NHS
Harrogate and Rural District
Clinical Commissioning Group

Policy and Guidance for Joint Working and Commercial Sponsorship with the Pharmaceutical Industry

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1. Scope

This document is intended as Policy for the staff of Harrogate and Rural District NHS CCG (HaRD CCG) that are or may be involved in joint working and commercial sponsorship with the Pharmaceutical Industry. It also seeks to provide guidance and instructions for the wider relationship with the 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 HaRD CCG as well as Members of the CCG and its Committees.

For the purpose of this Policy, joint working is defined as situations where, for the benefit of patients, organisations pool their skills, experience and/or resources for the joint development and implementation of patient centred projects, sharing a commitment to successful delivery. Joint working agreements and management arrangements must be conducted in an open and transparent manner.

It is important that all Parties recognise that operating outside of this Policy could give rise to a challenge of improper conduct on the part of either the staff member concerned or the pharmaceutical company.

NB: 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 including the following;

- The Salary or Costs of staff
- Costs of NHS research
- Training
- Non Pay items such as equipment
- 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 or discounted products of any description
- Provision of free stationery bearing commercial advertising

This Policy should be read in conjunction with HaRD CCG's Standing Orders (SOs) and Standing Financial Instructions (SFIs), which will take precedence over this or any other guidance. Failure to comply with SOs and SFIs is a disciplinary offence.

2. Introduction

Department of Health (DH) Guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry and for commercial sponsorship,

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.

3. Aims and Objectives

The aim of this policy is to:

- Assist HaRD CCG 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 considering entering into joint working arrangements and commercial 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 value for money and the best possible health care within the resources available.

- Avoid situations where approaches from representatives of the Pharmaceutical Industry could amount to inducements or bribes.

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.

4. Meetings of the Governing Body

The CCG holds meetings of its Governing Body in public and indeed is required to do so both by statute and it's Constitution. They are often attended by representatives of pharmaceutical company's.

Those representatives attend meetings in their capacity as members of the public have no special privileges when they do so. They should receive no greater or lesser opportunity to participate in the meeting or engage with individual members of the Governing Body than would any other member of the public.

It has been reported that, GP members of the Governing Body in particular have been approached by representatives who seek to engage with them for the purpose of promoting their particular products or canvassing support for products or projects.

It is recommended in the strongest possible terms **that GPs politely but firmly decline to engage with pharmaceutical representatives in these circumstances**. Governing Body members who chose to disregard this recommendation should be aware that they may place themselves in breach of this Policy or even in beach of the NHS Code of Conduct. Please refer to section 5 and section 10 for further information.

5. Values

In line with the NHS Code of Conduct 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 as well, potentially, as judicial scrutiny in the Courts;

- **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 any HaRD CCG 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.

6. Principles

Joint working must be for the benefit of patients or of the NHS and preserve patient care. Any joint working between the NHS and the Pharmaceutical Industry should be conducted in an open and transparent manner. The principal beneficiary of any relationship must be the local patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

The following principles will also apply to joint working:

- Staff should comply with CCG Standing Orders (SO) and Standing Financial Instructions (SFI) and 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 conducted in line with SO, SFI and 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 subject to a thorough process of risk assessment

- 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. Procedure

There are strict rules about how contracts are awarded through a CCG and the NHS as a whole. Before entering into a joint working arrangement, discussions must take place with CCG Finance, Procurement and Information Governance experts to ensure:

- That the pharmaceutical company has adequate financial standing and that there are no potential irregularities that may affect the Company's ability to meet any contract commitments. For example, performing a Company search or checking with a credit reference agency.

- That there is a robust assessment of the estimated costs and potential benefits involved and that an options appraisal is undertaken where applicable. This should help to ensure that the decision-making process is sound, transparent and defendable from challenges.

- That Information Governance requirement is met and that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with.

- That disclosure for research purposes should not take place without the approval of the appropriate research committees.

- That it is determined how clinical and financial outcomes will be measured and monitored.

- That the sponsorship agreement has a provision to enable the agreement to be terminated if it becomes clear that it is not providing expected agreed outcomes.

The following general guidelines seek to put the relationship between the Pharmaceutical Industry and HaRD CCG staff on a sound and professional footing:

- Staff will extend co-operation to pharmaceutical and other companies where this is in direct interest of patient care and outcomes.

- Company representatives will be seen by the most appropriate member of staff by appointment. The purpose of the visit should be stated in advance. A request for a meeting by a representative does not create an obligation to see that person and may be politely declined at any stage.

- All Pharmaceutical Industry activity should comply with the ABPI Code of Practice published most recently in 2012 or any future revision thereof.

- Medical representatives should be informed about the products on which they are reporting. They should be able to provide information on what is being promoted, the basis of promotion, the specific place the product is expected to have in therapy and technical and clinical data.

- Pharmaceutical companies planning to undertake clinical trials of a drug may seek the co-operation of HaRD CCG (for example by identifying the appropriate patient cohort). The member of staff will require a copy of the trial protocol and has a responsibility to ensure appropriate support for the trial, patient safety, patient confidentiality and compliance with the law. It will normally be appropriate to seek specialist advice to ensure these requirements are met. Such trials should also go through the local ethics committee for approval.

- For reasons of security, representatives must wear an identification badge while on the premises.

- No attempts should be made to seek information of a confidential nature from any member of staff, for example relating to a competitor's prices.

- HaRD CCG has a strict **"No Sample Policy"** and members of staff should not accept any drug samples other than with the express approval, in writing, of the Accountable Officer.

- Completion of the Quality Standards checklist for confidential commercial partnerships must be undertaken and attached to the application form (please see appendices A & B). The application form should be submitted for approval and no form of agreement should be made until specific approval has been given.

8. Value Added Tax for Commercial Sponsorship

Sponsorship is the term commonly used for financial or other support given by either a business or members of the public, to support the activities and aims of that third party. If sponsors receive benefits directly linked to the event then the support is subject to standard VAT at current appropriate levels. If the sponsor gives the money without requiring anything in return then the funding can be regarded as a donation. If it is thought that this would be the case, further advice should be sought from the Chief Finance Officer.

Unless advice has been given to the contrary it **must** be assumed that the sponsorship is subject to VAT and in order to account for this correctly, an invoice should be sent to the sponsor showing the amount of the sponsorship and then adding VAT at the appropriate rate. All invoices must be raised by the finance department.

9. Confidentiality and Data Protection

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

- The Data Protection Act 1998 and any subsequent amendments or sub-ordinate legislation together with any relevant Directions from the DH or other government department.

- The Data Protection Registration of HaRD CCG currently operative.

- Work within requirements set out in HaRD CCG Information Governance Policy.

Staff must be aware that pharmaceutical companies will often seek to impose very wide ranging confidentiality agreements. Legal advice has been obtained which suggests that such agreements will often be contrary to public policy in that they seek to limit the application of the Freedom of Information Act and are contrary to both the statutory Code of Practice issued by the Lord Chancellor on the FOIA as well as the Information Commissioners Guidance to Public Authorities on confidentiality. Specialist advice should be sought in these circumstances.

10. Conflicts of Interest, Payments and Hospitality

HaRD CCG staff are required to declare and record financial or personal interests such as, but not limited to, company shares, research grant awards or consultancy fees in any organisation with which they have to work with. Staff must 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 their private interests or that of others.

Staff and Governing Body members are reminded of the requirement to acquaint themselves with the HaRD CCG Business Conduct policy on the acceptance of gifts and other benefits in kind. This policy follows the guidance contained in the Department of Health circular HSG (93) 5 'Standards of Business Conduct for NHS Staff' and is also deemed to be an integral part of Standing Orders and Standing Financial Instructions.

Staff working in HaRD CCG should follow existing professional codes of conduct and the standards of business conduct for NHS Staff. All staff are also expected to:

- Refuse gifts, benefits, hospitality or sponsorship which might reasonably be seen to compromise their personal judgement or integrity.

- Declare and register gifts, benefits, or sponsorship within 20 working days of the offer being made (provided that they are worth at least £25) whether refused or accepted.

- In addition gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related source in a 12 month period.

Extracts from the Human Medicines Regulations 2012

Regulation 300

(1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is –

a. Inexpensive; and
b. Relevant to the practice of medicine or pharmacy.

(2) A person may not provide hospitality at a meeting or event held for the purposes for the promotion of medicinal product unless –

a. The hospitality is strictly limited to the main purposes of the meeting or event; and
b. The person to whom it is provide or offered is a health care professional.

(3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that –

a. The hospitality is strictly limited to the main scientific objective of the event; and
b. The person to whom it is provided or offered is a health care professional

(4) A person qualified to prescribe or supply medicinal products may not solicitor or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.

(5) In this regulation "hospitality" includes –

a. Sponsorship of a person's attendance at a meeting or event; and
b. The payment of travelling or accommodation expenses.

(6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

The regulations create criminal offences for breach of these requirements which carry a maximum fine of £5,000 and a term of imprisonment of up to two years. Particularly egregious examples may also amount to offences under the Bribery Act 2010 in which case the maximum prison sentence is increased to 10 years and both the individual and their employer can be fined an unlimited sum.

11. Approval of Joint Working Arrangements

Approval of the Chief Financial Officer will be required whenever there are financial or potential contract implications. The Chief Financial Officer or the Accountable Officer may wish to bring a paper outlining the arrangements to Governing Body. However, larger more complex initiatives will require Governing Body approval in accordance with the Scheme of Delegation.

12. Approval of Commercial Sponsorship

All arrangements for commercial sponsorship must be approved by the Governing Body. The Chief Financial Officer will confirm the format of documents that must be submitted to support the case.

13. Equality and Diversity

HaRD CCG recognises the diversity of the local community and those in its employ. The aim is therefore to provide a safe environment free from discrimination and a place where all individuals are treated fairly, with dignity and appropriately to their need, regardless of age, disability, race, nationality, ethnic or national origin, gender, religion, beliefs, sexual orientation, gender reassignment or employment status. HaRD CCG recognises that equality impacts on all aspects of its day to day operations and has produced an Equality and Human Rights Strategy and Equal Opportunities Policy to reflect this. All strategies, policies and procedures are assessed in accordance with the Equality & Diversity Assessment Toolkit, the results for which are monitored centrally.

14. Reference and Additional Reading

Standards of business conduct for NHS Staff HSG (93) 5 DH Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008 Department of Health, 2008.

Best practice guidance for joint working between the NHS and the pharmaceutical industry ABPI 2006 (Gateway Reference 8926), Code of Practice for the Pharmaceutical Industry Department of Health, 2004. Code of Conduct: Code of Accountability in the NHS. 2nd Ed

Harrogate & Rural District CCG **Appendix A**

Proposal for Sponsorship from a Pharmaceutical Company

Title of Project/Event/Training etc	
Aim	
Project Plan	
Expected Outcome	
Sponsor(s) **Amount of sponsorship offered from each sponsor (if not financial give details on separate sheet)**	
Total Funding details **NHS** **Non NHS (sponsor(s))**	
Evaluation Mechanism	

Name:_____Location: _____

Signature: _____

Please send the completed proposal to:
Chief Finance Officer
Harrogate & Rural District CCG
1 Grimbald Crag Court, St James Business Park, Knaresborough, HG5 8QB

Signed by Chief Finance Officer _____ Date: _____

Appendix B

Quality Standards Checklist for Considering Commercial Partnerships			
No.	**Consideration**	**Yes**	**No**
		Please tick	
1	Is the company or organisation “legitimate” – that is, is it a registered company capable of being independently audited?		
2	Does the scheme have aims and objectives?		
3	Does the sponsorship offer any benefits to the following aspects of health care?		
a)	Diagnostic and referral		
b)	Investigations and measurements		
c)	Informing and educating patients (if yes answer 3c (i))		
c (i)	Is the material non-promotional accurate and culturally appropriate		
c (ii)	Will the material be checked by the CCG before it is distributed		
d)	Informing and educating health professionals (if yes answer 3d (i)		
d) (i)	Is the information valid, complete, balanced and up to date		
4	**Sponsorship that is directly related to patient treatment**		
a)	Is the sponsorship related to patient treatment? (if no go to question 5)		
b)	Have alternative treatments been considered and evaluated?		
c)	Has an assessment of the costs and benefits of the package in relation to alternative options been investigated?		
d)	Has monitoring of the patients been considered as part of the treatment?		
e)	Has a criteria for success of the project been established?		
f)	Has patient perceptions been included as part of the criteria?		
g)	Has a health care professional been designated clinically responsible for the patient at each stage of the package?		
h)	Has an assessment been made as to how the package fits with existing systems of primary and secondary care?		

		Yes	No
		Please tick	
5	**Sponsorship that relates to information systems or flows**		
a)	Is the sponsorship related to the collection of data? *(if no go to question 6)*		
b)	Who will own the data?		
	The CCG		
	The Sponsor		
c)	Will the sponsor have access to the data?		
d)	Have the provisions of the Data Protection Act been taken into consideration?		
e)	Who will evaluate the data?		
	The CCG		
	The Sponsor		
6	**Sponsorship related to the provision of events or hospitality**		
a)	Is the sponsorship related to the provision of events/hospitality *(if no go to 7)*		
b)	Is the event organised by:		
	The CCG		
	The sponsor		
c)	Will the sponsor be represented at the event?		
d)	Will the sponsor advertise at the event?		
e)	Has sponsorship of the event been open to other sponsors?		
f)	Have other sponsors offered sponsorship?		
g)	Has other sponsorship been:		
	Accepted		
	Declined		

		Yes	No
		Please tick	
7	**Sponsorship related to the provision of products**		
	Is the sponsorship related to any of the following:- *(if no go to question 8)*		
a)	Provision of clinical products? *(if yes answer questions a (i) and a (ii))*		
a) (i)	If clinical products will this encourage the use of a particular product in the future?		
a) (ii)	Will the use of the product limit patient choice?		
b)	Provision of equipment – *(if yes answer b(i) and b(ii))*		
b) (i)	Is the equipment linked to the use of one particular brand of consumables?		
b) (ii)	Has an assessment been undertaken to establish that it is the best for purpose?		
c)	Provision of free stationery:- *(if yes answer c(i) and c(ii)*		
c) (i)	Does the stationery include commercial advertising?		
c) (ii)	Has the CCG control over the content of the advertising?		
8	Are there any recurring costs for the scheme?		
9	Who will be responsible for recurring costs?		
10	Has VAT been considered? (see paragraph 6)		
Notes.	Further Information		
Question No	Answer all questions with one of the following:- Yes No Where additional information is shown on the bottom section of the page, add ‘N/A’ for questions which are ‘not applicable’ to the type of sponsorship		
1			
2	Any application to have commercial sponsorship agreed must have this checklist attached		