Relationships between health professionals and industry: maintaining a delicate balance

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Summary

The power and influence of the pharmaceutical industry has raised concerns among health professionals and the wider community and led to calls for increased regulation. Overwhelming evidence that advertising, contact with company representatives, gift giving, sponsorship of meetings and other forms of promotion influence prescribing behaviour, has drawn particular attention to drug promotion. In answer to these concerns a range of responses has developed, including rules set by government, processes for the review and management of research, industry codes of conduct, community responses, and guidelines generated by practitioner associations. The various forms of regulation taken together strike a delicate balance that aims to protect the interests of the community and individual patients, foster research and the development of new products, maintain public confidence in pharmaceuticals and medicine, and facilitate ethical decision making among the various participants. Although guidelines for health professionals provide some advice, they cannot cover all situations where conflicts and dualities may arise in practice.

Key words: drug promotion, drug regulation, ethics.

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Introduction

Despite improvements achieved in the management of complex medical conditions in recent years and widespread and increasing use of pharmaceuticals, the pharmaceutical industry has been increasingly portrayed in both the academic literature and the popular media in an unfavourable light. While it may be true that the industry's negative reputation is not completely justified, it is not difficult to understand the source of the concerns.

General practitioners and other health professionals such as pharmacists are frequently visited by representatives of pharmaceutical companies. The purpose of these visits is to promote the company's drugs and to build a relationship. In dealing with such encounters, situations may arise where there is an ethical dilemma or conflict of interest. It is important for health professionals to be aware of these and to respond appropriately.

Drug promotion

In Australia the primary targets of drug promotion are doctors, who may be provided with gifts, offers of travel, and other inducements to prescribe.[1] More subtle promotion may include educational activities, drug samples and drug familiarisation schemes, and support for the practice such as providing a nurse to collect data.

Even though doctors generally deny that they are influenced by such approaches[2,3], there is overwhelming evidence that advertising influences prescribing behaviour. Physicians who attend pharmaceutical events are more likely to use the products of the sponsors, even in the absence of reliable and credible evidence in their favour.[4,5] Promotional activities in general lead to increased prescribing of drugs, acceptance of commercial rather than scientific views, a propensity to engage in non-rational prescribing behaviour[6,7,8], and biases in favour of a company's drugs.[9,10]

While research undertaken by industry is often rigorous and well conducted, it may be driven by commercial imperatives leading to biased presentation and interpretation of results.[11,12] Protocols and methodologies may reflect and support intended outcomes rather than disinterested inquiry.[13]

Perhaps of even greater concern is the well documented fact that industry interests substantially influence the social agenda relating to the understanding of health and disease, sexuality, body image and lifestyles.[14,15]

What is special about drug promotion?

Concern about the role and influence of the pharmaceutical industry is heightened because of the special features of medicines compared to other commercial products. The consumers of medications are often extremely vulnerable, for the obvious reason that their health may be at stake in using a product. Decisions about what drugs to use are often taken

not by them alone but by their medical practitioners, whose interests are not always identical to those of their patients.

For prescription drugs, medical practitioners have great influence and are charged with the responsibility of balancing patients' needs and the public interest. They have knowledge and expertise to assess the scientific evidence, and access to the specific contextual details of medical need in particular cases.

For over-the-counter products, pharmacists advise patients and directly benefit from making a sale. They may also be offered incentives to stock particular brands.

The ongoing debates about the role and power of the drug industry in the popular media[16,17,18] have no doubt influenced community attitudes, although it is difficult to determine just what impact these may have had. While some consumer groups have expressed suspicion and hostility to the industry, other groups have emphasised the importance of improved co-operation and development of active collaborations.[19] Public scepticism may help to control doctors' dealings with industry, but may also damage the doctor–patient relationship.

Physicians need to be aware of the evidence about the impact of advertising on behaviour and community perceptions. While bans on the provision of information by drug companies are inappropriate, high levels of critical awareness, supported by educational programs, are needed by clinicians.

In many countries, including Australia, the purchase of medications is heavily subsidised from public funds. The prescriber therefore does not directly bear the cost of their decisions.

Conflicts of interests

One of the key requirements of a health professional involved in interactions with industry is to be able to distinguish dualities and conflicts of interests. A duality exists where there are two or more social roles that overlap, each of which is associated with a moral imperative. A conflict exists where these imperatives are contradictory and threaten to compromise the primary goal of one of them.

A duality of interest would exist when a general practitioner involved in research is considering recruiting their own patients for a study, or when a doctor considers accepting travel assistance from a pharmaceutical company to attend a meeting with undisputed scientific content at a pleasant resort location. The principles for responding to a duality are straightforward. It needs to be identified and disclosed publicly to the relevant community. This community should decide whether it constitutes a conflict and, if so, this needs to be managed, usually by disengaging the two conflicting roles.

Sometimes this process of disengagement is straightforward – for example, if researchers propose to include their own patients in a research project they should in general not approach the patient themselves but leave the consent process to third parties. On other occasions, such as where a researcher has direct pecuniary interests in a product being tested, more elaborate mechanisms, such as an arm's length committee or divestment of shareholdings, may be necessary.

Regulation of drug promotion

In response to the real or perceived risks associated with the pharmaceutical industry's influence and power, an array of formal and informal mechanisms for regulating the industry has developed. These include rules set by government, industry codes of conduct, guidelines generated by practitioner associations, processes for the review and management of research, and community responses. Together, they seek to ensure a wide range of goals, including protection of the interests of the community and individual patients, responsiveness to specific clinical contexts, fostering of research and development of new products, maintenance of public confidence in pharmaceuticals and medicine, facilitation of ethical decision making among the various participants, and enhancement of options and freedom to act.

Government

Although government regulation undoubtedly plays a key role, it is a blunt instrument that may not be able to provide specific guidance for all circumstances that occur in a clinical setting. Statutory regulatory regimes are also cumbersome and bureaucratic and require elaborate and expensive systems of enforcement.

Industry

The industry itself has developed a code of conduct, which is administered through the industry peak body, Medicines Australia.[20] This Code has been criticised, for example, on the basis that membership of Medicines Australia, and thus allegiance to its policies, is voluntary and does not include all manufacturers. Areas of concern, such as the collection and control of data, are omitted altogether. Enforcement of the Code is incomplete and mostly relies on complaints. Sanctions for breaches are generally modest.[21] Nonetheless, it is believed that the Code represents a substantial achievement and that it has contributed to significant change in the commercial behaviour of the pharmaceutical industry in Australia. For example, a recent amendment to the Code now requires pharmaceutical companies to publicly disclose the cost of events organised for doctors.

Guidelines for health professionals

A number of professional associations have developed guidelines about the ethical relationships between health professionals and the pharmaceutical industry.[22,23] Among these are the Royal Australasian College of Physicians (RACP)[24], the Royal Australian College of General Practitioners (RACGP)[25], and the Pharmaceutical Society of Australia.[26]

RACP recommendations

These guidelines seek to demonstrate how dualities may be managed in specific circumstances that arise in common practice. They recommend that gifts should be rejected, even items of trivial value. In general, acceptance of travel expenses is discouraged. However, where a practitioner is making a formal contribution to a meeting it may be acceptable for the organising committee to offer assistance with travel and other costs.

For scientific meetings or professional development events, it is important that programs are developed by committees at arm's length from sponsors and that sponsorship is not negotiated on the basis of conditions relating to speakers or content.

The RACP guidelines cover many issues regarding research, including design of experiments, management and interpretation of data, and publication of results, which raise the possibility of conflicts of interests. Researchers have special responsibilities to ensure that the conduct and outcomes of research are not influenced by pecuniary or non-pecuniary interests and that the public can have full confidence in the integrity of any data that are disseminated.

RACGP recommendations

The RACGP makes similar recommendations to general practitioners but is more relaxed about doctors accepting gifts. A gift may be accepted but the patient should be the primary beneficiary and the gift should be related to the general practitioner's work. So, for instance, gifts such as a stethoscope or a textbook are acceptable, whereas gifts of a holiday, frequent flyer points, a computer or cash payments are not acceptable.

The guidelines also recommend that if a general practitioner is involved in postmarketing surveillance studies, they should make it clear to the patient that the patient's welfare is not dependent on participation in the study and they can withdraw at any time and start an alternative treatment if they wish.

The Pharmaceutical Society of Australia Code

Although very brief, the Code obligates pharmacists to avoid situations that may present a conflict of interest. Accepting inappropriate gifts is also contrary to the Code.

Conclusion

Opinions differ and controversies continue about the influence of the pharmaceutical industry and the proper responses to it. The system of regulation that has evolved in Australia is complex and heterogeneous, incorporating components from government, industry, community and the professions. Although each would on its own be insufficient, together these elements constitute a delicately balanced equilibrium that goes at least some way towards ensuring that the diverse tasks and goals set by the various stakeholders are addressed and acknowledged. Whether the balance should shift more in the direction of regulation, whether a more punitive approach would be more or less effective, how best to maintain both economic incentives and public responsibility – or even if it is possible to do so – remains uncertain.

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Dental notes

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The level of prescribing that occurs in the average dental practice is not usually such that it attracts the attention of pharmaceutical companies' marketing departments. However, we are large consumers of restorative materials, medicaments and other products. We rely on a good working relationship with dental supply companies who not only offer access to these products, but are also often involved in research related to them. It is most likely that dentists are not aware of the influence that advertising, 'special offers', personal visits by company representatives, endorsements and trade shows have on our purchasing habits.

What dental practitioners purchase or prescribe should always be done on the basis of available scientific evidence with patients' interest utmost in our minds. In fact, in the majority of practices it is not the dentists who purchase these items, but rather the practice manager on the advice of the dentist, advice that may not be consistently available. Situations of conflict and duality of interest may well be relatively common in the dental profession, and these should be acknowledged and dealt with in an open manner. Currently, the Australian Dental Association is developing a policy to advise its members where these conflicts and dualities of interests arise.

Medicines Australia Code of Conduct: breaches

Medicines Australia has a Code of Conduct to guide the promotion of prescription drugs by pharmaceutical companies in Australia. A new edition of the Code has recently been approved.[1] Complaints are considered by the Code of Conduct Committee and the results are published in its annual report. The report for 2006–07 is available on the Medicines Australia website.[2]

This year's report contains detailed information about 41 complaints. In fourteen cases no breach of the Code was found. Table 1 shows the 27 complaints in which at least one breach of the Code was found. As usual, most of the complaints were made by rival pharmaceutical companies, but 12 were made by health professionals.

Most of the breaches were for using misleading information in promotional material. Some of the larger fines were imposed on companies that had allowed the public to be exposed to their promotions. Two complaints related to a company which sponsored the national conference of a patient support