Policy for the Sponsorship of Activities and Joint Working with the Pharmaceutical Industry

March 2017 NOTE: This policy will be subject to review in 2017/18 as part of the partnership work between North East Hampshire and Farnham CCG, South East Hampshire CCG, Fareham and Gosport CCG, and North Hampshire CCG.

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Head of Governance

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CONTENTS **Page**

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1. Introduction

1.1 This document sets out North East Hampshire and Farnham Clinical Commissioning Group's (NEH&F CCG) policy 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. This is consistent with Department of Health Best practice guidance for joint working between the NHS and pharmaceutical industry and other relevant organisations[1] and managing conflicts of interest.

2. Policies statement

2.1 The aim of this policy is to assist the CCG to achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry and to inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical industry.

2.2 It specifically aims to assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business and to highlight that NHS staff are accountable for achieving the best possible health care within the resources available.

2.3 The main objectives are to:

- provide all CCG employees a policy framework and guidance for independent contractors for communication with members of the pharmaceutical industry in an appropriate manner;
- make all employees and contractors aware of the limitations of the sponsorship they are at liberty to accept from the pharmaceutical industry;
- introduce mechanisms to recognise potential conflicts of interest;
- ensure that all employees and independent contractors approached by the pharmaceutical industry respond in a consistent manner;
- ensure the interests of patients, the public and the CCG are maintained
- ensure that any sponsorship accepted from the industry is declared publicly to ensure transparency;
- ensure that clinical and financial decisions taken by NHS employees and independent contractors do not rely solely on the advice and interventions of the industry representatives.

2.4 Staff are reminded that at all times they have a responsibility to comply with their own professional codes of conduct and NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCGs.[2] Representatives of the pharmaceutical industry must comply with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry.[3]

3. Scope of this policy

3.1 This document is intended as policy for the CCG and staff who are involved in working with the pharmaceutical industry and should be read in conjunction with the CCG Gifts and Hospitality Policy and Managing Conflict of Interest Policy. The policy includes joint working with the pharmaceutical industry, sponsorship (including meetings) from the pharmaceutical industry, training and education, goods & services. This policy does not cover primary care rebates schemes as the CCG has a separate policy for the Approval of Primary Care Rebate Schemes.

4. Who this policy applies to

4.1 This Policy must be adhered to by all staff (whole or part time) and by Governing Body and Committee Members in their role as representatives of the CCG.

4.2 The term Staff includes individuals who are

- Employed under a contract of employment with the CCG;
- unpaid volunteers of the CCG;
- not employed by the CCG but who exercise functions on behalf of e.g. non-NHS contract staff.

4.3 This policy is recommended as a guide to good practice for independent contractors, their staff and locum practitioners. Therefore member GP practices have the option to adopt this policy for use within the practice, for example maintaining their own logs of gifts, hospitality or sponsorship. In addition, 'Good Medical Practice'[4] published by the GMC sets out standards of conduct expected of all doctors and has specific requirements which relate to commercial sponsorship.

5. Definitions used in this policy

5.1 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.

5.2 Commercial sponsorship is defined as including: NHS funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings or premises.

5.3 For the purpose of this policy the Pharmaceutical industry is defined as other organisations potentially supplying NHS with clinical support, e.g. homecare companies, manufacturers of nutritional products, manufacturers/suppliers of stoma and continence products, other companies whose products are subject to the licensing provisions of the Medicines Act, third party commercial organisations.

6. Roles and responsibilities

6.1 It is the responsibility of each individual employee to follow the policy framework. They must also refer to their line-manager for approval.

6.2 It is the responsibility of line-managers to ensure that employees are fully aware of this policy. They are responsible for checking that requests from all employees to form collaborations with the pharmaceutical industry are thoroughly examined. They must ensure that the work is beneficial to the organisation, that there is no conflict of interest and the framework is adhered to.

6.3 The CCG should be accountable for any agreement and be in a position to evaluate and monitor these agreements. No organisation should be given preferential treatment and individuals must be accountable for their reason for forming relationships with industry members.

6.4 Final consideration and approval for any joint working arrangements will be sought from the Clinical Executive.

6.5 If members of staff are in any doubt about the policy for gifts, hospitality, sponsorship or expenses from the Pharmaceutical Industry they should consult a member of the Governance Team or Executive Director.

6.6 NHS staff should be aware that pharmaceutical industry representatives must follow the "ABPI Code of Practice for the Pharmaceutical Industry".[3] This code of practice is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through self-regulation.

6.7 If an individual staff member becomes aware of a breach of this policy or the Conflict of Interest Policy they should follow section 16 'Failure to disclose/declare and management of breaches' in the CCG Conflict of Interest Policy and the CCG Whistleblowing Policy.

7. Joint Working with the Pharmaceutical Industry

7.1 Joint working between the pharmaceutical industry and the NHS must be for the benefit of the patients or 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.

7.2 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.

7.3 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 existing CCG policies and NHS guidance
- contract negotiations will be negotiated in line with NHS values

- any joint working arrangements agreed must be consistent with existing local prescribing policies, clinical guidelines and pathways e.g NICE, Frimley Health Area Prescribing Committee Joint Formulary decisions
- 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 corporate, rather than at an individual level
- clinical and financial outcomes will be assessed through a process of risk assessment

7.4 Potential joint working arrangements with the Pharmaceutical Industry will be considered through a process for consideration, approval, recording, monitoring and evaluation.

7.5 Examples of particular areas of potential joint working (not exhaustive) include:

- training and development of staff - some companies offer management and organisational development training.
- development and implementation of prescribing strategies, protocols or guidelines (including guideline publication costs).
- educational leaflets - companies may contribute to the cost of producing leaflets in exchange for the company logo being printed on the leaflet, where the size and position of the logo is agreed by the CCG.
- Information technology and other data collection tools.
- Funding of all or part of the costs of a member of staff.

7.6 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. Any other risks or governance issues (clinical or business) need to be considered at the planning stage for any joint working to remove or minimise risk to the CCG or patients.

7.7 For a proposed initiative, the project lead should complete a Proposal Form (Appendix 1), and submit to the Medicines Optimisation Group for consideration and approval to continue to business case stage. The project lead should then complete Appendix 2 which will be submitted to the Clinical Executive for final approval.

7.8 Once the project has been approved, a Joint Working Agreement form (Appendix 3) must be completed and returned to the Medicines Management Team. A register of all joint working projects will be maintained by the Medicines Management Team and held by the Governance Team**.**

8. Sponsorship of Education and Training Events

8.1 Staff should follow the principles outlined in clause 19 of The ABPI Code of Practice for the Pharmaceutical Industry 2016 relating to meetings and hospitality from the pharmaceutical/external industry.[5]

8.2 When organising training or an event, staff must always consider approaching a number of companies so that the CCG is not seen to be favouring one particular company or product in line with the CCG's Standing Financial Instructions.

8.3 Industry representatives may sponsor the venue, refreshments, expenses of practitioners attending the event etc. for local educational meetings. Authorisation to do so must be sought by completion of Appendix 4 'Pharmaceutical Company

Sponsorship Form for Educational and Training Events'. Companies must not provide hospitality to staff except in association with scientific meetings, promotional meetings and scientific congresses and other such meetings.

8.4 Sponsorship for training is accepted on the understanding that:

- The CCG course organiser retains overall control of the event.
- 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, e.g. minutes, action notes.
- The sponsor does not have the right to present any material.
- Where the organiser considers additional value may be gained from a presentation by the sponsor, the presentation is agreed by the CCG in advance of the meeting.
- Course material provided by the pharmaceutical company has no promotion of specific products (the name of the company supporting the training event is acceptable).
- The sponsor does not use the CCG contact to promote products outside the meeting.
- Any stand the sponsor uses to promote products is to be outside the main meeting room where practicable.
- Promotion of the education event excludes product advertisement and must be agreed prior to circulation.
- Honorarium received by any speakers or chair are declared.
- Sponsors do not have the right to insist that the CCG accepts any direct payment for events, training, hospitality

8.5 Details of the sponsorship (from the 'Pharmaceutical Company Sponsorship Form for Educational and Training Events') must be given to the Governance Team for entry in the CCG's Gifts and Hospitality Register.

9. Access to CCG staff and premises by representatives of the Pharmaceutical Industry

9.1 Pharmaceutical Company representatives should be seen by appointment only.

9.2 Visits to the premises should be made only to keep an agreed appointment, or to make such an appointment. Representatives are not allowed to tour the premises looking for staff.

9.4 For the Medicines Management Team, first contact by a pharmaceutical company representative should be directed to the Project Officer for Medicines Management or a member of the Medicines Management team.

9.4 Pharmaceutical representatives requesting a meeting with the Medicines Management team are required to complete the 'Pharmaceutical Representatives requesting an appointment with Medicines Management Team' form (Appendix 5). Request forms will be reviewed at the monthly Medicines Management Team meetings before agreeing to meet.

9.5 All meetings with representatives from the Pharmaceutical Industry should be recorded on the 'Meeting with representatives from commercial organisations' form (Appendix 6) and saved electronically.

10. Conflicts of interest

All staff should follow the CCG Gifts and Hospitality Policy and Managing Conflict of Interest Policy.

11. Bribery legislation

Bribery Act 2010 ("the Act") imposes extensive obligations on all commercial organisations, including those in the healthcare sector, to ensure that they have adequate procedures in place to prevent bribery from occurring within their organisation.

Please refer to the CCG Anti-fraud and Corruption Policy, Gifts and Hospitality Policy and Managing Conflict of Interest Policy.

12. Primary Care Rebate Schemes

12.1 Please refer to the CCG Policy for the Approval of Primary Care Rebate Schemes.

13. Training and Education

13.1 Employees must seek authorisation by their line manager before attending external events sponsored by the pharmaceutical industry. It must be agreed whether the training should be attended in the employees own time, or during working hours. Attendance at training and educational events must demonstrate a benefit to the priorities of the CCG.

13.2 Managers should be careful to ensure that staff are not pressurised by sponsors of training to alter their own practice to accord with the sponsors wishes where these are not backed up by appropriate evidence. This includes pressure to receive direct payment from the sponsoring pharmaceutical company.

14. Dissemination and implementation

This policy and all associated forms will be made available on the CCG's Intranet.

15. Monitoring

15.1 The Governance Team will hold a register of all Proposal Forms and Project Frameworks for Joint Working between the CCG and the Pharmaceutical Industry.

15.2 The Medicines Management Team will hold a register of Primary Care Rebate Schemes.

15.3 Summaries of the respective registers will be subject to an annual corporate review by the Audit and Risk Committee.

Appendix 1

STAGE 1 JOINT WORKING WITH THE PHARMACEUTICAL INDUSTRY
PROPOSAL FORM For a proposed initiative, the project lead should complete this Proposal Form, and submit to the Medicines Optimisation Group for consideration. If approved, a formal application (Appendix 2) will be submitted to the Clinical Executive for a decision.

Name of member of staff ……

Position/ directorate……

Name of sponsoring organisation……..

Sponsor contact name…… Date……...

PLEASE SUMMARISE THE JOINT WORK PROPOSAL

Please include:
TITLE OF PROJECT
AIMS & OBJECTIVES (IS THE PROJECT A PILOT?)
HOW DOES IT CONTRIBUTE TO THE CCG'S OBJECTIVES AND PRIORITIES?
SUMMARY OF EXPECTED OUTCOMES
NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT
NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION
EXACT NATURE OF THE JOINT WORKING PROPOSAL
START DATE/ FINISH DATE (estimated)
EXIT STRATEGY (if applicable)
FINANCIAL IMPLICATIONS
OVERALL COST OF THE JOINT WORKING PROJECT
METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS
INFORMATION ON COST EFFECTIVENESS (Has value for money been shown?)

What is the proposed contribution by the sponsoring organisation?

Submit to Jennie Fynn, Head of Medicines Management
jennifer.fynn@nhs.net

MEDICINES OPTIMISATION GROUP **Review date ……**

Comment on proposal

Approved to proceed to develop formal application to CLINICAL EXECUTIVE:

Approved	**N/Y**

Signed……..

Name……

Position……

Date……

Appendix 2

STAGE 2 JOINT WORKING WITH THE PHARMACEUTICAL INDUSTRY BUSINESS CASE FORM

Complete form and submit recommendation for decision to the **CLINICAL EXECUTIVE.**

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.

Appendix 3

JOINT WORKING AGREEMENT FORM
North East Hampshire and Farnham Clinical Commissioning Group
AND
Insert second party (and any others as necessary)
FOR
Insert title of joint working initiative

1. Principles governing this Joint Working agreement

The following principles and those defined in the framework for joint working will apply:

- All joint working must be for the benefit of patients;
- Joint working will be conducted in an open and transparent manner;
- Arrangements will be of mutual benefit, the principal beneficiary being the patient;
- Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project;
- The CCG retains overall control of the project outlined above
- All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act; Patient confidentiality will be maintained at all times.
- Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
- No data will be disclosed to any third party except on the explicit agreement of all parties;
- Joint working must not be used or seen as endorsement or promotion of any specific medicine or product;
- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;

2. Declaration of Interests

All individuals are required to complete the CCG's Conflicts of Interest Declaration Form which can be obtained from the Governance Team. Declarations of interest will be recorded and maintained by the Governance Team.

I have read and commit to the terms of the Joint Working Agreement and the framework for Joint Working.

Signed: …….. on behalf of: ……

Print name:…….. Date:……

Signed: ……on behalf of……..

Print name:…… Date: ……..

Appendix 4

Pharmaceutical Company Sponsorship Form for Educational and Training Events

To be completed by the event organiser. Please attach details of meeting.

To (Name of Company Lead)

.....
of (Insert company name)

.....
Thank you for agreeing to sponsor the meeting on (Date)

.....
Venue:

……
….
Title of event:

.....
Sponsorship is accepted on the understanding that: -

- The course organiser retains overall control of the training event
- The sponsor does not have a right to present teaching material
- Where the organiser considers additional value may be gained from a presentation by the sponsor, that the content of the material is agreed in advance of the meeting
- Where course material is provided by a 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 the CCG contact to promote products outside the meeting
- Any stand the sponsor uses to promote products is to be outside the main meeting room where practicable
- Promotion of the education event excludes product advertisement
- Honorarium received by any speakers or chair are declared
- Attendance of the meeting by the sponsor is at the discretion of the CCG course organiser and must be agreed before the meeting and disclosed. If a sponsor is attending, please indicate name below. If approved, this must be made clear to attendees and chair of meeting at the start of the meeting.

Name : .....

Designation:.....

Please confirm that you accept the terms detailed above

Signed ..... Date .....

Print name ..... Company .....

For CCG Use Only – Organisational approval

Submitted by: Name:

Department:

Date:

Telephone number:

Email:

Executive approval

Approved / declined (please delete as appropriate)

Director Name:

Signature:

Date:

A copy of this form should be submitted to the Governance Team to record on relevant corporate registers.

Appendix 5

NHS North East Hampshire and Farnham Clinical Commissioning Group
Medicines Management Team

Standard questions for Pharmaceutical Representatives requesting an appointment with Medicines Management Team

To help us deal with your request please could you complete the following short questionnaire.

Please include all topics you would like to discuss.

1. Is your request medicine-specific or about service design?

   ……..

2. If medicine specific, please give trade and generic names of medicine

   .....

3. Is the medicine a PBR excluded drug? YES/NO*
   (Is this drug listed or likely to be included on the Department of Health Payment by Results High Cost Drug Exclusion list for 2010/11 Annex D) {*Please delete)

4. Is the medicine a new product? YES/NO*

   If new product what is the expected launch date? ……..

5. Short summary of topic/s to be discussed

   ……..

   ……..

   ……..

Name of Company ……...

Name of representative/s to attend meeting …….

Email/telephone number ……..

PLEASE RETURN COMPLETED FORM TO: emilydewey@nhs.net

Appendix 6

Meeting with representatives from commercial organisations

Date:	Company:	
Attendees:		
Products discussed		
Points discussed		
Actions Agreed		
Actions Agreed Company		

References

1. Department of Health, 2008. Best practice guidance for joint working between the NHS and pharmaceutical industry and other relevant organisations. https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/dh_082569.pdf

2. NHS England Managing Conflicts of Interest: Revised Statutory Guidance for CCGs https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/revsd-coi-guidance-june16.pdf

3. ABPI Code of Practice for the Pharmaceutical Industry (2016) http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf

4. General Medical Council-Good Medical Practice (2013)- http://www.gmc-uk.org/guidance/good_medical_practice.asp

5. The ABPI Code of Practice for the Pharmaceutical Industry 2016 clause 19 http://www.pmcpa.org.uk/thecode/interactivecode/Pages/clause19.aspx