These guidelines represent general advice to support and assist pharmacists. It is expected that professional judgement will be exercised in adapting these guidelines to specific presenting circumstances.

1. Introduction

These guidelines are provided to support and assist pharmacists working in sectors other than the pharmaceutical industry to liaise with the industry. The guidance provided here is equally applicable to the relationship pharmacists maintain with manufacturers of medical devices and suppliers of other health care products, including infant formulae.

Pharmaceutical industry representatives regularly interact with pharmacists in a variety of work environments over professional and business issues. The pharmaceutical industry provides valuable assistance and support to health professionals and to the professional organisations or associations in which they hold membership. This support may take the form of provision of product and therapeutic information, educational materials, equipment, and financial and other resources for educational and research activities. It also encompasses access to the expertise of industry personnel.

Mutually beneficial relationships have resulted from the cooperative interaction of pharmacists and/or pharmacy organisations with members of the pharmaceutical industry. However, an examination of the basis on which future interactions should occur is timely in view of the growing role of pharmacists in many aspects of therapeutics and the need to avoid perceived or real conflicts of interest or compromise to professional pharmacy practice.

Much of the guidance provided to prescribers about their relationship with the pharmaceutical industry is also applicable to pharmacists. This is evidenced by the fact that guidelines similar to those provided by the Royal Australian College of General Practitioners (RACGP) have been used by pharmacy departments of some public hospitals in WA since 1992. Some of the guidance provided to prescribers is used in later sections of these Guidelines.

1.1 General principles

Pharmacists recognise that it is in the public interest for them to exercise professional control over the supply of medicines to ensure that, as far as possible, patients achieve the best possible therapeutic outcomes. Patient need should always take precedence over commercial considerations and self-interest in the supply of medicines so pharmacists, particularly those in the community who are involved in the distribution of medicines for profit, are expected to temper their actions in accordance with ethical professional practises.

The Code of Professional Conduct of the Pharmaceutical Society of Australia (PSA) and The Society of Hospital Pharmacists of Australia (SHPA) Code of Ethics establish guiding principles for the conduct of professional practice by pharmacists. These principles are intended to be consistent with community expectations of the profession and to ensure that the high level of trust placed in the profession by the community is vindicated.

Among the principles espoused in these documents several are of particular relevance to the interaction and relationship pharmacists have with members of the pharmaceutical industry. In particular, pharmacists should be cognisant of the principles that they:

- recognise the primacy of the health and well-being of patients in undertaking professional activities;
- ensure their competence by maintaining up-to-date professional knowledge;
- maintain objectivity, independence and integrity in professional practice; and
- maintain respectful and cooperative relationships with colleagues and other health professionals.

Interactions with members of the pharmaceutical industry will be appropriate only to the extent that they do not breach or distort the obligations created by these principles.

2. Promotion of Health Care Products

The Therapeutic Goods Administration (TGA) administers the Therapeutic Goods Act 1989 (the Act) which establishes a national framework for the regulation of therapeutic goods in Australia. The term “therapeutic goods” is defined by the Act and encompasses prescription medicines as well as non-prescription health care products, including devices. The Act also provides for a national register of all therapeutic goods able to be sold in Australia – the Australian Register of Therapeutic Goods (ARTG).

Therapeutic goods are entered into the ARTG as either listed (AUST L) or registered (AUST R) products.
These categories are determined by the product ingredients and therapeutic claims made by sponsors, and show whether the products have been through a listing process (sponsor assessment against quality and safety criteria) or registration process (evaluation by the TGA of quality, safety and efficacy).6,7

Under the Act prescription medicines may be promoted only to health care professionals whereas non-prescription products may generally be advertised to the public.6,7

2.1 Prescription medicines
Medicines Australia, formerly the Australian Pharmaceutical Manufacturers Association, represents pharmaceutical companies that manufacture prescription medicines. The Medicines Australia Code of Conduct establishes standards for the marketing and promotion of prescription medicines and compliance with the requirements of the Code is compulsory for its members. The Code also includes a mechanism for adjudication of complaints.

The Medicines Australia Code details the expected conduct of pharmaceutical companies in relation to the advertising and promotion of their products. It addresses the quality of information they provide and their ability to substantiate claims made in respect of their products. For this reason it is a valuable resource for guiding the expectations of health professionals, such as pharmacists, who regularly interact with members of the pharmaceutical industry.

2.2 Non-prescription healthcare products
All advertisements for therapeutic goods that are directed to consumers are required by law to comply with the Therapeutic Goods Advertising Code (TGAC) which is maintained through the Therapeutic Goods Advertising Code Council (TGACC). The stated object of the Code is "to ensure that the marketing of and advertising of therapeutic goods to consumers is conducted in a manner that promotes the quality use of therapeutic goods, is socially responsible and does not mislead or deceive the consumer".7

Pharmacists who are invited to participate in campaigns that promote non-prescription medicines or other therapeutic goods (as defined in the Act) to the general public would be well advised to familiarise themselves with the TGAC and to seek assurance of compliance with it from the sponsor company.

Additional information on the expected conduct of companies that promote non-prescription and complementary health care products can be obtained from industry codes. The Australian Self-Medication Industry (ASMI), the peak body representing manufacturers of non-prescription consumer health care products, has adopted a Code of Practice to promote consistently high standards of commercial conduct, particularly in advertising and promotional practises. Similarly, the Complementary Healthcare Council of Australia (CHC) – a body that represents a variety of organisations and individual practitioners in the health and nutrition industry – has developed a Code of Practice for the Marketing of Complementary Healthcare Products.10

The TGAC indicates that the authority to approve various types of advertisements of therapeutic goods to consumers has been delegated to ASMI or CHC. *

Pharmacists should be especially wary of providing support, either directly or by implication, for therapeutic claims made in relation to health care products that have not been scientifically evaluated in accordance with procedures required for medicines on the ARTG. In such circumstances pharmacists should consider:

- the possibility that a decision to market through pharmacies has been influenced by the credibility that it may bring to those claims; and
- the degree to which the credibility and trust vested in the profession by consumers may be diminished should the claims be disproved.

2.3 Loyalty schemes
In seeking health care advice and products consumers place a great deal of trust in pharmacists and expect them to provide sound, objective advice. With this in mind pharmacists should carefully scrutinise marketing activities directed toward themselves or their staff to ensure they do not become, or appear to become, susceptible to influence. Thus, pharmacists wishing to participate in a loyalty scheme offered by industry should ensure that there are no incentives or inducements being offered to either themselves or their staff that would adversely impact on their primary obligation to provide the most appropriate product and advice to meet patient needs.

2.4 Medicines information
Pharmacists are required to provide objective advice to individual patients about their therapeutic needs. Indeed, the right of consumers to access medicines information that is "independent, accurate,
comprehensive and balanced” has been recognised as a guiding principle to the Consumers’ Health Forum (CHF), the peak national organisation representing consumers on health care issues, establishing the terms of its relationship with the pharmaceutical industry.11

Product sponsors are often a key source of medicines information and they will usually have more information about their products than is available elsewhere. However, in order to provide comprehensive and objective medicines information to consumers, pharmacists may have to obtain and evaluate information from several sources. Pharmacists should not hesitate to “seek clarification of, or justification for, any claims or statements” made by industry representatives1 or in sponsor materials to assist their assessment of the information.

2.5 Complaints about information or claims

The Medicines Australia Code of Conduct describes the nature of information and claims that may be presented to health professionals by medical representatives as well as when and how different types of promotional material may be used and presented.

In the event that a medical representative is thought to have presented biased or misleading information it is recommended that, in the first instance, contact is made with the representative’s company.8,12 In most instances the medical department of the company will be the most appropriate point of contact.12 Should this fail to produce a satisfactory explanation or solution then a complaint may be lodged with Medicines Australia.8,12 The Board of Medicines Australia administers a complaint handling process under its Code, details of which are provided in the Code.8

The ASMI Code of Practice describes in detail the requirements applicable to the advertising and promotion of non-prescription health care products as well as the sanctions that may apply for breaches of the Code. Similar information is available in relation to the advertising and promotion of complementary health care products in the Code issued by CHC.10

Though the TGAC and ASMI and CHC Codes all make reference to complaints handling processes these are currently under review as part of the overall review of advertising approval and complaints handling processes as mentioned previously.

3. Conduct of Meetings with Medical Representatives†

“Respectful communication combined with an inquiring and critical attitude” will assist health professionals to maximise the benefits achieved from time invested in meeting with medical representatives.12

A visit by a medical representative can be used to enhance knowledge of a product’s safety, efficacy and utility, particularly in relation to other drugs used to treat the same condition.12 Many medical representatives have a science based degree and an increasing number have undertaken Medicines Australia’s Medical Representatives Educational Program (MedREP) or Continuing Education Program (CEP).12 These programs are offered to ensure representatives acquire or sustain the required level of medical and technical knowledge to present information about medicines in an accurate and balanced manner.8

Medical representatives are required under the Medicines Australia Code “to ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as to not cause inconvenience”. Pharmacists should not seek or accept payment for meeting with pharmaceutical company representatives.1 It is generally desirable for such meetings to occur by appointment and for a specified purpose, with participants clear from the outset what time is available for the meeting.1

As only 5 – 15 minutes may be allocated for the meeting12 it is important to remain focused on the purpose of the meeting. Planning and preparation for a meeting (for example undertaking background reading or discussions with colleagues) will enhance the value of the meeting.1 Where a pharmacist works closely with local general practitioners it is useful to check to ensure that the same level of detail is being provided as is given to those medical practitioners.1

4. Gifts and Inducements

Maintenance of independence and objectivity in professional practice is critical to furthering the health care needs of patients and maintaining their trust and confidence.2,13 Acceptance of gifts has the potential to give rise to expectations of reciprocity, perceptions that objectivity and independence may be compromised or that a conflict of interest exists even when

† A medical representative is defined as meaning “a person expressly employed by a company whose main purpose is the promoting of the company’s products to health care professionals”.8
therapeutic advice or decision-making is unaffected. The nature of the problem as it affects pharmacists was highlighted in an article written in 2000 by the then National President of PSA. Pharmacists should not generally seek or accept gifts of material value. The policy Gifts from Pharmaceutical Companies indicates that pharmacists should not accept inappropriate gifts and that to do so would be contrary to the Code of Professional Conduct. In relation to this policy, acceptance of gifts such as cash payments, holidays, frequent flyer points, opportunities to participate in sporting events and computing or other office equipment is inappropriate. However, receipt of gifts may be deemed acceptable where patients are the primary beneficiaries (for example materials that assist patient education and counselling) or the gifts relate directly to the pharmacist’s work or contribute to a genuine pharmaceutical educational function (eg. a textbook). If in doubt about the acceptability of a gift pharmacists are advised to err on the side of caution and decline the gift.

Items of insignificant value that are relevant to work, such as pens, memo pads or diaries may also be considered appropriate to accept. However care should be exercised in deciding the appropriate circumstances in which to use items of this type which carry a pharmaceutical company name or logo and are provided as ‘brand name reminders’.  

5. Commercial Sponsorship

Sponsorship arrangements may be proposed for a wide range of purposes including:

- educational meetings for health professionals;
- management development training for health professionals;
- funding of a position within an organisation or business entity; or
- a health promotion or disease management forum for consumers (that is not specific to a product).

Agreement to proceed with a significant sponsorship arrangement should be represented in a legally robust form and will usually require significant consultation and negotiation to ensure that clarity and transparency exist over the arrangements and the expectations encompassed by them. In larger organisations the involvement of the Executive or Board will be essential.

To maintain openness and transparency, pharmacists who have entered into a commercial sponsorship arrangement with members of the pharmaceutical industry should be willing to disclose the nature of that arrangement. Disclosures of this type do not in themselves imply a conflict of interest but do allow public scrutiny of the arrangements to ensure such conflicts do not arise.

5.1 Support of educational activities

[This section does not apply to situations where a pharmaceutical manufacturer engages speakers and sponsors for an event for health professionals that is specifically (and explicitly) focussed on enhancing usage/sales of their products.]

Financial support from the pharmaceutical industry can enhance educational opportunities available to health professionals, including pharmacists by:

- supporting the attendance of a prominent speaker;
- providing for reduced registration fees; or
- providing travel grants for attendance at educational forums.

As is the case with continuing medical education, educational events for pharmacists should be focussed on meeting identified educational needs. The key conditions under which sponsorship of continuing education and professional meetings for pharmacists is acceptable are summarised below.

1. Acknowledgment of pharmaceutical company sponsorship should be given in event materials. This should occur by reference to the company rather than by endorsement of a product.

2. The organiser of the event should retain control of and responsibility for the program, speakers and other aspects of event format.

3. The sponsorship arrangement should not give rise to a conflict of interest for the organiser or damage the profession’s public standing or reputation for independence.

4. Individual pharmacists attending an event should not receive direct subsidy from a sponsor to offset the costs of their participation. Sponsorship should be received by the organiser who may then apply it to reduce the costs of attendance for all registrants (eg. reduced registration fees).

5. The organiser may also use sponsorship arrangements to meet the costs of attendance (travel, accommodation and meals) and payment of honoraria for individuals.

† ‘Brand name reminders’ are defined in the Medicines Australia Code as items of low monetary value which are intended to remind health professionals of the existence of a product.
providing genuine services at an educational event. However, as in (4) above the payment should not come to those individuals directly from the sponsor.2,16

6. Scholarships or grants to support attendance of pharmacy students at selected educational events is permissible provided the selection process and payment are made by an academic institution.2

5.2 Hospitality
Offers of hospitality associated with an educational event may be considered appropriate to accept where:
• hospitality is secondary to the educational purpose of the event;
• the level of hospitality is proportional to the occasion; and
• the level of hospitality does not exceed the level that would apply if the recipients paid for themselves.1,16

6. Funding for Research
Formal approval of research proposals by an appropriately constituted ethics committee should be a prerequisite to pharmacists participating in clinical research or post marketing surveillance studies (as distinct from marketing programs) funded by pharmaceutical companies. Pharmacists are referred to the SHPA Standards of Practice for Pharmacy Investigational Drugs Services17 for further information. Pharmacists may also find it beneficial to refer to the guidance provided to doctors wishing to participate in industry sponsored research and post marketing surveillance studies.2,13,16

References:

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