DRUG PROMOTION

the latter does not conflict with product information.

The Code of Conduct restricts many activities, including those proscribed by legislation. For example, prescription medicines cannot be promoted to the general public, companies cannot promote their products for indications which are not listed in approved product information. Starter packs cannot be left with receptionists unless there is a signed request form from the doctor. In addition, pharmaceutical representatives cannot promote products over the telephone unless you first agree, and promotional material must not be marked for urgent attention. Unsolicited reprints of journal articles must be consistent with product information, and the word "safe" cannot be used unless it is substantiated.

How does the APMA Code work?

The majority of promotional material is not screened by an independent body before publication. Responsible companies, however, usually screen material in-house. The APMA has established a monitoring subcommittee that monitors promotional material retrospectively. The monitoring committee reviewed 380 pieces of promotional material concerning anti-infectives and antihypertensives between July 2000 and June 2001. Overall, 88% of the 269 items concerning anti-infectives were considered to abide by the Code, while 92% of the 111 items concerning antihypertensives were considered in accord with the Code.

The main means for ensuring that promotional claims are in accord with the Code's standards is through a complaints mechanism. Health professionals, pharmaceutical companies and other interested parties are encouraged to lodge complaints with the APMA when they perceive promotional practice to be inappropriate.

Complaints have to be in writing and include "the nature of the practice being complained about and a simple explanation of the reasons(s) for the objection". Once lodged, complaints are heard by the Code of Conduct Subcommittee, which is chaired by a lawyer with experience in trade practice, and includes medical, industry and consumer representatives. In the year 1 July 2000 to 30 June 2001, the APMA Code of Conduct Committee evaluated 27 complaints, of which 17 were found to breach the Code.

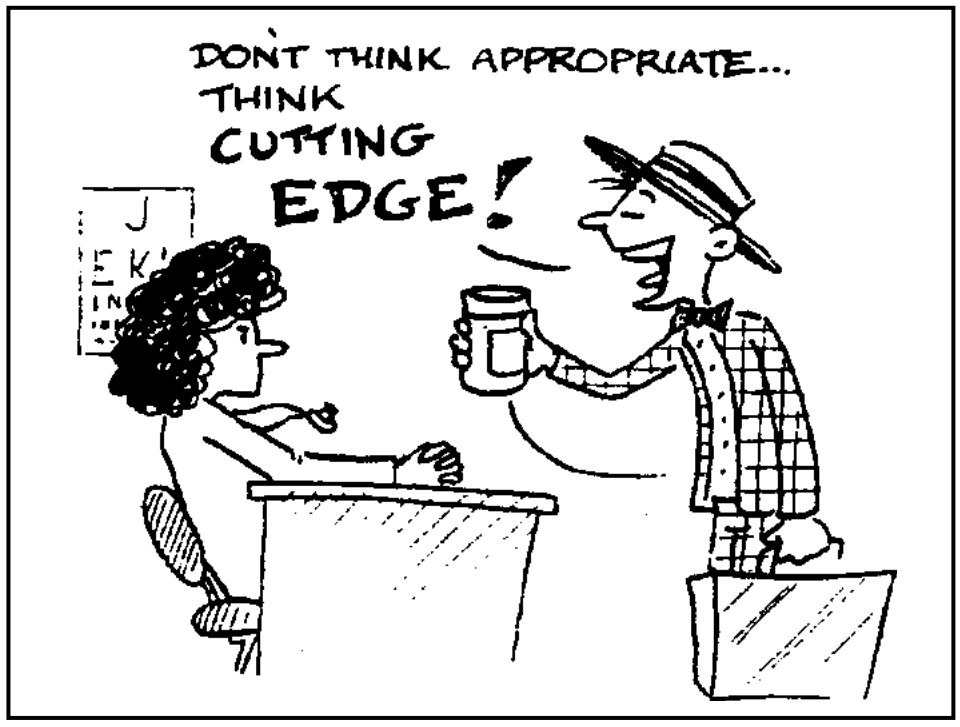
Deciding if a piece of promotion is misleading can be difficult, particularly if you are hearing about a new product for the first time. However, there are some common causes of misleading claims. These include claims based on poorly designed studies, obsolete data, information outside of approved product information and the use of animal or in-vitro data to support clinical claims.

Who complains?

To date, most complaints received by the APMA are lodged by pharmaceutical companies, with very few originating from health professionals. Complaints from health professionals are vital to ensure the system is robust, as very often health professionals are in the best position to scrutinise promotional practice. For example, it is very difficult for anyone other than health professionals to monitor the activities of pharmaceutical representatives.

What happens if the Code is breached?

Where promotional claims have been found to be in breach of the Code, the APMA Code of Conduct Subcommittee may impose a sanction. Sanctions include the requirement to cease or modify the promotional practice, or publishing corrective letters or retraction statements, the imposition of fines of up to $75,000 or expulsion from the APMA membership. For example, a complaint was lodged in 2000 regarding a product for hormone replacement therapy, claiming "protection of bone mineral density" and "cardiovascular protection". The claim regarding cardiovascular protection was ruled to be inaccurate, potentially misleading and not an approved use in Australia. The company was required to withdraw the promotional material and was not entitled to use it again. A $5,000 fine was imposed[3].



A humorous portrayal of a drug representative's visit to a doctor, but the Australian Code of Conduct sets standards for the country's pharmaceutical representatives

Is the Code effective?

There has been much debate over whether codes of conduct are an effective mechanism for controlling pharmaceutical promotion[4,5]. A series of studies by clinical pharmacologists, conducted between 1985 and 1992, led to the conclusion that the quality of information in advertisements had improved over that time[6]. The adherence of many other activities, such as symposia and the activities of pharmaceutical representatives, to the Code has not been well studied. A small study of pharmaceutical representatives' presentations to doctors suggested that the information provided was not always accurate, nor in accord with the Code[7].

The current system is limited by the retrospective detection of Code breaches. Complaints against misleading or inaccurate promotional messages can only be lodged after the messages have been published, by which time they have had the potential to influence practice. Monitoring does not overcome this, as it is also retrospective. While promotional messages which are in breach of the Code may be required to be withdrawn and not appear in future, this does not redress their prior dissemination. The only recourse for re-education under the current system is the publication of corrective letters. The success of such letters as a method for righting erroneous beliefs that have resulted from misleading promotion is an area that requires more consideration. The distribution of printed material alone as a mechanism for improving use of medicines has been shown to have little effect, so is unlikely to be effective in this arena.

Although fines can be imposed for Code breaches, when compared with promotional budgets these may not be significant. The uppermost sanction that can be imposed is expulsion from membership of the APMA, a sanction which has not yet been employed. A further limitation is that non-member companies are not bound by the Code.

These limitations highlight the need for a co-regulatory approach to pharmaceutical promotion. Government must take an active stance in regulating promotional practice where the Code is limited. Further, evidence has shown the regulatory system is strengthened if an active, interested third party operates a "watchdog" role. Support for an organization of this type is warranted. In Australia, the Medical Lobby for Appropriate Marketing (MaLAM) Australia has undertaken this role in the past with funding from the Australian Government. MaLAM Australia ceased to exist after funding stopped. MaLAM International is still in operation, now known as Healthy Skepticism.

Limits to the Code

Even if the Code worked optimally, practitioners should be aware that promotional messages can be accurate but may still not support the quality use of medicines. This situation arises because medicines may be promoted for any indication listed in product information, which may not be in accord with recommendations in sources of objective information such as the *Therapeutic Guidelines* or the *Australian Medicines Handbook*. For example, dextropropoxyphene is indicated for mild to moderate pain, but the *Australian Medicines Handbook* recommends its use should be avoided.

Conclusion

Enforcement of the legislation and Code of Conduct guiding promotional practice is vital to ensuring that promotional material is accurate, balanced, not misleading and promotes appropriate use of medicines. The current self-regulatory system relies on a complaints mechanism for recognising Code breaches and can only be effective if complaints are lodged whenever there is concern that promotional practice is inappropriate. It is essential that health professionals become more active participants in this process. The effectiveness of the system is equally dependent on appropriate sanctions. It would appear that current sanctions may not be severe enough to act as a barrier to inappropriate promotional practice and should be increased. Further, governments must be prepared to play an active role, where codes appear to be failing, and provide funding for independent 'watchdog' activities to increase the effectiveness of the system. ❑

* Dr Libby Roughead is Senior Lecturer in Pharmacy Practice, School of Pharmaceutical, Molecular and Biomedical Sciences, University of South Australia.

This article has been adapted and updated from an article in *Australian Prescriber* 1999;22:78–80. Reproduced with the permission of the Editor.

References

1. Peay MY, Peay ER. The role of commercial sources in the adoption of a new drug. Soc Sci Med 1988;26: 1183–1189.

2. WHO. Ethical criteria for medicinal drug promotion. Geneva: World Health Organization; 1988.

3. APMA Code of conduct: annual report 2001. Canberra: Australian Pharmaceutical Manufacturers Association; 2001.

4. Langman M. The code for promoting drugs. BMJ 1988;297:499–500.

5. Herxheimer A, Collier J. Promotion by the British pharmaceutical industry, 1983–8: a critical analysis of self-regulation. BMJ 1990;300:307–311.

6. Carandang ED, Moulds RFW. Pharmaceutical advertisements in Australian medical publications – have they improved? Med J Aus 1994;161:671–672.

7. Roughead E.E, Gilbert AL, Harvey KJ. Self-regulatory codes of conduct: are they effective in controlling pharmaceutical representatives' presentations to general medical practitioners? Intern J Health Services 1998;28:269–279.