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DEPT OF HEALTH LOGO

COMMERCIAL SPONSORSHIP – ETHICAL
STANDARDS FOR THE NHS

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COMMERCIAL SPONSORSHIP: ETHICAL STANDARDS FOR THE NHS

1. *The New NHS: Modern and Dependable* places an obligation on Primary Care Groups, Health Authorities, NHS Trusts and Primary Care Trusts to work together and in collaboration with other agencies to improve the health of the population they serve and the health services provided for that population.
2. All health professionals including independent contractors, locum practitioners, working under NHS terms and conditions are intended to be covered by the document. The guidance contained in this document should apply equally to charitable sources of funding as well as GP Co-operatives and initiatives such as PMS, NHS Direct, Walk In Centres, Health Action Zones etc.
3. Collaborative partnerships with industry can have a number of benefits in the context of this obligation. An important part of that joint working will be a transparent approach to any sponsorship proposed to a Primary Care Group, HA, NHS Trust or Primary Care Trust, or to independent contractors and their staff. If any such partnership is to work, there must be trust and reasonable contact between the sponsoring company and the NHS. Such relationships, if properly managed, are of mutual benefit to the organisations concerned.
4. A previous circular on *Standards of Business Conduct for NHS Staff* was issued in 1993 (HSG(93)5) regarding the general standards which should be maintained by staff working in the NHS. This guidance is still extant. The purpose of the current document is to emphasise that NHS bodies and primary care contractors and their staff are accountable for achieving the best possible health care within the resources available. It advises them to consider fully the implications of a proposed sponsorship deal before entering into any arrangement. In particular it is important to seek advice when necessary from the Health Authority on the effect on other aspects of healthcare.
5. 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. A simple ledger may suffice - to avoid any unnecessary paperwork.

6. 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 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 regulation 21(5) is also guilty of an offence and liable, on summary conviction to a fine not exceeding £5000.' The MCA Guidelines on Promotion and Advertising set out the standards to be followed.

7. 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.
8. The arrangements in para 5 do not apply to-
 - personal gifts of less than £25 per gift e.g. gifts of post-it pads, pens etc. However 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
 - gifts from patients to GPs which are being addressed by changes to the terms of service of GPs
 - income generation schemes which will be logged separately at local level
 - discounts on particular pharmaceuticals.
9. A model code is attached at Annex 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 regulated.

Considerations

10. PCGs, Health Authorities and primary care contractors will need to consider issues such as:
 - industry often wishes to have close involvement with the NHS. Quite often this may be to mutual advantage, but both partners should assess and understand the costs and benefits of any such agreement;
 - purchasing decisions, including those concerning pharmaceuticals and appliances, should always be taken on the basis of best clinical practice and value for money. Such decisions should take into account their impact on other parts of the health care system, for example, products dispensed in hospital which are likely to be required by patients regularly at home;
 - Hospital trusts who are offered significant discounts on drugs may wish to consult the relevant PCGs/PCTs about possible implications for subsequent prescribing in primary care.
 - 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 Annex 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 (eg. 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, Primary Care Trusts, Health Authorities and Primary Care Groups should be at a corporate, rather than individual level.

Hospitality and meetings

11. 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.
12. 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.
13. Where meetings are sponsored by external sources, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Research and development

14. Guidance on research and development is contained in Annex C.

Charitable funding

15. Trustees should take steps to remove any non-charitable items within charitable trust fund accounts. Examples include drug trials undertaken directly by a consultant and supported by funding from non-official sources (ie not part of the R&D programme managed by the provider). Not all consultant drug trials are non-charitable (see “NHS Charitable Funds: A Guide”, published by the Charity Commission), but, where they do not have charitable status, they should be removed from the charitable trust fund accounts. If the drug trial contract is made between industry and the NHS Trust or Primary Care Trust, then the transaction should be recorded as a normal income generation scheme. In other cases, the NHS Trust or Primary Care Trust should consider other options including the transfer of responsibility back to the consultant concerned.

Examples of Potential Conflict

16. Some examples of potential conflict are set out at Annex D.

Monitoring Arrangements

17. 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, eg. 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.

18. Employers finding evidence of unapproved sponsorship should act swiftly to deal with the situation and bring it within their local arrangements.

Action

19. Employers (eg NHS Trust, Primary Care Trust, HA, Primary Care Group) and independent contractors should:

- make all staff aware of NHS guidance, the legal position and appropriate professional codes of conduct, eg GDC, GMC, RCN, RPSGB, UKCC, and Prescription Medicines Code of Practice Authority (PMCPA) codes;
- 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;
- ensure all sponsorship deals are documented through use of a register or simple ledger, held by the employer e.g. the Health Authority, NHS Trust or Primary

Care Trust, 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 HA board meetings;

- make it a matter of policy that offers which could possibly breach the code must be reported to the relevant Board (NHS Trusts/Primary Care Trusts/HAs/Primary Care Groups) or Health Authority (independent contractors). Minimum standards for the reporting system should be determined locally, but ideally should include some time limit (eg. two weeks) for the reporting of any such offers;
- ensure that all staff record with their HA, in the interests of transparency, any financial interest in organisations (eg. company shares or research grant) which impact upon funding, whether through contracts, sales or other arrangements that they may make with non NHS organisations.

20. **Before** entering into any sponsorship agreement, HAs, NHS Trusts, Primary Care Trusts, PCG staff and independent contractors should:

- 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 eg. checking financial standing by referring to company accounts;
- assess the costs and benefits in relation to alternative options where applicable, and to ensure that the decision-making process is transparent and defensible;
- 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;
- determine how clinical and financial outcomes will be monitored
- ensure that the sponsorship agreement has break clauses built in to enable the NHS Trust, Primary Care Trust, PCG, independent contractor to terminate the agreement if it becomes clear that it is not providing expected VFM/clinical outcomes.

21. Existing contracts, which include any element of sponsorship agreement, should be reviewed and any clauses which do not follow the recommendations set out above should, where possible, be renegotiated to ensure that real patient need is being met.

22. Existing corporate governance policies and disciplinary procedures should be reviewed to ensure that they cover the need for open declaration and to enable sanctions against those failing to comply. In the event that they do not do so, the policies should be strengthened or amended. Corporate and or clinical governance policies should address the ethical implications of commercial sponsorship.

Summary

23. Employers should take action as set out in paragraphs 19-22 having taken account of considerations in paragraph 10.

Department of Health

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CODE OF CONDUCT

Staff and independent contractors working in 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 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 (eg. 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/Primary Care Trust/Health Authorities/Primary Care Groups) or to the Health Authority (independent contractors);
- 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.

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.

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.

EXAMPLES OF POTENTIAL CONFLICT

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 eg. company shares, research grant, in the Trust Formulary.* Trust committee (eg 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 pharmaceutical industry representative wishes to present the case for a new product being included on a Trust Formulary.* The 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;
- C. *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 (eg exposure to NHS, professional contacts, potential allies to use later, names of who to influence, often without the participants realising);
- D. *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.
- E. *A manufacturer of a particular type of Nicotine Replacement Therapy offers to provide their product at a reduced rate to a Health Action Zone or a HA.* 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.
- F. *A pharmaceutical company offers to provide starter packs at a discounted price.* This type of sponsorship is acceptable, but should always be declared in order to avoid any suspicion that subsequent prescribing might be inappropriate and linked to the provision of starter packs.

- G. *A catering company offers to provide discounted products to an NHS Trust. This agreement is acceptable, but should be routinely declared to the Health Authority.*
- H. *High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product. Health authority 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.*
- I. *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/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.*