The Northern Neonatal Network
An Operational Delivery Network
Website - **www.nornet.org.uk**

NHS

Commercial Sponsorship Policy

June 2017

Due for review – June 2019

Northern Neonatal Network

Policy on Commercial Interests and Business Standards

Purpose and summary

This policy is intended to give guidance on commercial sponsorship arrangements that are made within the Northern Neonatal Network, but only where the Network itself is involved. It is NOT applicable to individual Trusts where the name or role of the Northern Neonatal Network is not involved. Examples of when the Policy would apply are given throughout this document but broadly speaking, events such as study days, conferences and workshops that are purely "in house" and not Network-specific or Network-wide would not come under this policy. If in doubt, always check the contents of the full Policy and seek the advice of the Network Manager or Clinical Lead.

The main points of the Policy to consider are as follows;

- All commercial sponsorship arrangements need to adhere to existing Department of Health advice, given below, although these are not particularly recent, but still apply.
- Individual Trust policies are not superseded by this one – it is merely to support them and give clarity where the Network is involved.
- Professional codes of conduct must always be adhered to and individuals are responsible for ensuring that any commercial sponsorship arrangements do not breach them.
- Clarity, transparency and honesty are the main principles behind this Policy and must always be the guiding values so that the name and reputation of the Northern Neonatal Network is never brought into disrepute through any inappropriate sponsorship arrangements.
- The Network Manager and Clinical Lead are the main points of contact for any queries relating to this Policy and are responsible for ensuring it is adhered to. Either can be utilised within this role and it is not necessary to involve both as mutual discussions are regular.
- The Network Board is ultimately responsible for final decisions relating to the Policy, but need not be involved in every case directly unless the Network Manager or Clinical Lead feel it appropriate to involve them in this capacity. In most cases, keeping them informed and making decisions on the basis of this Policy as agreed will be sufficient to avoid unnecessary delays between the quarterly Board meetings.
- Financial arrangements by way of sponsorship for Network events may be overseen by a Trust if it is hosting the event, but the Network need to be fully informed of the arrangements through the Manager or Clinical Lead as detailed in the Policy (section 3:13)
- Any study day that is sponsored by one of the artificial feed companies must not provide a conflict of interests with any Host Trust that has, or is seeking the UNICEF Baby Friendly award

The Policy has been agreed and signed off by the Network Board but is subject to periodic revision as detailed on page 2 or sooner if required, but must always be ratified again if any significant changes are made, particularly in the light of new government legislation or NHS England/DH guidance.

1 Introduction

The November 2000 DH document "Commercial Sponsorship – Ethical Standards for the NHS" outlined guidelines for all NHS employees and organisations. It built on the previous circular "Standards of Business Conduct for NHS Staff - 1993 (HSG (93)5)" regarding the general standards which should be maintained by staff working in the NHS when it comes to outside business interests, conflicts and potential issues arising from commercial sponsorship. It made clear that "collaborative partnerships with industry" can be beneficial to NHS organisations but that there needs to be "a fully transparent approach to any sponsorship proposed to an NHS Trust or Organisation such as a Clinical Commissioning Group (CCG), or to independent contractors and their staff."

With this in mind, it is appropriate to give due consideration to all matters regarding commercial interests and business standards which we wish to adopt and adhere to in the Northern Neonatal Network. This is particularly relevant where companies may approach the Network and seek to sponsor events or Board members for particular purposes. Individuals are obviously bound by their own professional codes of conduct as well as their employing NHS organisations, but where it is the Network itself that is involved as the main point of contact with any commercial company, it is important that similar principles govern the interaction between the two. For this reason and drawing on the existing guidance mentioned above, the following principles should apply at all times;

1.1 Principles

- Accountability – everything done by those who work in the NHS and thus the Northern Neonatal Network must be able to stand the test of parliamentary scrutiny, public judgements on propriety and professional codes of conduct.

- Probity – there should be an absolute standard of honesty in dealing with the assets of the NHS and Network: 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 and Network duties.

- Openness – there should be sufficient transparency about NHS and Network activities to promote confidence between the NHS or Trust/organisation and its' staff, patients and the public.

2 Commercial Sponsorship Policies – DH Guidance

In terms of the specifics that are naturally underpinned by these summary principles, the DH guidance is clear and can be defined according to the following from which they are taken;

- The Network needs to fully consider the implications of a proposed sponsorship deal before entering into any arrangement. In particular it is important to seek advice when necessary from NHS England on the effect on other aspects of healthcare.
- For the purposes of this guidance, 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. In all these cases

NHS bodies, members of NHS staff and independent contractors should use local arrangements to publicly declare sponsorship or any commercial relationship linked to the supply of goods or services and be prepared to be held to account for it.

- Where such collaborative partnerships involve a pharmaceutical company then the proposed arrangements must comply fully with the Medicines (Advertising) Regulations 1994 (regulation 21 'Inducements and hospitality' attached at annex B). Any person who contravenes regulation 21(1) is guilty of an offence, and liable, on summary conviction to a fine, and on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or both. Anyone contravening regulation 21(5) is also guilty of an offence and liable, on summary conviction to a fine.
- The MCA Guidelines on Promotion and Advertising set out the standards to be followed. Whatever type of agreement is entered into, clinicians' judgement should always be based upon clinical evidence that the product is the best for their patients. A model code is attached at Appendix A, for use by those who do not have an existing professional code of conduct. Where an Employer's code is used, this should be in addition to professional codes, or be for the benefit of those staff who are not.
- When making purchasing decisions on products which originate from NHS intellectual property, ethical standards must ensure that the standard is based on best clinical practice and not on whether royalties will accrue to an NHS body.
- Deals whereby sponsorship is linked to the purchase of particular products, or to supply from particular sources, are not allowed, unless as a result of a transparent tender for a defined package of goods and services, (see Appendix C on research and development).
- Patient information attracts a legal duty of confidence and is treated as particularly sensitive under Data Protection legislation. Professional codes of conduct also include clear confidentiality requirements. It is extremely important therefore that NHS bodies assure themselves, taking advice when necessary, that sponsorship arrangements are both lawful and meet appropriate ethical standards.
- Where a sponsorship arrangement permitting access to patient information appears to be legally and ethically sound (e.g. where the sponsor is to carry out or support NHS functions, where patients have explicitly consented), a contract should be drawn up which draws attention to obligations of confidentiality, specifies security standards that should be applied, limits use of the information to purposes specified in the contract and makes it clear that the contract will be terminated if the conditions are not met.
- Where the major incentive to entering into a sponsorship arrangement is the generation of income rather than other benefits, then the scheme should be properly governed by income generation principles rather than sponsorship arrangements. Such schemes should be managed in accordance with income generation requirements, i.e. they must not interfere with the duties or obligations of the trust. A memorandum trading account should be kept for all income generation schemes.
- As a general rule, sponsorship arrangements involving NHS Trusts and other bodies (NHS England, CCGs etc) should be at a corporate, rather than individual level.
- Industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have been incurred. If none is required, there is no obligation, or right, to provide any such hospitality, or indeed any benefit of equivalent value.
- Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion and the costs involved must not exceed that level which the recipients would normally adopt when

paying for themselves or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.

- Where meetings are sponsored by external sources, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.
- Employers should ensure that monitoring arrangements are established to ensure that staff register any sponsorship and are held accountable for it. This may be through scrutiny by an appropriate committee, e.g. local audit or ethics committees, as part of their normal activity, as well as through publication in the Annual Report, where this is practicable. An official register of interests should be established as part of the monitoring arrangements. At corporate level, employers should ensure that contract negotiations are conducted according to high ethical standards.
- Employers finding evidence of unapproved sponsorship should act swiftly to deal with the situation and bring it within their local arrangements.
- Employers (e.g. NHS Trust, NHS England, CCGs) and independent contractors should:

    1. Make all staff aware of NHS guidance, the legal position and appropriate professional codes of conduct, e.g. GDC, GMC, RCN, RPSGB, NMC, and Prescription Medicines Code of Practice Authority (PMCPA) codes;
    2. Take responsibility for ensuring that they and their staff adhere to their professional code, or for unregulated staff a code devised by the organisation. The code should contain clear guidance around offers of sponsorship
    3. Ensure all sponsorship deals are documented through use of a register or simple ledger, held by the employer, which can be audited as appropriate. In order to demonstrate openness, it is essential that the Register should be available on request to the public and be made available at all Board meetings;
    4. Make it a matter of policy that offers which could possibly breach the code must be reported. Minimum standards for the reporting system should be determined locally, but ideally should include some time limit (e.g. two weeks) for the reporting of any such offers;
    5. Ensure that all staff record with their Employer/Board, in the interests of transparency, any financial interest in organisations (e.g. company shares or research grant) which impact upon funding, whether through contracts, sales or other arrangements that they may make with non NHS organisations.

- Before entering into any sponsorship agreement, NHS Trusts, other NHS employers, CCGs and independent contractors should:

    1. Satisfy themselves, with reference to information available, that there are no potential irregularities that may affect a company's ability to meet the conditions of the agreement or impact on it in any way e.g. checking financial standing by referring to company accounts.
    2. Assess the costs and benefits in relation to alternative options where applicable, and to ensure that the decision-making process is transparent and defensible.
    3. Ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee;
    4. Determine how clinical and financial outcomes will be monitored
    5. Ensure that the sponsorship agreement has break clauses built in to enable the NHS Trust, CCG, independent contractor etc to terminate the agreement if it becomes clear that it is not providing expected value for money/clinical outcomes.

3 Implementation

3.1 Guidelines for Partnerships

The common aim with any engagement with a commercial company seeking to undertake sponsorship of a Network event should be to promote high quality effective healthcare for a specific priority area. The following criteria must be explicitly addressed in any proposals for partnership:

- How it links to the Network's priority objectives;
- How it links to local and national strategic priorities;
- How it benefits the health of the local population, especially in terms of quality of healthcare delivered and evidence based clinical practice;
- How it links to the sponsoring companies corporate objectives.

3.2 Product and Company Names

Any proposal will need to state explicitly the quantity and/or nature of any advertising and promotion of individual products and pharmaceutical or other companies.

The Network will not endorse or support proposals where there is excessive promotion of individual products, services or companies.

The Network will evaluate proposals in terms of measurable improvement in the quality of care providing in line with evidence-based practice.

The Network will actively encourage the pharmaceutical industry and other companies to reduce resources currently invested in goodwill activity and brand promotion and reinvest in appropriate partnership activity.

3.3 Publicity

Before the commencement of any proposal, the Pharmaceutical Company or other third party should undertake not to publicise its involvement with the Network without the prior knowledge and agreement of the Network.

3.4 Contact Policy

The Network encourages Independent Contactors to apply the core principles and guidelines outlined in this policy and the appendices below.

The contact points for clarification are the Neonatal Network Manager and Clinical Lead, but need not be both and are merely the initial point of contact for clarity and transparency. If other clinicians and/or nurses within the Network are seeking to obtain sponsorship for a *Network* event or study day for example, they need to ensure that the Network Manager or Clinical Lead are fully briefed and kept informed so that the Policy can be adhered to and potential conflicts prevented. In any event the Network management team should always be fully aware of any commercial sponsorship arrangements and in any doubt, approached for advice and support

Network Staff:

Any pharmaceutical or other company should inform the Network through the Network Manager or Clinical Lead before contact is made with Network staff where it is Network projects, as opposed to individual NICU/SCBU sponsorship that is being explored. This will ensure that the most appropriate member of staff or contact can be identified and that staff time and resources are maximised rather than duplicated for both parties. Staff who are approached should redirect

the approach as appropriate. Verbal contact must also be supported by written notification. For initiatives concerning strategic development, direct contact should be made with the Network Manager or Clinical Lead.

Network-wide initiatives.
Initiatives, which include

- Involving more than a single Unit
- The roll out of evidence based practice across the Network;
- A research element;

should be taken through the process described below.

1. Written/phoned request for a meeting should be directed to the Network Manager or Clinical Lead.

2. Outline the proposed area for collaboration/partnership prepared in advance, preferably written with due consideration of the principles and guidelines contained in this policy.

3. The Network Manager or Clinical Lead will direct the contact to the most appropriate individual(s) for further action. This might include:
   - Network Educator/Lead;
   - Project Leads
   - Board members, such as Unit links;
   - Lead Clinicians for the specific priority area within the proposal;

4. The process below should then be followed:
   - Hold a face-to-face meeting regarding the proposal. A meeting summary will be produced for the benefit of the company and the Network and a copy kept on file by the Network Manager;
   - The sponsoring company should produce a written proposal outlining the initiative in detail and submit this to the Network Manager;
   - The written proposal, after discussion with relevant clinicians and managers may need to sent to the Network Board for a decision. This need not be at the quarterly Board meeting itself as timeframes may make this impractical, but the Network manager can arrange suitable Board discussion and feedback via means such as email distribution or telephone as felt most appropriate.
   - If supported, the proposal will be taken forward by a nominated lead from the Network.

This has been developed to ensure a single point of contact for the Pharmaceutical Industry and other sponsoring organisations and a robust and transparent decision-making system for the Network.

The Pharmaceutical Industry and other sponsoring organisations are strongly discouraged from cold-calling members of Network staff or Network Board Members to discuss promotional events.

3.5 Network led initiatives

Where the Network has identified projects that could be taken forward in collaboration with the Pharmaceutical Industry or other sponsoring organisations, the Network manager or Clinical Lead should be informed. The system to develop a proposal and contact the Pharmaceutical

Sector or other appropriate sponsor should be agreed and noted in writing between the individual proposer, the Network Manager or Clinical Lead. The developed proposal must be taken to the Network Board for a final decision regarding implementation and management.

Approaches the Network will consider for initiative development
• Funding or (rarely) personnel on short term secondment to develop policies to address specific issues;
• Funding to facilitate training and educational initiatives that are aimed at improving the management of a condition;

• Funding or (rarely) personnel on short term secondment to implement the delivery of agreed policies at practice level;
• Use of industry educational or management resources to augment existing Network resources for specific projects.

Approaches the Network will not support
• Nursing support for setting up clinics. An organised approach addressing the whole pathway of care would be more appropriate than pump priming.
• Company representatives seeing several members of the Network or individual Units to deliver the same message;
• Activity where there is no explicit benefit other than that of promoting good will, a product or company;
• Sponsorship of practice based events other than those outlined above and in line with the guidelines contained in this policy;
• Initiatives that duplicate or conflict with existing practices;
• Any partnership specifically linked to the purchase of particular products or to supply from particular source, unless they result from a transparent tender for defined goods and services.

3.6 Hospitality and Meetings

Representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs that may have been incurred. For example, if the refreshments have been organised and paid for by a medical practice the cost may be reimbursed as long as it is reasonable in relation to what was provided and the refreshments themselves were appropriate for the occasion. Donations in lieu of hospitality are unacceptable as they are inducements for the purpose of holding a meeting. If hospitality is not required at a meeting there is no obligation or right to provide some benefit of an equivalent value. Donations to charities in return for representatives gaining interviews are prohibited.

The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.

Where meetings are sponsored by external companies, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

The provision of hospitality includes the payment of reasonable, actual travel costs, which a company may provide to sponsor a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate is not permitted. The payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, for speakers, is permissible. If the honoraria relates to a meeting attended in Network work time then it should be made payable to the Network.

Pharmaceutical companies may appropriately sponsor a wide range of meetings. These range from small lunchtime audio-visual presentations in individual hospital Unit meetings and meetings at postgraduate education centres, launch meetings for new products, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia through to large international meetings organised by independent bodies with sponsorship from pharmaceutical companies.

In summary, therefore, with any meeting, certain basic principles apply:

• The meeting must have a clear educational content;
• The hospitality associated with the meeting must be secondary to the nature of the meeting, must be appropriate and not out of proportion to the occasion and:
• Any hospitality provided must not extend to a spouse or other such person unless that person is a member of the health professions or appropriate administrative staff and qualifies as a proper delegate or participant at the meeting in their own right;
• Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves are the responsibility of those they accompany;
• Administrative staff may be invited to meetings where appropriate.

Meetings organised for groups of doctors, other health professionals and/or for administrative staff, which are wholly or mainly, of a social or sporting nature are unacceptable.

3.7 Acceptance of Commercial Sponsorship for attendance at Conferences and Courses
Acceptance by members of the Northern Neonatal Network management team or Board of commercial sponsorship for attendance at relevant conferences and courses as a representative of the Network itself is acceptable, but only where permission has been sought and granted in advance and the Network is satisfied that acceptance will not compromise its decisions via the Board in any way.

3.8 Provision of Information to Commercial Sponsors
Patient information attracts a legal duty of confidence and is treated as particularly sensitive under Data Protection legislation. Professional codes of conduct also include clear confidentiality requirements. It is extremely important therefore that NHS bodies in general and the Network in particular, assure themselves, taking advice when necessary, that sponsorship arrangements are both lawful and meet appropriate ethical standards. A principal component of such assurance will be compliance with the principles of the Caldicott report.

The Data Protection Act 1998 requires that each database should have a data controller responsible for the satisfactory administration of the data and its conformance with the DPA. The Network Data Manager is the named person for all databases and content that are generated and by and on behalf of the Network. Data controllers have a duty to ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee.

Recent case law has suggested that disclosure of anonymised patient information does not constitute a breach of confidentiality. However, there is a breach of confidence if information is disclosed in any form by which the patient can be identified. The Northern Neonatal Network will not, therefore, under any circumstances, allow information to be given to commercial sponsors by the Network's officers or representatives that will identify either individual patients,

staff, Units, contractors or premises without their informed consent.

Where a sponsorship arrangement permitting access to patient information appears to be legally and ethically sound (e.g. where the sponsor is to carry out or support NHS functions, where patients have explicitly consented), a contract should be drawn up which:
• Draws attention to obligations of confidentiality;
• Specifies security standards that should be applied;
• Limits use of the information to purposes specified in the contract; and
• Makes it clear that the contract will be terminated if the conditions are not met.

All information generated as a result of commercial sponsorship activity or research and subsequent publications shall remain the property and copyright of the Network.

Disclosure of patient information to commercial healthcare organisations is generally a point of major concern with patients and it has not been established in any detail as to what forms of disclosure might be acceptable. Consistent with current standards of best practice, the Northern Neonatal Network would carefully vet any such exchanges at the highest level, and information should only be shared where it is in the overall best interests of patients or the public at large. This would be via Board approval.

3.9 Commercial Sponsorship of Posts – 'Linked Deals'
The Network should not enter into such agreements unless it has been made abundantly clear to the company involved that the sponsorship will have no effect on Network decisions. Where such sponsorship is accepted, the Network will arrange for monitoring systems to be established to ensure that purchasing decisions are not being influenced by the sponsorship agreement.

The Network should under no circumstances agree to 'linked deals' whereby sponsorship is linked to the purchase of particular products or to supply from particular sources.

3.10 Sponsored Travel
On occasions where the Network considers it necessary for staff advising on the use and subsequent potential purchase of equipment, pharmaceuticals etc and to inspect such items in operation in other parts of the country (or, exceptionally, overseas), the Network should meet the cost, so as to avoid putting in jeopardy the integrity of future purchasing decisions.

3.11 Income from Sponsorship
The Network will not enter into any sponsorship arrangement where there is direct generation of income rather than other benefits. Any such arrangements offered must be declined and reported via the Network Manager or Clinical Lead. Only arrangements of the non-income generating type detailed above will be considered via the approved routes already laid out.

3.12 Monitoring Arrangements
In order to demonstrate openness and transparency the Network will ensure that:
• All sponsorship is reported to the Network Board;
• Details of sponsored projects and research initiatives will be recorded in a clear and open manner in the Network's Annual Report;
• All staff (employed by and associated with the Network) should record any financial interest in organisations (e.g. company shares or research grant), which impact upon funding, whether through contracts, sales or other arrangements that they may make with non-NHS organisations to the Board via a Network Register of Members and Staff's Interests. The Register should be reviewed annually by the Network Board if any entries have been made;
• All staff (employed by or associated with the Network) involved in setting up and

implementing joint projects must take note of and comply with the Codes of Conduct of the NHS and the relevant professional bodies such as the GMC and NMC.

• Any issues relating to implementation or further development of this policy should be directed to the Network manager in the first instance.

• Offers that could possibly breach codes of conduct must be reported to the Network Board at the next available board meeting.

3.13 Financial arrangements

In many or most cases, the Network will merely play a role as overseer of any commercial sponsorship arrangement. In terms of the actual "funding" of Network events where sponsorship has been secured by a clinician or nurse/manager for an event being held at their own base, even though for a Network purpose, it is probably best that individual Trusts who are acting as "host" for any event or study day for example usually deal with the finances through their own departments, obviously always on a not-for-profit arrangement. They would, however need to ensure that the Network, by way of Manager or Lead Clinician as previously detailed is fully aware of the arrangements and are given copies of any invoices and receipts.

Where the Network itself has secured commercial sponsorship for an event, the Manager or Clinical Lead will hold receipts and make them available for the Board as required. These will usually be processed by the Trust overseeing their contract or the host Trust for the event, as appropriate. As long as the audit trail is clear, transparent and adheres to the Policy and Network Manager/Clinical Lead and through them the Board are aware of any commercial sponsorship arrangement, potential problems and conflicts of interest should be avoided. If in doubt, always seek the advice of Network Manager or Clinical Lead as a first step.

3.14 Research and Development

Exceptionally, in the case of non-commercial research and development (R&D) originated or hosted by NHS providers, commercial sponsorship may be linked to the purchase of particular products, or to supply from particular sources. This should be in accordance with the guidance at paragraph 28 of HSG (97) 32 Responsibilities for meeting Patient Care Costs Associated with Research and Development in the NHS.

Paragraph 28 of HSG (97) 32 states:

"At present, industry frequently contributes to the costs of pharmaceuticals (and other products), which are the subject of non-commercial R&D in the NHS. Although, by definition, such items constitute Treatment Costs, the NHS will continue, under the Partnership Arrangements, to look to researchers and non-commercial research funders to secure such contributions before approaching the NHS for support."

Where there is industry collaboration in such studies, companies may alternatively make a contribution towards the study's costs, rather than supply of product.

Any funding for research purposes should be transparent. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, the Network will wish to consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended and as such should be submitted to the Network Board for discussion of the impact of the research.

Where R&D is primarily for commercial purposes, NHS providers are expected to recover the

full cost from the commercial company on whose behalf it is carried out. (HSG (97) 32, paragraph 7). An industry-sponsored trial should not commence until an indemnity agreement is in place; see the guidelines in HSC (96) 48 NHS Indemnity, Arrangements for Clinical Negligence Claims in the NHS. A standard form of indemnity agreement, agreed with ABPI, can be found at Annex B of that guidance.

The NHS should benefit from commercial exploitation of intellectual property derived from R&D that the NHS has funded, or for which it has been funded, even where people outside the NHS own the intellectual property itself. The Network will ensure that an agreement to this effect is included in any contracts concerning R&D. The guidelines in HSC 1998/106 Policy Framework for the Management of Intellectual Property within the NHS from R&D should be followed.

3.15 Milk companies and the UNICEF Baby Friendly Initiative

It is important to be particularly careful whenever sponsorship or commercial arrangements involve any organisation or company involved in the manufacture and/or promotion or artificial milk formula feeds. Many of the nine Trusts in the Network have either been accredited for the UNICEF baby Friendly Initiative, or are in the process of seeking it and any direct links with such a company in this way may be detrimental to it. Whilst the UNICEF statement on this issue is clear that "Baby Friendly Initiative standards do not expressly prohibit health professionals' attendance at formula company study days", they also state that "attendance is strongly discouraged". This is laid out on their website –

In order to avoid any potential conflicts of interest, it is therefore suggested that anybody seeking to organise a ***Network*** study day seeks the advice of both the Network manager or Clinical Lead AND their own Trust's Head of Midwifery before proceeding, but that where the UNICEF Baby Friendly accreditation is in place or being sought, it is probably unlikely to be possible to proceed. Individuals attending study days where they are *not* representing the Network itself are not governed by this but still advised to read the statement at the website beforehand to avoid any potential conflicts of interest with their own Trust policy.

APPENDIX A

CODE OF CONDUCT

Staff and independent contractors working in the NHS should follow existing codes of conduct. Staff that 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 exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused;
- Declare and register gifts, benefits, or sponsorship 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 over £100 are received from the same or closely related source in a 12 month period.
- Declare and record financial or personal interest (e.g. company shares, research grant) 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;
- Make it a matter of policy that offers of sponsorship that could possibly breach the Code be reported to their Board (NHS Trusts, CCGs etc).
- Not misuse their official position or information acquired in the course of 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 sponsorship, where this might impinge on professional judgement and impartiality;
- Neither agree to practise under any conditions which compromise professional independence or judgement, nor impose such conditions on other professionals.

APPENDIX B

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 at a reasonable 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.

APPENDIX C

RESEARCH AND DEVELOPMENT

1. Exceptionally, in the case of non-commercial research and development (R&D) originated or hosted by NHS providers, commercial sponsorship may be linked to the purchase of particular products, or to supply from particular sources. This should be in accordance with the guidance at paragraph 28 of HSG(97)32 Responsibilities for meeting Patient Care Costs Associated with Research and Development in the NHS.1 Where there is industry collaboration in such studies, companies may alternatively make a contribution towards the study's costs, rather than supply of product.
2. Any funding for research purposes should be transparent. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, NHS bodies will wish to consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended.
3. Separate Guidelines exist for pharmaceutical company Sponsored Safety Assessment of Market Medicines (SAMM) which remain in force.
4. Where R&D is primarily for commercial purposes, NHS providers are expected to recover the full cost from the commercial company on whose behalf it is carried out. (HSG (97)32, paragraph 7). An industry-sponsored trial should not commence until an indemnity agreement is in place; see the guidelines in HSC (96)48 NHS Indemnity, Arrangements for Clinical Negligence Claims in the NHS. A standard form of indemnity agreement, agreed with ABPI, can be found at Annex B of that guidance.
5. The NHS should benefit from commercial exploitation of intellectual property derived from R&D that the NHS has funded, or for which it has been funded, even where the intellectual property itself is owned by people outside the NHS. NHS bodies should ensure that an agreement to this effect is included in any contracts concerning R&D. The guidelines in HSC 1998/106 Policy Framework for the 1 Paragraph 28 of HSG (97)32 states: At present, industry frequently contributes to the costs of pharmaceuticals (and other products) which are the subject on non-commercial R&D in the NHS. Although, by definition, such items constitute Treatment Costs, the NHS will continue, under the Partnership Arrangements, to look to researchers and non-commercial research funders to secure such contributions before approaching the NHS for support. Management of Intellectual Property within the NHS from R&D should be followed.

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