occur. The information recorded will be available for inspection by the Registrar& Secretary and the University's auditors. **All staff Grade 6 and above must make a return, even if it is a nil return.**

Name: (*please*

print)…… Please delete

as appropriate:

(a) I have no interests to declare

OR

(b) I wish to register the following information in the Register of Interests, Gifts and Hospitality - Yes

Organisation	**Nature of interest**	**Pecuniary/Non-Pecuniary?**	**Personal/family?** (Is interest personal or that of a family member?)

Nature of Gift/Hospitality	Company /Individual	Approximate value

Signed …… Date ……

PLEASE RETURN ON COMPLETION TO: SHARON FARRELL – sharon.farrell@manchester.ac.uk