



NORTH WEST LONDON CARDIAC NETWORK

**Draft Policy for Collaborating with the Pharmaceutical Industry
and Allied Commercial Organisations**

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Central Southern Cardiac Network
Neath Port Talbot Local Health Board
Suffolk West Primary Care Trust
South and East Dorset Primary Care Trust



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1.0 INTRODUCTION

In recent years there have been several key policy documents in which the Department of Health (DoH) urges NHS organisations to develop greater partnerships with the pharmaceutical industry and other commercial organisations. In particular, in the *New NHS: Modern, Dependable*, the DoH places an obligation on Primary Care Groups, Health Authorities, NHS Trusts and Primary Care Trusts to work collaboratively with other agencies to improve the health of the population they serve.¹ NHS organisations must make themselves aware of what available support there is in terms of funding, training and other services, in order to develop high quality, cost effective and equitable healthcare for the population and make the best use of limited publicly funded resources.

There are a variety of areas in which working collaboratively can be mutually beneficial to both the NHS and private industry. The NHS is by far one of the biggest customers for commercial industries in the UK. It is important to remember that a major objective of these companies is to maximise profits; the 'hard-sell' style of marketing is gradually being substituted for more subtle approaches to developing relationships with the NHS. It is imperative that high ethical and professional standards are upheld throughout all dealings with the individuals from the commercial sector.

The North West London Cardiac Network (NWLCN) seeks to develop new and build upon existing partnerships with the pharmaceutical industry and allied commercial organisations (collectively referred to as 'industry' from this point onwards), as one way of meeting its key objective, which is to ensure the delivery of high quality and equitable cardiac services across the whole of North West London. In doing so, the NWLCN must make certain that all joint working with industry primarily benefits all patients within the local health economy, that all dealings with individuals from industry is open and transparent and meets the high ethical standards of practice as befits a publicly funded body.

¹ DoH (1997). *The New NHS: Modern, Dependable*. The Stationery Office: London



2.0 PURPOSE

The NWLCN recognises the mutual benefits which can be gained from working collaboratively with industry and welcomes opportunities to develop such partnership working wherever it is deemed appropriate. The purpose of this policy therefore is five-fold:

- (i) To promote openness and transparency in all joint working between representatives from industry and representatives of the NWLCN.
- (ii) To ensure unbiased, evidence-based, cost effective and equitable cardiovascular healthcare for the population of North West London, through the development of collaborative working with industry.
- (iii) To ensure that the implications of entering into joint arrangements with industry are considered fully prior to formalising any agreement and that agreements made do not compromise relationships between NWLCN constituent organisations.
- (iv) To provide a framework within which all health professional and non-health professional members who are working in the capacity of the Network are fully aware of their obligations and the procedures and processes which must be followed.
- (v) To ensure that systems are in place to manage and review communications and joint working with industry, under corporate governance arrangements.

3.0 SCOPE

For the purposes of this policy, the term 'industry' applies to all commercial companies including and allied to the pharmaceutical industry (e.g. device manufacturers). Joint working between members of the NWLCN and charitable and voluntary organisations, as well as funding received from lottery grants are dealt with separately in Section 6.0.

This policy applies to all forms of direct and indirect contact between these organisations and an individual acting in their professional capacity for the NWLCN. It is not a replacement for and therefore must be read in conjunction with the various codes of conduct for healthcare professions to which some of our members belong. Individual practices, GPs and members of other constituent



organisations will continue to be able to engage with industry as they deem appropriate and in line with the relevant codes of practice.

Collaborative projects may involve, but are not limited to:

- Funding of all or part of the costs of a member of staff
- NHS research
- Staff training
- Provision of pharmaceuticals and/or equipment
- Meeting rooms and costs associated with meetings
- Hotel and transport costs
- Meals
- Hospitality
- Provision of free services such as speakers or premises
- Gifts*

*National guidance² excludes gifts and sponsorship which are less than £25 in value e.g. post-it pads, pens etc. However if several small gifts amounting to a total of £100 or more are received from the same or closely related source within a 12-month period, then, these should be declared.

² DoH (2000). Commercial Sponsorship: Ethical Standards for the NHS. The Stationery Office: London.



4.0 GUIDING PRINCIPLES

- **Patients needs first**

Joint working between NWLCN and industry should be for the benefit of our patients and service users.

Any relationship with industry must promote and enhance equitable access to evidence-based, high quality and cost effective healthcare for cardiovascular patients in North West London.

- **Alignment with Network priorities**

NWLCN will only support collaborative working with industry and other agencies that addresses local and national priorities.

NWLCN will preferentially support projects that develop the expertise and capabilities of the staff and organisations within the Network. Exceptions may be for short-life projects, local recruitment difficulties or short term cover.

- **A balanced, whole systems approach to healthcare delivery AND a consensus based, collaborative approach to decision making**

Any collaboration with industry and other agencies will be considered fully in the context of the North West London sector and the NHS as a whole. The Network will not pursue collaborations which may have a significant negative impact on other parts of the healthcare system.

A consensus based decision making approach will be pursued in order to ensure equality of service provision across the whole of the sector.

Collaborative projects which focus on broader cardiovascular health improvement initiatives are preferable to those which focus on specific drugs or products.

Wherever appropriate, collaborations must be long term to enable benefits to be sustained.

- **Mutual trust, honesty and respect**

NWLCN recognises the needs of industry to promote specific drugs, devices and other products and maintain profitability.

NWLCN will not enter into agreements with organisations whose business or conduct is ethically unacceptable or who do not respect the needs of the Network and the NHS as a whole to deliver evidence-based, cost effective and equitable care.



- **Impartiality**

Clinical and prescribing policies and guidelines will be based upon the principles of evidence-based medicine and best practice and hence clinical decision making within the Network will be unbiased by the collaboration. These policies and guidelines will be consistent with national recommendations and guidance from expert bodies such as the National Institute for Health and Clinical Excellence (NICE), British Cardiovascular Society (BCS), Joint British Societies (JBS), European Society of Cardiology (ESC) and the American College of Cardiology (ACC), to name a few.

In entering into partnership arrangements, the Network will ensure that they are not conditional on the use of the organisation's product in preference to other, more cost effective and clinically appropriate products or services.

Collaborations with multi partners are desirable. If the Network is approached by one company, other companies who provide similar products or services should be invited to contribute to the partnership.

- **Openness and transparency**

All documents relating to communications and agreements made between the NWLCN and industry and other agencies will be open for inspection to the public.

- **Responsibility and clinical accountability**

Clinical aspects of projects must always be under local control. Development of prescribing or clinical guidelines and protocols will be developed in accordance with usual procedures in the respective host organisations in conjunction with the relevant prescribing and clinical governance groups.

Clinicians will retain the ability to select the most clinically appropriate and cost effective treatment for individual patients (subject to the policies and procedures of their host organisation).

NWLCN may decide that advice or guidelines developed by industry are consistent with NWLCN policies and suitable for distribution.



5.0 OBLIGATIONS

5.1 Obligations of the NWLCN

The NWLCN should:

- Make all staff aware of this policy and the necessity to abide by relevant codes of practice and follow the processes set out herewith.
- Ensure that the interests of patients are foremost in any proposed partnership agreement.
- Ensure that the principles of **patient confidentiality and data protection** are respected at all times. All collaborative projects must comply with the Caldicott principles, Data Protection Act (1998) and Freedom of Information Act (2000). All data remains the property of the Network and/or host NHS organisation. Only data that has been agreed beforehand and itemised in the formal agreement, shall be released to the company.
- Ensure consultation with the Network Clinical Lead and/or Clinical Governance sub-group to ensure robust clinical assessment of any proposed arrangement – This is in line with the Network's strategic responsibility to highlight areas and make recommendations for improvement to clinical practice across the sector.
- Ensure that the Network is not seen to promote the products and services of individual companies.
- Satisfy itself that there are no potential irregularities that may affect the company's ability to meet the conditions of the agreement.
- Ensure that agreements contain a break clause in order that they can be terminated should it become clear that the company is not able to meet the conditions of the agreement.
- Ensure that contract negotiations are conducted according to high ethical standards.
- Review existing contracts which include any element of sponsorship arrangements to ensure that they meet the standards as set out in this policy.



5.2 Obligations of staff working in the capacity of the NWLCN

All staff should:

- Ensure that they have read and fully understand this policy and behave in accordance with the relevant codes of practice. For staff whose roles do not come under the remit of professional codes of practice, a model code of practice can be found in Appendix 1.
- Declare any relevant personal or financial interests that they, a close relative or associates (as far as they are aware) may have in any other organisation (particularly those which the Network are considering going into partnership with), that may conflict with their NHS responsibilities.
In liaising with staff from industry, NWLCN staff must ensure that they are not placed in a position that could result in a conflict of interest between their private interests and their NHS duties.
- Refuse to accept direct payment of fees by a commercial organisation, when s/he is acting in the capacity of the Network, under NHS terms and conditions in an authorised working arrangement with a commercial company. Any such fee must be paid to the Network of host organisations and not to the individual.
e.g. There may be some instances whereby staff working in the capacity of the Network may be offered money or other inducements by industry representatives to complete questionnaires or partake in other such research. It is not the Network's policy to participate in any such activity regardless of whether any inducements are offered.

5.3 Obligations of Industry

All representatives working in the capacity of pharmaceutical and allied industries should:

- Comply fully with the *ABPI Code of Practice for the Pharmaceutical Industry* and/or other code of practice relevant to the commercial sector.
- Comply fully with the *Medicines (Advertising) Regulations 1994*, an extract of which can be found in Appendix 2. Particular attention is drawn to regulation 21(2,c) which implies that industry representatives must not offer hospitality at events to members of the public.

Complaints about the promotion of medicines, including the content of advertisements and breaches of the ABPI code of practice should be submitted to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London SW12 2DY – Telephone (020 7930 9677).



6.0 CORPORATE GOVERNANCE

6.1 Reporting, review and monitoring arrangements

The Network recognises the need for the establishment of an Industry sub-group of the Network Board. This group will be chaired jointly by the Network Director and Clinical Lead. Terms of reference will be agreed which will include responsibility for the production, implementation and monitoring of this policy. However, until such a time as the Industry sub-group is fully operational;

The Network Executive³ is responsible for producing, reviewing and monitoring the implementation of this policy. The policy will be reviewed and ratified by the Network Board every *two* years.

All proposals for sponsorship and joint working must be presented to the Network Executive for approval. They must be assessed regarding the costs and benefits as compared with alternative options, as well as in line with the guiding principles as outlined previously in this document. The checklist and agreement proforma found in Appendices 3 and 5, should be used.

Individuals involved in the development or consideration of a proposal must declare any potential conflicts of interest at the outset of the process. These may include:

- Shareholding or directorships in companies
- Research or educational grants
- Consultancy work
- Speaking at industry-sponsored events

Any arrangements for sponsorship and/or joint projects will be set out explicitly in writing and will contain the aims and objectives of the collaboration, a start and finish date and details of the obligations of each party, as a minimum. All supporting documentation e.g. details of meetings will be written using the proforma supplied in the appendices to this policy and will be kept with the relevant agreement and/or formal contract. All agreements and/or formal contracts will be signed by the Network Director and the appropriate representative from the commercial organisation (e.g. Senior Manager). Counter-signatory arrangements will be in place when agreements are to be signed in the absence of the Network Director and/or senior manager from the commercial organisation.

The Network Director will maintain a register of all sponsorship and collaborative agreements. The register (NWLCN Register of Sponsorship and Collaborations with Industry) will record details of those proposals which were submitted and approved or not-approved, including the reason(s) for non-approval. The register will be available to the public for inspection via the Network's website. A summary of its contents will be reported on a regular basis in the Network's Annual Report.

³ For the purposes of this policy, the Network Executive is taken to include the following: Network Chair, Network Director and Network Clinical Lead.



The following offers specific guidance for staff working in the capacity of the Network with regards to the internal reporting arrangements:

6.2 Contacts with Industry representatives

For the purposes of this policy, the term 'contact' refers to all forms of direct or indirect communications with industry representatives e.g. face-to-face, telephone, email, post etc.

The Network Director will be the official lead contact for industry and all contacts must be reported to the Network Director at the earliest opportunity.

Individuals employed by the Network and/or its constituent organisations will continue to have the professional freedom to engage with industry, however they must ensure that all contacts are in line with relevant codes of conduct.

6.2.1 Meetings

The Network Board recognises that individual staff may be approached by industry representatives who have not first contacted the Network Director. All contact should be appropriate to the Network employee's role within the organisation.

Staff should fully consider whether it is necessary or appropriate to meet with an industry representative before agreeing an appointment; there may be circumstances when obtaining written information from the company will suffice or when meeting the representative as a team rather than individually may be more appropriate.

It is usually good practice to arrange meetings by appointment. Industry representatives should request to meet with Network staff by prior appointment only.

Staff should, wherever possible, request information from a company prior to meeting with a representative. This will allow time to critically appraise the information and to prepare relevant questions to ask.

Staff should use the proforma provided when holding meetings with industry representatives. This can be found in Appendix 4.

Meetings with industry will be monitored by the Network Executive to assess the appropriateness and frequency of meetings to ensure there is no bias towards one particular company.



6.3 Sponsorship

The reporting arrangements for sponsorship and/or gifts received from industry will be dependant upon the monetary value of that sponsorship or gift. All offers of sponsorship will be approved or not approved by the Network Director. Table 1 below outlines the process which staff working in the capacity of the Network must follow:

Table 1

Sponsorship Value	Authorisation Required?	Process to be followed
Less than £25	No	Notify the Network Director at the earliest opportunity
£25 to £100 (either as a single gift or several small value gifts from the same or closely related source)	Yes	Notify the Network Director. Network Director to enter details in the NWLCN Register of Sponsorship and Collaborations with Industry.
£100 to £1000	Yes	Submission of proposal to the Network Director. Network Director to enter details in the NWLCN Register of Sponsorship and Collaborations with Industry.
Greater than £1000	Yes	Submission of proposal to the Network Director. Network Director to enter details in the NWLCN Register of Sponsorship and Collaborations with Industry. All proposals valued at £1000 or more will be reported to the Network Board.



6.4 Sponsorship of Network events

Where Network events are sponsored by external sources, this must be disclosed in all publications relating to the event in addition to a statement which states that the Network does not endorse the products or services of the company.

The selection of speakers and invitation of delegates must remain in the sole control of the Network.

Commercial organisations are able to offer 'reasonable' hospitality at meetings and events, provided that it is secondary to the purpose of the meeting or event. The level of hospitality must not be out of proportion to the occasion and the payment of costs must not exceed that level which the participants would normally pay themselves.

The provision of hospitality does not give the commercial organisation the right to address the attendees (including patients and public) at the meeting or event. They must first have the permission of the Network if they wish to take part in the event.

The commercial organisation must not advertise or imply, either verbally or in writing that the Network endorses the use of a particular product.

6.5 Sponsorship of staff training

The potential for industry to influence the practice of staff, particularly clinical practice, should be borne in mind whenever sponsorship for staff training is offered.

Sponsorship of training must not be conditional on the use of a particular product or service.

Details of the sponsorship of staff training must be recorded in the NWLCN Register of Collaborations with Industry.

6.6 Funding of all or part of a post

The potential for industry to influence the practice of staff, particularly clinical practice, should be borne in mind whenever the offer of funding for all or part of an NHS post is offered.

The Network will not accept offers of outside clinical support provided by the commercial organisation.

Individuals employed as part of a collaborative project must be made aware of their obligation to behave in a manner consistent with relevant codes of conduct independent of any influence of the commercial organisation.



6.7 Sponsorship of Research & Development

Any staff working in the capacity of the Network and undertaking company sponsored research, must seek authorisation through existing local arrangements and details recorded in the NWLCN Register.

7.0 Charitable and Voluntary Organisations and Lottery Funding

The NWLCN, as an NHS body, endeavours to work closely with charitable and voluntary organisations. The Network must refer to guidance on income generation by NHS bodies as regards charitable funds, detailed in the policies and procedures of the Network organisations and in line with the revised National Health Service Income Generation-Best Practice Guidance.⁴

The NWLCN will take into account any voluntary activities already undertaken within its partner NHS organisations, before considering agreeing new arrangements for working with relevant voluntary organisations.

Lotteries can be a useful method of providing resources for NHS charitable funds. Any funding provided using lottery funds must comply with criteria provided in the Lottery and Amusement Act (1976) as amended by the National Lottery Act (1993).

⁴ DoH (2006). National Health Service Income Generation – Best Practice. Revised Guidance on Income Generation in the NHS. The Stationery Office: London



APPENDICES

Appendix 1 – Model Code of Practice

NHS staff and independent contractors working for the NHS should follow existing codes of conduct. Staff who are not covered by such a code are expected to:

- Act impartially in all their work.
- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking influence to obtain preferential consideration. All such gifts should be returned or hospitality refused.
- Declare and register gifts, benefits or partnership arrangements of any kind, in accordance with time limits agreed locally (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 £100 are received from the same or closely related source in a 12-month period. The ABPI code of practice permits the provision of promotional aids, which cost the company no more than £6 + VAT.
- Declare and record material, financial or personal interests (e.g. company shares, research grants) 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.
- Not misuse their official position or information required in their official duties to further their private interests or those of others.
- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services.
- Beware of bias generated through partnership arrangements, where this might impinge on professional judgement and impartiality.
- Neither agrees to practice under conditions which compromise professional independence or judgement, nor impose such conditions on their professionals.



Appendix 2 – Extract from the Medicines (Advertising) Regulations 1994

Inducements and hospitality

- 21.—(1) Subject to paragraphs (2) and (4), where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.
- (2) The provisions of paragraph (1) shall not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that—
- (a) such hospitality is reasonable in level,
 - (b) it is subordinate to the main scientific objective of the meeting and
 - (c) it is offered only to health professionals.
- (3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless—
- (a) such hospitality is reasonable in level,
 - (b) it is subordinate to the main purpose of the meeting or event, and
 - (c) the person to whom it is offered is a health professional.
- (4) Nothing in this regulation shall affect measures or trade practices relating to prices, margins or discounts which were in existence on 1st January 1993.
- (5) No person qualified to prescribe or supply relevant medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

Any person who contravenes regulations 21 (1) is guilty of an offence and liable, on summary conviction, to a fine not exceeding £5000, and on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years or both. Anyone contravening 21 (5), is also guilty of an offence and liable, on summary conviction to a fine not exceeding £5000.

**Appendix 3 – Sample Checklist for Considering Proposals**

	YES	NO
Is the NWLCN satisfied with its knowledge of the sponsoring organisation(s) i.e. Is there evidence of audited accounts, is the organisation and its ownership known, is it capable of being independently audited?		
Does the service on offer align with current views on evidence-based clinical practice (check with Clinical Lead and prescribing advisers as appropriate)?		
Is the service on offer consistent with NWLCN priorities?		
Is this or a similar service available from another source e.g. from within the Network's stakeholder NHS organisations?		
Can the NWLCN confirm that there is no current or potential conflict of interest for the NWLCN or any of the staff in relation to the services offered?		
Have the NWLCN discussed the proposed collaboration with relevant parties e.g. GPs, Trusts etc?		
Will the NWLCN be provided with a full documented service agreement?		
Are there clear lines of accountability in terms of clinical, professional and managerial responsibilities clearly documented and appropriate?		
Is it clear how and when patients are to be involved and are the requirements of data protection and patient confidentiality met?		
Is Research Ethics Committee approval required for this project?		

**Appendix 4 - Proforma for Meeting with Industry Representatives**

Meeting Title:	
Date and Time:	
Name(s) of NWLCN representative(s) present:	
Name(s) of industry representative(s) present:	
Purpose of meeting:	
Summary of discussion:	
Further action required (if any):	

Please submit a completed copy of this proforma to the NWLCN Director, with a copy to your line manager.



Appendix 5 – Proforma for the Joint Working Agreement between the NWLCN and Industry

NHS Organisation:	Network Director North West London Cardiac Network
Agreement with:	
Project Title:	
Aim(s) of project:	<i>Define the aim(s) of the project</i>
Project Objective(s):	<i>A list of clearly defined objectives describing exactly what the project has been established to achieve</i>
Summary of expected outcomes:	
Service to be provided Inclusions: Exclusions:	<i>Description of all the services to be provided by the commercial organisation. A description of any areas or activities in which the commercial organisation must not be involved or where approval must be obtained. Details of the project plan, personnel to be involved and how the project will be managed must be stated.</i>
Period of agreement Start Date: Finish Date:	
Financial arrangements* Total cost of the partnership agreement:	



<p>Breakdown of direct and indirect costs associated with the project.</p> <p>Details of the cost/benefit or value for money analysis:</p> <p>Method of payment:</p>	<p><i>Payment terms must be agreed in advance. The NWLCN should not commit to any start-up costs for which no funding has been agreed and received in advance.</i></p> <p><i>The method for making payments or receiving funding must be identified and comply with Standing Orders and Standing Financial Instructions.</i></p>
<p>Period of notice:</p>	<p><i>The period of notice by which the agreement may be terminated by either party.</i></p>
<p>Performance:</p>	<p><i>The performance monitoring arrangements must be clearly stated.</i></p> <p><i>Details of a break clause which allows the termination of the agreement as a result of unsatisfactory performance, must be clearly stated.</i></p>
<p>Confidentiality:</p>	<p><i>A comprehensive confidentiality clause must be included.</i></p>
<p>Arbitration:</p>	<p><i>Arrangements for arbitration or other dispute resolving mechanisms must be stated.</i></p>
<p>Agreement:</p>	<p><i>The agreement must be signed and dated by the Network Director and an appropriate member of the commercial organisation (e.g. Senior Manager).</i></p> <p>Name (NWLCN Network Director):.....</p> <p>Signed By (NWLCN Network Director):-----</p> <p>Name (Industry Senior Manager):.....</p> <p>Signed By (Industry Senior Manager):-----</p>

* The amount and duration of any funding must be agreed in advance and mechanisms must be in place to amend or adjust the funding arrangements during the course of a project.

Clear and unambiguous arrangements regarding the longer term funding for projects for a duration beyond that envisaged by the initial project, must be stated. Cont'd.....



Funding must not be contingent upon any arrangement to use a specific product other than in circumstances where this is the basis of the project itself.

Financial arrangement should not be entered into with a single individual with the company, but must be entered into and approved by a senior member of the company as appropriate.

Funding must be kept in separate cost centres and must comply with current accounting conventions adhered to by the NHS and be available for audit by internal and external auditors.