

General Practitioners and Commercial Sponsorship

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Background

Pharmaceutical and other companies offer gifts such as travel expenses to conferences or workshops, software, CD ROMs, notepads and pens to general practitioners to enhance recognition of their products [1]. Gifts may also be offered as reimbursement for time spent with a representative to market products and discuss issues related to therapeutics management. Although the giving of a gift is seen as an act of generosity, gifts are also given out of self interest. Pharmaceutical and other companies give gifts in anticipation that the general practitioner will prescribe their product(s) [2]. Overseas, this practice has been subject to increasing scrutiny from medical professionals, consumer advocates and representatives of government [1]. There are a number of cogent arguments for and against the acceptance of gifts from pharmaceutical companies:

Reasons for accepting gifts

1. Gifts may improve the transmission of medical knowledge through subsidies which enable:
 - professional organisation, continuing medical education (CME) providers, hospitals and medical schools to invite prominent speakers
 - reductions in registration fees for conferences, seminars and workshops
 - access to CME events and professional meetings through individual travel grants
 - increased attendance at CME event and professional meetings through the provision of refreshments [1]
2. There is little evidence that accepting small gifts impairs clinical judgement [1]
3. If gifts are refused:
 - medical education could possibly suffer through lack of sponsorship

- it would be unlikely that the costs of medications would be reduced as funding would probably be reallocated to other forms of advertising or drug detailing [1]

Objections to the acceptance of gifts

1. Gifts may create, and perpetuate, an expectation of reciprocity [1]
2. Objectivity may be compromised where:
 - pharmaceutical companies nominate topics and speakers for CME events and professional meetings
 - attendees at CME events and professional meetings are unaware that a pharmaceutical company has determined the program and speakers
 - speakers selectively present only favourable data about a particular drug or one class of drugs without considering all pertinent information [1]
3. Gifts may increase health care costs to patients as they may ultimately pay for pharmaceutical company promotion to general practitioners [1]
4. Gifts may be demeaning to the profession e.g. negative public perceptions [1]
5. Gifts may introduce an appearance of bias or conflict of interest even when they have no influence on therapeutic decision making [1].

Introduction and Principles

A review of the international literature was conducted to identify existing guidelines and to ascertain the policies of medical organisations and opinions of medical professionals about the acceptance of gifts from the pharmaceutical industry.

The focus of professional interactions between general practitioners and the pharmaceuticals and other industry should remain on advancing the health of all Australians rather than on the private good of either party [3,4].

The RACGP supports the Australian Medical Association Code of Ethics. This provides further guidance about the relationship between medical professionals and the pharmaceutical industry [3].

The general practitioner's primary obligation is toward the patient [4]. The role of the general practitioner is to hold the trust and confidence of the patient and to facilitate access to appropriate health care. Relationships with the pharmaceutical industry can only be appropriate insofar as they do not breach or distort the obligation of the general practitioner-patient relationship [3,4]. The RACGP is supportive of a majority of the principles detailed in Medicine Australia's Code of Conduct.

Professional autonomy, independence and commitment to the scientific method should always be maintained in any relationship between a general practitioner who is not an

employee of the pharmaceutical industry and the industry proper [3,4]. The general practitioner should be willing to disclose the nature of such relationships to patients, CPD event organisers at which she or he is a speaker, and in any comparable situation [1,4,6].

Proposed Guidelines

- The patient should be the primary beneficiary of any gift accepted by the general practitioner and the gift should be related to the general practitioner's work [7-9]
- Gifts such as textbooks, modest meals etc are appropriate if they contribute to a genuine educational function [7]
- Individual gifts (e.g. equipment such as stethoscopes, note pads and pens) including those which bear a pharmaceutical company name, are acceptable if they relate to the general practitioner's work [1,6]
- Gifts, including holidays, frequent flyer points, opportunities to participate in major sporting events and similar activities, computers and equipment are not acceptable [1,7,10]
- Under no circumstances should general practitioners accept cash payments as gifts [1,7,11]
- It is a requirement that pharmaceutical and other companies provide indemnity for the RACGP, its Ethics committee (NREEC) and each general practitioner involved in pharmaceutical trials. In any other circumstances, a pharmaceutical company's offer to indemnify a general practitioner for legal action arising from the general practitioner's prescription or use of the company's drugs, products or medical devices may influence medical decision making and therefore, constitutes an inappropriate gift. [7]

Support for Continuing Professional Development

The RACGP acknowledges a distinction between education, training and the promotion and marketing of products. CPD activities should address the identified educational needs of the general practitioner audience for the benefit of their patients [3,4].

Pharmaceutical and other company subsidisation of CPD events and professional meetings may contribute to the improvement of patient care and is therefore permissible [7] in the following circumstances:

- any involvement by a pharmaceutical or other company must be declared in advertisements and invitations
- the general practitioner organisers of the event should retain ultimate responsibility and control over the organisation, content, selection of speakers, educational methods and materials and selection of general practitioner attendees [1,3,4,6]

- the general practitioner organisers of the event should retain ultimate responsibility for preparing slides and drafting journal articles [1]
- no conflict of interest should arise by virtue of the organiser(s)' affiliation with any pharmaceutical or other company sponsor(s) of those CPD activities [3,4]
- general practitioner attendees of CPD events or professional meetings should not directly accept payments from pharmaceutical or other companies to offset the costs of participation [7] such as time away from the practice
- subsidies should only be accepted by the event organiser who in turn may use the subsidy to defray costs e.g. reduce registration fees [1,7]
- in general, general practitioners attending CPD events should neither accept, directly or indirectly, subsidies from pharmaceutical or other companies to pay the costs of travel, accommodation, other personal expenses nor compensation for their time [1,3,4,6]. PD meetings should be considered on a case by case basis.
- compensation to general practitioners for "token" consulting or advisory arrangements [7] and associated travel, accommodation, out of pocket expenses and time cannot be justified
- subsidies for hospitality, outside of modest meals or social events that form part of a conference or meeting, should not be accepted [4,7]
- any offer of entertainment should remain secondary to the educational event
- it is appropriate for individuals who provide genuine services at conferences and meetings to accept reasonable honoraria and reimbursement for travel, accommodation and meals [4,7] . Ideally this should be paid through the conference organisers rather than directly by the pharmaceutical company.
- scholarships, grants or bursaries to enable medical students, residents and fellows to attend educational events are permissible where the selection of candidates for these funds is made by their academic institution [4,7] and the payment is made through the institution.

Funding for Research

A prerequisite for general practitioner involvement in any pharmaceutical or other industry sponsored activities is evidence of the merit, ethical defensibility, social responsibility and scientific validity of those activities [3,4].

Formal approval based on ethics and scientific merit by an appropriate Ethics committee should precede general practitioner involvement in any research activities sponsored by the pharmaceutical industry [2,3,4].

The source of funding should be available for disclosure to the public [3].

Post Marketing Surveillance Studies

A post marketing surveillance study is defined as a "scientifically rigorous study of a product approved for registration in Australia" which is "designed to produce reliable information about drug safety" [12].

All post marketing surveillance studies should be submitted for consideration by an Ethics committee which is constituted according to National Health and Medical Research Council recommendations.

General practitioners should only participate in post marketing surveillance studies relevant to their area of practice. The degree and manner of their participation should be consistent with the accepted standards of ethical medical practice and research [3,4].

Given concerns regarding marketing strategies, the RACGP recommends that general practitioners before agreeing to participate in post marketing surveillance studies take the following precautions:

- general practitioners should ascertain that the study has been approved by an Ethics committee
- to assist their decision making about participating in post marketing surveillance studies, general practitioners should consult appropriate resources. Existing review boards and Ethics committees may serve in this capacity [3,4].
- general practitioners should only accept remuneration for participation in post marketing surveillance studies where their participation involves a substantial amount of professional time and skill beyond that directly applied to patient care. The remuneration should reflect the professional time and skill required and may include reimbursement of opportunity costs without constituting an enticement to prescribe inappropriately. Parameters including the complexity of the study and time expenditure may be taken into account when determining remuneration [3,4].
- regardless of whether diagnostic procedures or patient services are involved, any incremental costs (those additional costs incurred directly in relation to participation in the study) should be borne by the pharmaceutical or other company and not be defrayed by government or other insurance agencies [3,4].
- patients should only participate in post marketing surveillance studies after giving their full and competent informed consent. The general practitioner has an obligation to ensure that the patient is fully aware:
 - that the general practitioner's continuing concern for the patient's welfare is not contingent upon the patient's participation in the study
 - of the availability of alternatives, their comparative advantages or disadvantages and other related matters which would establish informed consent under normal circumstances

- that the patient may withdraw from the study at any time to return to alternative therapies indicated if they are medically feasible [3,4] without it affecting their future medical management.
- the general practitioner who enrolls a patient in a surveillance study has an obligation to ensure the protection of the patient's identity if that patient so wishes. If that patient desires such protection but this can not be guaranteed, the general practitioner should so inform the patient as part of the informed consent [3,4].
- the RACGP refers general practitioners to the National Health and Medical Research Committee's guidelines on providing information to patients as a useful basis for structuring and obtaining relevant consent [3].

References

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