



# Good psychiatric practice: interim guidance on the relationship between psychiatrists and commercial sponsors and the sponsorship of College activities (CR117)

This document was approved by Council in June 2003. It is published here in full and is freely available on the College website.

This article is intended to provide guidance on the boundaries of good practice for psychiatrists in their relationships with pharmaceutical companies and other commercial organisations. The first part addresses issues relating to good practice for individual practitioners. It has been written in recognition of the increasing need for the College to issue guidance at this level despite the considerable diversity of opinion among College members. The second part concerns the proper regulation of College activities and is a revision of the previous *Guidelines on the Sponsorship of College Activities*, approved by Council in February 1999.

The College recognises the important and valid contribution made by pharmaceutical companies and other commercial organisations to patient care, to research and to education. Indeed, it is estimated that large pharmaceutical companies provide 60% of the total budget to medical research in the UK. The assumption that commercial sponsorship is necessary or inevitable, however, should always be examined critically. The decision to accept sponsorship should only be taken after considering alternatives, such as securing alternative funding sources or reducing the level of industry-sponsored educational events.

This guidance is intended to stimulate debate within the College. There should be increased opportunities at College meetings, including the Annual Meeting, to address issues of concern regarding the interface between the College and commercial organisations. The guidance set out below should be seen as an interim stage in a continuing process. It is anticipated that any revised guidance will be evidence-based and auditable.

## Part I: Relationship between psychiatrist and commercial sponsors

The following definition is adapted from *Commercial Sponsorship – Ethical Standards for the NHS* (Department of Health, 2000):

Sponsorship is defined as funding from any external source, including funding of all or part of the costs of employing a member of staff, research, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, accommodation and transport costs (including trips

abroad), and provision of free services (speakers), buildings or premises.

### Principles

- Psychiatrists should avoid accepting inducements that might compromise the independence of their professional judgement and practice.
- Psychiatrists need to recognise that although commercial organisations (and their representatives) might have similar goals to their own, the primary responsibility of such organisations towards their shareholders or sales targets may result in conflicts of interest.
- Psychiatrists should aim for full public disclosure and transparency with regard to competing interests both in clinical practice and when involved in any College activity.
- Psychiatrists must comply with the requirements of:
  - Good Medical Practice* (General Medical Council, 2001);
  - Good Psychiatric Practice* (Royal College of Psychiatrists, 2000)
  - Guidance for Researchers and for Ethics Committees on Psychiatric Research Involving Human Participants* (Royal College of Psychiatrists, 2001).

Psychiatrists should also be aware of:

- The Code of Practice produced by the Association of the British Pharmaceutical Industry (ABPI): this has been agreed with the Medicines Control Agency, the Royal Pharmaceutical Society and the British Medical Association.
- *Commercial Sponsorship – Ethical Standards for the NHS* (Department of Health, 2000) (<http://www.doh.gov.uk/comspon1.htm>).
- Guidance and Model Clinical Trial Agreement between the ABPI and the National Health Service (NHS) Research and Development Directorate as part of the Pharmaceutical Industry Competitiveness Task Force clinical research discussions launched by the Minister of Health on 23 January 2003.
- No Free Lunch: this is a web-based organisation of health care providers who have pledged to be free of pharmaceutical company money and influence in their clinical teaching and research. It also contains a detailed reading list on pharmaceutical promotion including original studies on

the influence of promotion on behaviour, beliefs and attitudes (<http://www.nofreelunch.org>).

- The *BMJ* edition entitled 'Time to untangle doctors from drug companies' (*BMJ*, **326**, 1155–1210; 31 May 2003) contains editorials, articles and scientific papers of direct relevance to this report.

### Specific recommendations

#### Gifts

- No condition should be attached to the receipt of gifts, items of equipment or other forms of aid from commercial organisations.
- 'Educational' gifts worth less than £6 per gift (notepads, pens, etc.) may be accepted if their purpose is genuinely educational. References to the donor organisation should be indicated by no more than a company name and/or logo.
- Gifts in the form of cash or other financial benefits directly to individual psychiatrists are not acceptable.
- Gifts worth a total of over £100 in a 12 month period from the same or a closely related source should be declared according to arrangements agreed within the local NHS or equivalent organisation.

#### Sponsorship of local educational meetings

- Company support for visiting speakers (honoraria, expenses) and/or for other meeting costs (hall and equipment hire, etc.) is acceptable only if the majority of speakers or presenters are *not* chosen by the sponsoring company. As is the case for College meetings, speakers who have competing interests should be required to make a brief oral declaration to this effect at the beginning of their presentation.
- Reference to the donor organisation should be limited to display of the company name and/or logo in the meeting papers, and a discreet exhibition stand if this is locally acceptable.
- Company advertising for local meetings should be within the limits set in the College's guidance on sponsorship of College activities (see below).
- Psychiatrists organising local meetings must have the freedom to select or reject any speakers suggested by a sponsoring company, particularly



where the possibility arises that the company recommendation reflects bias on the part of the proposed speaker towards the company's product.

- Consideration should be given to ensuring that there is an overall balance of sponsored educational events and avoiding the predominance of biological psychiatric events to the detriment of education in other areas of psychiatry, such as psychotherapy.

#### **Company-organised meetings**

- Psychiatrists should only agree to participate in company-organised meetings (as speakers or attendees) if they are satisfied that the meetings have a genuinely educational (rather than purely promotional) purpose.
- Travel, accommodation and the provision of food and drink should not be of a standard greater than that which the recipients would normally adopt when paying for themselves (see below).
- Honoraria for speakers should be declared according to the local trust or employer arrangements.
- Psychiatrists speaking at these meetings should make clear the extent to which their presentation is based on their own original work, their own review of the evidence or on information supplied by the sponsor. Psychiatrists should not give purely promotional presentations.

#### **Sponsored attendance at regional, national or international meetings**

- Travel, accommodation and the provision of food and drink should not be at a greater level than that which the recipients would normally adopt when paying for themselves (see below).
- Attendance should be free of commercial pressure (such as obligation to attend promotional events). The meeting must be predominantly scientific rather than touristic.
- Psychiatrists accepting such sponsorship should be prepared to declare any resultant conflict of interest.
- Sponsorship for accompanying persons should be limited to those whose role makes it appropriate for them to attend the meeting (i.e. other members of staff, such as psychologists and nurses).

#### **Hospitality and meetings**

The following is adapted from *Commercial Sponsorship – Ethical Standards for the NHS* (Department of Health, 2000).

- Industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable actual costs that might have been incurred. If no hospitality is

required there is no obligation or right to provide any, 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; the costs involved must not exceed the level that the recipients would normally adopt when paying for themselves.

#### **Research including clinical practice guideline development**

- This guidance is not intended to discourage company-funded trials initiated by the investigator, nor is it intended to discourage psychiatrists or their employers benefiting from intellectual property where appropriate.
- Local research ethics committee approval is mandatory.
- Payments for research need to be open and transparent and should meet standards of both ethical and fiscal probity. Participating psychiatrists should not receive personal payment for carrying out commercially sponsored research.
- If the research is commercially sponsored, then the sponsoring company must indemnify patients or health volunteers for any harm that might arise as a result of participation where such research has been carried out in accordance with previously agreed protocol. This does not apply if a company is providing some funding but is not the sponsor: in these cases indemnity is the responsibility of the investigator or the employer.
- Participating psychiatrists should be free to publish valid findings arising from sponsored studies even if these are not supportive of the sponsoring company's product. Sponsoring should be acknowledged in any such publication. The NHS/ABPI Model Clinical Trial Agreement gives advice on the content and timing of such publications.
- If data for jointly authored publications are analysed by the sponsoring company, full access to the raw data and analyses must be available to the participating psychiatrists.

#### **Authorship**

- The nature of work undertaken by participating psychiatrists and the nature and extent of sponsorship should be explicit in any jointly authored scientific paper.
- Honoraria or other support received for other authorial work such as review articles should be explicit.
- Psychiatrists should not agree to 'author' articles that have been ghost-

written for them. Collaboration on review articles is, however, acceptable if the nature of the work undertaken by each author is explicit.

#### **Consultancy, provision of expert opinions and policy advice**

- Any advice or other part-time employment provided by a psychiatrist for a commercial organisation should be agreed in advance and subject to contract, which should also specify fees and expenses.
- Payments for seeing representatives, writing letters to journals or reporting adverse reactions are not acceptable.
- Employees of trusts, universities or similar organisations should seek their employer's permission in advance if such work takes place during working hours.
- Psychiatrists should declare any financial interests according to local NHS trust or employer arrangements, even if fees are paid into departmental accounts rather than directly to them as individuals.

#### **Register of members' interests**

The College already has a register of competing interests for members of Council (who are defined as trustees of the College). Consideration has been given to widening this register to include all College members. The College considers, however, that such registers are best maintained locally. The guidance issued by the NHS recommends that monitoring arrangements are established to ensure that staff register any sponsorship and are held accountable for it. An official register of interests should be established as part of the NHS monitoring arrangements. The College will, however, expand its existing register to cover all members elected or appointed to College positions including faculty and divisional committees, College examiners and educational supervisors.

## **Part II: Sponsorship of College activities**

This guidance applies to *all* College activities and meetings including those of faculties, sections, special interest groups, divisions, any subgroups thereof, and the College Research Unit (CRU). The 'relevant College officer' may be an honorary officer, or an officer of a division, faculty, section, special interest group, standing or special committee.

## **Principles**

These principles refer only to activities organised in the name of the College. Please refer to Part I for guidance on sponsorship matters for individual psychiatrists.



### Uses of sponsorship

- The principal use of sponsorship is to improve the quality of educational or scientific activities. This may include research, meetings and conferences, prizes and Fellowships, public education materials, newsletters and scientific publications (see below).
- There will be some publications for which it is inappropriate to seek sponsorship.
- Commercial sponsorship may not be used to support the publication or distribution of guidelines on good practice, or consensus statements such as clinical guidelines.
- Sponsorship must not be purely for hospitality or social events.
- The advice of the Development Manager should always be sought if College members or staff are uncertain about accepting sponsorship.

### Ownership and acknowledgement

- The contribution of sponsors, including pharmaceutical companies, in supporting medical educational activities and other College activities is understood and appreciated. The overriding principle is that the College retains control of the title, educational and/or scientific content of any event or product, the level of advertising and, in the case of meetings, the level of hospitality.
- Appropriate acknowledgement of the sponsorship should be given, as agreed between the Development Manager and the sponsors.
- Acceptance of sponsorship by the College should never be represented by the sponsor as an endorsement of its products. Individual products and brands should not be referred to in any acknowledgement of sponsorship.

## Specific recommendations

### Approaches to sponsors

- Initial approaches to or from potential sponsors, whether they be commercial biomedical companies or other organisations, should be negotiated only by officers of the College or the College staff (primarily the Development Manager) acting on their behalf.
- Every effort should be made to attract a wide range of sponsors – including government agencies, charitable trusts and foundations, as well as commercial organisations – so that there is no dependence on sponsorship from any one source.

### Impartiality

All sponsorship packages should be negotiated to represent the best interests

of the College and/or the relevant faculty, section, special interest group or division. College officers and/or staff should remain impartial.

### Financial transactions

All financial transactions within the UK should be handled by the Finance Department. This will ensure that all sponsored activities receive the benefits of the College's charitable status.

The Irish Division will keep the Finance Department informed of any sponsorship received. The Finance Department will aim to produce detailed accounts for any meeting or initiative on request and will keep the Development Manager informed of all transactions.

### Meetings, conferences and educational events

This section only relates to meetings, conferences and events organised in the name of the College. Please refer to Part I for guidance on individuals attending educational meetings, company organised meetings and sponsored attendance at regional, national and international meetings.

- Sponsorship may be used for speakers' expenses, hiring of premises, printing and circulating of programmes, and provision of visual aids. Hospitality and/or social events that are part of an educational or scientific activity may be sponsored at a level commensurate with the event as a whole. Sponsorship must not be purely for hospitality or social events.
- College members do not receive honoraria to participate in College meetings and sponsorship may not be used for this purpose. Speakers need to be informed of these arrangements, and chairmen of faculties, sections, special interest groups and divisions are responsible for this. The policy for honoraria is currently under review.
- When meetings are held in hospitals all arrangements, including the choice of speakers, should remain under the control of the doctor organising the meeting.
- When a commercial organisation organises its own educational meeting, no implicit or explicit endorsement from the College should be claimed (although in Ireland Continuing Professional Development credits may be acknowledged). It is acceptable for speakers, chairmen or discussants who are College office holders to be described as such at these meetings.
- When such educational meetings take place within a College function (e.g. a satellite symposium or workshop), the use of the College's name must be authorised by the relevant College officer. It is acceptable for speakers, chairmen or discussants who are

College office holders to be described as such at these meetings.

- The College should retain control of the title, educational and/or scientific content and the level of hospitality and advertising.
- Every effort should be made to select suitable titles for named lectures. The use of the name of a commercial organisation must be approved by the Court of Electors.
- Appropriate acknowledgement of the source of sponsorship should appear in the notice to any meeting so sponsored (see above).
- Dominating or intrusive presence of commercial organisations sponsoring College meetings is not appropriate. The presence of commercial exhibitors, biomedical or otherwise, at College meetings should not intrude on the overall activities.

### Research

Where sponsorship is used to fund research, there should be clear acknowledgement of the sponsor's involvement and a full declaration of interest. All research should be independent of the sponsor and the purpose of the sponsorship should be to promote genuine scientific research. The College should retain control of the title, educational and/or scientific content, and results of any sponsored research. Sponsorship should not affect the outcome or the dissemination of the outcome of any research. Individual products should not be identified or promoted. The Development Manager should be informed of any sponsorship being negotiated.

### Prizes and Fellowships

The title of prizes and Fellowships, and regulations for their award, must be determined by the Dean and endorsed by the Court of Electors. The Development Manager should be informed of any sponsorship being negotiated.

### Public education activities

Sponsorship may be used to produce and facilitate the distribution of mental health promotion literature, teaching packages and other publications. The contents or production of written materials should remain under the control of the Head of External Affairs.

### Scientific publications

- Authors of papers published in College journals must declare any conflicts of interest (see below).
- Sponsorship may be used to produce scientific publications. The level of such sponsorship should be determined by the Editor, advised by the Publications Management Board. The Development Manager should be informed of any sponsorship being negotiated.



columns

### Newsletters

Sponsorship may be obtained to support the production and circulation of newsletters for any of the College subgroups. The advice of the Development Manager must be sought at an early stage and details must be submitted to the Executive and Finance Committees for approval. Details of any proposed advertisements must be included in the budget. Modest acknowledgement of any sponsorship may be made in the text of the newsletter. Further details are contained in 'Guidelines for the production of College Newsletters' (Appendix 1).

### Website

The core pages of the College website should not be sponsored. Credit can be given for help with creating specialist areas or subdirectories. Where electronic versions of sponsored materials (e.g. campaigns and public education information) appear on the College website, then the original sponsor may be credited. Links to sponsored educational sites are permitted but there should be no direct link to commercial sponsors.

### Declaration of competing interests

- Speakers and discussants at College meetings must declare any personal association with any potential sponsor which could be construed as a potential conflict of interest, in accordance with College guidelines (see Appendix 2).
- Authors of College publications, including articles published in any College journal, must declare any personal interest or association with organisations relevant to the subject of the publication or article.
- The College already has a register of competing interests for members of Council (who are defined as the trustees of the College). Consideration has been given to widening this register to include all College members. The College considers, however, that such registers are best maintained locally. The guidance issued by the NHS recommends that monitoring arrangements are established to ensure that staff register any sponsorship and are held accountable for it. An official register of interests should be established as part of the NHS monitoring arrangements.
- The College will, however, expand its existing register to cover all members elected or appointed to College positions including faculty and divisional committees, College examiners and educational supervisors.

### Gifts

- College officers and staff should not receive gifts or any other form of

inducement in relation to commercial sponsorship of College activities.

It is the sole responsibility of the relevant College officer to ensure that the Guidelines are followed. If in doubt or if the Guidelines cannot be followed for any reason, then the officer should seek advice from the Development Manager. Subject to that, the College is unable to take responsibility for any consequences arising out of the failure of an officer to follow the Guidelines.

### References

- DEPARTMENT OF HEALTH (2000) *Commercial Sponsorship – Ethical Standards for the NHS*. London: DoH (<http://www.doh.gov.uk/comspon1.htm>).
- GENERAL MEDICAL COUNCIL (2001) *Good Medical Practice*. London: GMC.
- ROYAL COLLEGE OF PSYCHIATRISTS (2000) *Good Psychiatric Practice*. Council Report CR83. London: Royal College of Psychiatrists.
- (2001) *Guidance for Researchers and for Ethics Committees on Psychiatric Research Involving Human Participants*. Council Report CR82. London: Royal College of Psychiatrists.

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### Appendix 1 Guidelines on the production of College newsletters

The publication of newsletters by Faculties, Sections, Special Interest Groups and Divisions of the College is welcomed and encouraged. The following guidelines are designed to ensure that these activities are costed and funded appropriately. They will also ensure that the Executive and Finance Committee is informed about issues raised or initiatives proposed, so that details of these may be promulgated to other parts of the College where appropriate, and unnecessary duplication of activities within the College may be prevented.

1. The Newsletter should state clearly and explicitly that it is an official publication of a Division / Faculty / Section / Special Interest Group of the Royal College of Psychiatrists;
2. The Newsletter should, however, contain a statement clarifying that views and opinions expressed within it are those of the authors and may not represent official College policy;
3. If the College crest appears on the Newsletter, this must be in the format available from the Head of Publications Services. The College crest must not be adorned or modified in any way;

4. The Newsletter may be circulated with routine College mailings. Production costs, including photocopying and additional postage charges, will not be met by College central funds, but will be charged to appropriate budgets (Faculties, Sections, Special Interest Groups or Divisions);
5. Sponsorship may be obtained from outside sources to support the production and circulation of the Newsletter, but details must be submitted in advance to the Executive and Finance Committee for approval. Details of any proposed advertisements should be included in the budget. Sponsorship may be acknowledged in the text of the Newsletter in accordance with the usual College procedures; i.e. modest reference may be made.
6. Each issue of the Newsletter should be submitted at the time of issue to the Committee Officer for circulation to the Executive and Finance Committee for information and interest.

### Executive and Finance Committee

21 March 1997

### Appendix 2 Notes on completion of the declaration of competing interests

All speakers at College meetings are asked to declare any competing interests (otherwise known as conflicts of interest) that they might have relating to their presentations.

### Definition

A competing interest exists when professional judgement, for example concerning presentation or critical appraisal of research evidence or discussion about the most appropriate management of a clinical case, may be influenced by a secondary interest (such as financial gain).

### Scope

An obvious example of a competing interest would be a psychopharmacologist employed by a pharmaceutical company presenting data on a drug developed by his/her own company or by a rival company. Other examples include receiving funds for research, or consultation fees, from any organisation that might have a financial interest in what is being presented. Such organisations include not only commercial sponsors, but also independent health care organisations and the Department of Health.

