Norfolk and Waveney
Integrated Care Board

Norfolk and Waveney ICB

SPONSORSHIP AND JOINT WORKING POLICY

Document Control Sheet

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Approved documents are valid for use after their approval date and remain in force beyond any expiry of their review date until a new version is available.

Name of document:	**Sponsorship and Joint Working Policy**
Version:	**1**
Date of this version:	**August 2023**
Produced by:	**Associate Director of Pharmacy and Medicines Optimisation**
What is it for?	The purpose of this policy is to raise awareness of proper process when seeking sponsorship to protect staff from undue influence. This policy should ensure that educational events and joint working projects are of an acceptable standard and in-line with ICB objectives. Financial risks of such work is kept to a minimum.
Evidence base:	
Who is it aimed at and which settings?	All ICB employees and community providers.
Impact Assessment:	
Other relevant approved documents:	ICB Conflict of Interest Policy July 2022 COI Policy (sharepoint.com)
References:	Please see references
Monitoring and Evaluation:	This policy will be reviewed every two years (or earlier in light of new legislation/guidance).
Training and competences:	
Consultation:	No public consultation undertaken
Reviewed by:	Planned Care and Medicines Management Working Group 24.08.23 Director of Corporate Affairs Senior Information Risk Officer
Approved by:	Executive Management Team
Date approved:	30 August 2023
Signed:	
Dissemination:	NWICB Intranet and website
Date disseminated:	31 August 2023
Review Date:	Bi-annually or earlier in light of new legislation/guidance.
Contact for Review:	Michael.dennis@nhs.net

Version control

Revision Date	Summary of changes	Author(s)	Version Number
Dec 2019	Scope adjusted to include only CCG's and community providers at this stage	M Dennis	0.6
Jan 2020	Further examples of inappropriate situations	M Dennis	0.7
July 2023	Policy updated to reflect change from CCG to ICB	Corporate Affairs	0.8
Aug 2023	Minor amendments and updates around ICB descriptors and name of group from committee to advisory group	M Dennis	0.85

CONTENTS

1. INTRODUCTION

The pharmaceutical industry is in the business of developing, marketing, and selling its patented medicines and devices. Products brought to market during the patent period are usually priced at a significant premium. When brought to market there will by definition be a lack of long-term outcome or safety data to support a product's use. NICE however take on the role of assessing cost-effectiveness with its programme of technology appraisals. Our area prescribing committee - Norfolk and Waveney Therapeutics Advisory Group (TAG) take on assessing new drugs and devices that are not subject to NICE guidance. Our regional Priorities Advisory Committee (PAC) also provide guidance on non-NICE drugs and technologies. Increasingly the regional medicines optimisation committees (RMOCs) are also taking views on various medicines. Integrated Care Boards (ICB's) only have a statutory obligation to make funding available for NICE approved technologies subject to technology appraisals within given timetables.

Products within a similar category that are late to market often price themselves lower in order to access market share at a faster rate. Such products often become preferred for first line use.

NHS Norfolk and Waveney Integrated Care Board's (hereafter referred to as the ICB) area prescribing committee makes recommendations for formulary inclusion based on:

- Preferred sequence of drugs in a disease area (1st line to specialist).
- Pathways of all drugs in a disease area including NICE approved drugs where there are several options.

The Code of Conduct Code of Accountability in the NHS second revision 2004 contains the following principles:

- **Accountability:** Everything done by those working 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 NHS trust, its staff and patients.
- **Relationship with suppliers:** NHS trusts should have an explicit procedure for declaring hospitality and sponsorship offered. They should be aware of the risk in incurring obligations to suppliers at any stage of a contracting relationship. Suppliers should be selected on the basis of their quality, suitability, reliability and value for money.

The Department of Health's guidelines on Commercial Sponsorship – Ethical Standards for the NHS (November 2000) presents standards for "basic sponsorship". Here there is guidance for dealing with commercial organisations providing funding (usually in full) for educational events and "small projects". The ICB's will have a register of interests available for public scrutiny. Organisations and individuals receiving money from the pharmaceutical industry will be listed in the database here.

Further Guidance - Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and other relevant Commercial Organisations (Jan 2008) has been provided. This guidance covers true joint working where NHS resources (financial and/or human) are combined with those of a commercial organisation to, for example, provide a service.

Because of the potential risk to NHS resources and patients a higher level of probity is required and a formal contract with full documentation must be established. For example, provision of health care services must be financially sound (not make a loss for the NHS and be highly cost-effective) and in particular, arrangements must be made in advance for exit strategies for both parties that allow for continuation of the care for patients once established.

Some of the dilemmas of working with the Pharmaceutical Industry are described in Doctors, Patients and the Drug Industry – Partners, Friends or Foes? Krumholz, H (2009).

Some research by the British Medical Journal (BMJ) suggests that hospital trusts have varying degrees of oversight and governance of joint working arrangements and sponsorship. This is something we may wish to address in a future version of this document as we further enhance integrated care system working. NHS joint working with industry is out of public sight, BMJ 2019;364:l1353 doi: 10.1136/bmj.l1353 (Published 27 March 2019)

2. PURPOSE

The aim of this policy is to:

- Assist the commissioning body 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 with the pharmaceutical industry. Specifically, it aims to:
    - assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business
    - highlight that NHS staff are accountable for achieving the best possible health care within the resources available

The purpose of this policy is to raise awareness of proper process when seeking sponsorship to protect staff from undue influence as sponsorship is rarely given without an expectation of return on the investment.

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 whose company is a member of the ABPI must comply with the *ABPI Code of Practice for the Pharmaceutical Industry.*

Misbehaviour or deviation from the Association of the British Pharmaceutical Industry (ABPI) code of practice by representatives of the pharmaceutical industry should be reported to the regulator via this link.

3. SCOPE

This policy will apply to all ICB employed staff, and community providers. Hospital trusts have their own governance arrangements for sponsorship and free samples. Hospital consultants and other staff wanting us to promote sponsored events should seek approval for this through this process. The ICB will not support or promote any events not approved in this way.

Any joint working arrangements supported by the pharmaceutical industry or other suppliers are covered by this policy.

Sponsorship may include the provision of hospitality and funding for one off events, these activities are thus covered by this policy. The provisions of significant quantities of free samples unless in formulary should be firmly declined. Trusts will have their own policies on free samples and these should be adhered to at all times. 'Free' stock is only ever given with the expectation of onward supply to patients, this is intended to create demand for repeat prescriptions. These items are nearly always premium priced and in those circumstances they are intended to circumvent NHS processes on the entry of new products.

The policy also covers rebates from suppliers, these should receive an appropriate level of scrutiny, they are normally presented to the PrescQipp Pharmaceutical Industry Scheme Governance Review Board (PISGRB) for a recommendation. All assessments are placed on the PrescQIPP website and are available to subscribers. Requests are welcomed for additional schemes that need assessing. Any comments about assessments should be directed to help@prescqipp.info. Some rebate agreements or discounts may fall outside of this arrangement if they are part of a portfolio buying arrangement through for example NHS supply chain, for example some dressings suppliers favour these kinds of arrangements.

The ICB has a separate policy and process for the approval of rebates.

4. POLICY

Key points which the commissioning organisation will need to note:

1. As a commissioning organisation within the new NHS, it is now more important than ever that we can demonstrate probity when dealing with potential providers.

2. As financial pressures escalate sponsorship/joint working may appear more attractive.

3. Those in contract with the ICB need to demonstrate that they abide by NHS guidance and local policies. This should form part of the contractual obligation with the provider.

4. Collaboration should be acceptable within the constraints of public accountability and the objectives of the collaboration should be clearly stated by each party.

5. All proposals for sponsorship, promotion of sponsored events or 'joint working' must be considered by the Sponsorship Advisory Group, which meets on an 'as required' virtual basis.

6. As most commercial sponsorship requests involve pharmaceutical companies, the ICB's Associate Director of Pharmacy and Medicines Optimisation should be required to give advice on whether proposals would compromise the organisation's aims to encourage safe, cost effective, and evidence-based prescribing.

7. Proposals apparently involving “loss leaders” and “introduction of patent extending products” need to be very carefully scrutinised in the context of costs and safety to the overall health economy.

8. Proposals should not involve endorsing a particular product or a use outside of local or national guidance.

9. The Sponsorship Advisory Group needs to consider the wider implications of sponsorship for specific projects e.g. creation of “credibility by association” which can lead to activities outside of any specific program which have not been endorsed by the commissioning body.

10. Individuals who are asked to present (or contribute) to sponsored educational events, when their presence is as a result of their current role within the Integrated Care Board (ICB) and Integrated Care System (ICS) (or could be taken as such) should seek permission from their line manager and consider “credibility by association” as above.

11. Sponsorship for meetings should not be proposed unless the products involved are in line with the approach to safe, cost-effective, and evidence-based prescribing.

12. Sponsorship for training should only be accepted if the training is in line with the commissioning bodies policy as set out in the strategic aims and objectives of the organisation. Ideally it will have been identified through a training needs assessment or to support the use of a cost-effective product on our formulary.

13. One company must not be favoured for sponsorship to the exclusion of all others.

14. If joint working is planned, there must be a written contract stating the exact conditions of the collaboration, audit criteria and a clear exit strategy.

15. Rebate proposals should be referred to the Associate Director of Pharmacy and Medicines Optimisation who will deal with them in line with our rebate policy.

16. Free samples intended for onward supply to patients should always be declined unless the product is on formulary.

5. PROCESS TO BE USED WHEN APPLYING FOR COMMERCIAL SPONSORSHIP FOR ICB OR COMMUNITY PROVIDER EVENTS OR FOR SUPPORT OF TRUST SPONSORED EVENTS WITHIN THE ICB/ICS

1. The applicant(s) will be expected to have read this policy and the associated guidance and to follow it.

2. The application form (Appendix 1) must be completed. Any Individual within the ICB or its community providers requesting sponsorship should ensure their Director or Senior Manager is aware of the proposal, has signed it, and approves of the application being forwarded to the Sponsorship Advisory Group.

3. Requests for commercial sponsorship will be considered by the Sponsorship Advisory Group, whose objectives are to assess the benefits or otherwise of proposals for the local NHS economy.

6. SPONSORSHIP ADVISORY GROUP PURPOSE

To assess the benefits, or otherwise, of proposals for commercial sponsorship and joint working arrangements for the local NHS economy.

6.1 Process

- The group will meet on an as required basis, usually virtually.
- The group will make its decisions in-line with the principals outlined in sections 1 and 2 of this document. These will be communicated to the applicant, in writing, having been endorsed by an ICB Director.
- Where major joint working is proposed the Sponsorship Committee may make a preliminary view/decision which may be referred back to the Planned Care and Medicines Management Group or other Committee (e.g. Finance Committee) for further consideration.

6.2 Committee Membership

The Sponsorship Committee core membership will consist of:

- The Executive Director of Nursing or his/her deputy
- Associate Director of Pharmacy and Medicines Optimisation or deputy.
- A GP chair of the Therapeutic Advisory Group
- Head of Formulary and Interface Pharmacist.

The Committee can co-opt further advice if it feels this is necessary.

7. APPROVALS

All applications must be approved by the Associate Director of Pharmacy and Medicines Optimisation or Medical Director AND the Executive Director of Corporate Affairs.

8. POLICY MONITORING AND REVIEW

The Associate Director of Pharmacy and Medicines Optimisation will undertake the monitoring and review of this policy. This policy and procedure will be reviewed every two years (or earlier in light of new legislation/guidance).

9. HOW DOES JOINT WORKING DIFFER FROM SPONSORSHIP?

Joint working is distinctly different from sponsorship. In sponsorship arrangements pharmaceutical companies simply provide funds for a specific event or work programme.

In joint working, goals are agreed jointly by the NHS organisation and company, in the interest of patients, and shared throughout the project. A joint working contract must be drawn up and management arrangements conducted with participation from both parties in an open and transparent manner.

10. REFERENCES

- The Code of Conduct: Code of Accountability in the NHS 2nd revision July 2004
- Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England November 2013
- Standards of business conduct for NHS staff (1993) (Amended, in part, by the Bribery Act 2010)
- Department of Health's guidelines on Commercial Sponsorship – Ethical Standards for the NHS (November 2000)
- Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and other relevant Commercial Organisations (Jan 2008)
- Pharmaceutical Industry are described in Doctors, Patients and the Drug Industry – Partners, Friends or Foes? Krumholz HM BMJ2009;338:b324
- Moving beyond sponsorship – joint working toolkit https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-harmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf

10. FURTHER READING

Innovating for Health: Patients, physicians, the pharmaceutical industry and the NHS. Royal College of General Practitioners February 2009 ISBN 9781860163517

APPENDIX 1: APPLICATION FORM

PART 1: APPLICATION FOR APPROVAL OF NON-NHS FUNDING	
Name of Project	
Purpose of Project	
Dates/Duration of Project	
Amount of proposed funding:	
Time limit for process of application (please note most applications will be dealt with as quickly as possible, but if you require decision in less than 1 month please indicate deadline)	
Responsibilities of Key Person for each party	
ICB or community provider	
Name:	
Contact Address:	
Telephone No:	
Email address:	
Role/responsibilities for the project:	
How does this proposal benefit the ICB and ICS?	
Are there any disadvantages in this proposal for ICB/ICS?	
Commercial Sponsor Details	
Contact Name:	
Organisation name:	

Contact Address:	
Telephone No:	
Email address:	
Role/responsibilities for the project:	
How does this proposal benefit the company?	
Details of any current involvement in ICB/ICS	
Potential quality improvements	
Potential financial risks	
Details of any current involvement in neighbouring NHS Organisations	
Current portfolio of marketed products available in the UK	
Other key person(s) involved (Names, Company (if applicable), Address and Role/Responsibilities)	
Additional/supporting Information – attach additional documents/pages if required.	

	Signature	**Print name**	**Date**
Person requesting sponsorship:			
Senior manager supporting sponsorship request:			

Please email completed application form to nwicb.medsqueries@nhs.net

PART 2: APPROVALS			
	Signature	**Print name**	**Date**
Associate Director of Pharmacy and Medicines Optimisation or Medical Director			
Executive Director of Corporate Affairs			

For Sponsorship Advisory Group use	
Group meeting date:	
Group recommendation:	
Group comments:	
Outcome	Approved / Declined
Date approved/declined	

Date to Planned Care and Medicines Management Working Group	
Date recommendation communicated to applicant	

APPENDIX 2: EXAMPLES OF POTENTIAL CONFLICT – COMMERCIAL SPONSORSHIP

It may be helpful to give some examples of the sorts of situation you could encounter and how they could be dealt with. These are given below:

A. A clinician wishes to include a new drug, manufactured by a company with which he has links e.g. Company shares, research grant, speaker fees or conference expenses in the Trust Formulary.
Trust Committee (e.g. Drug and Therapeutics Committee) should require declarations of interest from clinicians submitting proposals for new products to be added to formularies and ensure the decision is based on clinical and cost effectiveness information;

B. A trust wants to use a manufacturer to pay for the printing of a new pathway that includes their products, the products have not been approved by our local formulary processes.
The trust should apply for formulary addition and seek approval of the pathway if that is appropriate, the benefit in kind should be declared and manufacturer influence in the wording should not occur.

C. A trust or community provider are planning a patient facing event to showcase new products e.g. stoma or urology. Samples will be given to patients
Trusts should be pro-active in preventing sponsored meetings where patients are targeted with samples with the sole purpose of creating demand for newer, probably more expensive products. Samples of all non-formulary products should be declined and never passed onto patients.

D. A pharmaceutical industry representative wishes to present the case for a new product being included on an ICB/Trust Formulary.
The ICB/Trust should establish and adopt a reasonable policy on approaches from industry representatives. Industry representatives should be required to sign up to compliance with such a policy before being given access to any meetings.

E. Offer from a company to provide for training of staff.
Employers should be careful to ensure that staff are not pressurised by sponsors of training, to alter their own activity to accord with sponsors' wishes, where these are not backed up by appropriate evidence. Training provided by industry may be above board if it is unbiased has mutual benefit for both the NHS and the sponsoring company, is evidence based and the hospitality is appropriate. However participants should assess whether they may be influenced unduly and also bear in mind what benefits the company might derive (e.g. exposure to NHS, professional contacts, potential allies to use later, names of who to influence, often without the participants realising);

F. A manufacturer of ostomy equipment offers to sponsor a stoma nurse post in an NHS Trust.
The Trust should not accept the sponsorship if it would require the stoma nurse to recommend the sponsor's in preference to other clinically appropriate appliances, nor if it requires the Trust to recommend patients to use a particular dispensing service or withhold information about other products. Existing contracts containing any such provisions should, where possible, be urgently renegotiated.

G. A manufacturer of a particular type of Nicotine Replacement Therapy offers to provide their product at a reduced rate to an NHS area.
This arrangement is acceptable **provided that** there is a clear clinical view that these products are appropriate to particular patients **and** there is no obligation to also prescribe these products to other patients for whom an alternative product would be at least as beneficial.

H. A catering company offers to provide discounted products to an NHS Trust.
This agreement is acceptable but should be routinely declared to NHS England.

I. High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product.
Contract negotiators should advise the company that any contract will not prejudice the provision of the most appropriate service to patients and will not bear any relation to other contracts.

J. A manufacturer offers to pay the travelling costs or accommodation costs for clinicians invited to a conference to view medical products.
Only clinicians with a specific interest in the products should attend and the travel costs incurred should be paid for by the trust, unless the Chief Executive/Executive Director of Finance gives approval for the potential supplier to take responsibility for the costs. Such decisions should be taken at least at Director of Finance level.

APPENDIX 3: DECLARATION OF INTEREST

Chairs, Board members, Sponsorship Advisory Group, Planned Care and Medicines Management Working Group and Primary Care Commissioning Committee members should act impartially and should not be influenced by social or business relationships; no-one should use their public position to further their private interests. Where there is potential for private interests to be material and relevant to NHS Business, these must be declared.

The Chair and Board members must declare, and keep up to date, details of any personal or business interests, which may influence, or may be *perceived* to influence, their judgement. This should include, as a minimum, personal direct and indirect financial interests and should normally also include such interests of close family members. Indirect financial interests arise from connections with bodies that have a direct financial interest in the business of the organisation, or from being a business partner of, or being employed by, a person with such an interest.

Positions of authority in a charity or voluntary body in the field of health and social care, and any connection with a voluntary or other body contracting for NHS services should be declared.

Sponsorship Advisory Group, Planned Care and Medicines Management Working Group and Primary Care Commissioning Committee members are reminded of auditors' recommendations in this regard and all parties are asked to complete the appropriate declaration when requested; this includes the submission of a 'nil' return where appropriate