APMA Code of Conduct

The Australian Pharmaceutical Manufacturers' Association Code of Conduct[1] provides guidelines for the ethical marketing and promotion of prescription pharmaceutical products in Australia. It complements the legal requirements of the Therapeutic Goods Regulations and the Therapeutic Goods Administration. The Code provides guidelines for promotional tools such as advertising, product starter packs (samples), mailings, gifts, trade displays, travel, sponsorship, entertainment, and the behaviour and training of medical representatives. It also covers relationships with health professionals, and most recently, information on the internet.

Compliance with the Code is a condition of APMA membership, and the Association's members represent more than 90% of pharmaceutical companies. The Code, established in 1960, is regularly revised.

The Code depends on a complaints process.[2] An independent Code of Conduct Committee considers complaints to determine whether a breach of the Code has occurred, and if so, the appropriate sanction that should be imposed. The most severe sanction is expulsion from the APMA, but this has never been used.[2] Pharmaceutical companies can appeal against the decision of the Committee.

The Committee comprises representatives from organisations such as the Therapeutic Goods Administration, Consumers' Health Forum, a patient support organisation – currently the Arthritis Foundation of Australia, the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, the Royal Australian College of General Practitioners and the Australian Medical Association.

Table 1

Breaches of the Code of Conduct July 1999 – June 2000

Company	*Breaches*	*Drug – brand name*	*Drug – generic name*	*Sanction imposed by Code of Conduct Committee*
Alcon	1	Betoptic S	betaxolol	Corrective letter to be sent to specialists
Boehringer Ingelheim	1	Persantin	dipyridamole	$5000 fine; withdrawal of promotional material
Bristol-Myers Squibb	4	Pravachol	pravastatin	$12500 fine for repeat of previous breach; withdrawal of material
		Serzone	nefazodone	$5000 fine
		Iscover	clopidogrel	Withdrawal of promotional material
Eli Lilly	1	Evista	raloxifene	Withdrawal of promotional material
Galderma	1	Loceryl	amorolfine	Withdrawal of promotional material
Glaxo Wellcome	2	Relenza	zanamivir	Withdrawal of advertising
		Pritor	telmisartan	Warning against future breach of Code; review of internal procedure
Merck Sharp & Dohme	4	Zocor	simvastatin	None
		Fosamax	alendronate	$5000 fine; withdrawal of advertising. Further $10 000 fine for repeat of previous breach
		Vioxx	rofecoxib	$10 000 fine
Mundipharma	1	Oxycontin	oxycodone	Material not to be used again
Novartis	1	Lamisil	terbinafine	Withdrawal of material
Novo Nordisk	2	Kliogest	norethisterone/ oestradiol	$5000 fine; material not to be used again
		Kliovance	norethisterone/ oestradiol	Cessation of activity; corrective letter to be sent to prescribers
Pfizer	2	Zoloft	sertraline	$10 000 fine; withdrawal of material. Further $25 000 fine (including $10 000 fine for repeat breach); withdrawal of material
Pfizer/Searle	1	Celebrex	celecoxib	$10 000 fine; withdrawal of promotional material
Pharmacia & Upjohn	2	Fragmin	dalteparin	Withdrawal of promotional material
		Caverject	alprostadil	Action to ensure use of correct font size in advertisements
Rhone-Poulenc Rorer	1	Clexane	enoxaparin	$15 000 fine; withdrawal of promotional material
Roche	1	Rocaltrol	calcitriol	$7500 fine; withdrawal of advertising
Sanofi-Synthelabo	1	Plavix	clopidogrel	Withdrawal of material
Searle	1	Lomotil	atropine/ diphenoxylate	Withdrawal of material; corrective advertisement placed
Wyeth	1	Premarin and Premia	conjugated oestrogens	Withdrawal of material

Breaches of the Code (Table 1)

In the interests of transparency, the Code includes a requirement for regular publication of Code breaches in medical journals. This information includes the names of companies who have had complaints brought against them, a summary of the complaints and sanctions imposed.

In 1999–2000 44 complaints were received. (Six of these were subsequently withdrawn, one was referred elsewhere and three were returned to the complainant.) Of the 34 complaints evaluated by the Committee, 28 were found to be in breach of the Code. There was a variety of problems dealt with by the Committee (see box).

Two complaints were found not to be breaches of the Code, but prompted the APMA to consider modifications to the Code:

- a complaint about using a telemarketing campaign to advise prescribers of a change in the availability of Losec
- a complaint about sending letters to patients encouraging them to lobby their Members of Parliament to support the listing of Aricept on the Pharmaceutical Benefits Scheme.

Examples of Code breaches

Oxycontin

Statements in the promotional material overstated the attributes of oxycontin and promised more than the product could reasonably be expected to deliver. One statement was probably misleading because it implied that oxycontin is first-line therapy (contrary to the approved indications). Statements used in an unqualified manner may have encouraged excess usage of oxycontin and were therefore inappropriate and misleading.

Kliovance

Healthcare professionals were invited to participate in a project that was not clearly identified as market research. Offering payment for their participation in a Product Familiarisation Programme and giving them a three month free supply of Kliovance was not permitted under the Code.

REFERENCES

1. Australian Pharmaceutical Manufacturers Association. Code of Conduct of the Australian Pharmaceutical Manufacturers Association. 13th ed. Sydney: Australian Pharmaceutical Manufacturers Association Inc.; 2000.
2. Roughead EE. The Australian Pharmaceutical Manufacturers Association Code of Conduct: guiding the promotion of prescription medicines. Aust Prescr 1999;22:78-80.

NOTE

The APMA Code of Conduct is available from:

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North Sydney NSW 2060
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Fax: (02) 9959 4860
http://www.apma.com.au

New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may have been little experience in Australia of their safety or efficacy. However, the Editorial Board believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Board is prepared to do this. Before new drugs are prescribed, the Board believes it is important that full information is obtained either from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Brinzolamide

Azopt (Alcon)

10 mg/mL in 5 mL dispensers

Approved indication: raised intraocular pressure

Australian Medicines Handbook Section 11.2.7

Conditions such as open-angle glaucoma cause increases in intraocular pressure which can result in blindness. The intraocular pressure can be reduced by drugs which decrease the production, or increase the outflow, of aqueous humour. Carbonic anhydrase inhibitors reduce the production of aqueous humour and can be given topically. Dorzolamide was the first topical member of the class to be approved in Australia.

Brinzolamide is structurally similar to dorzolamide. It has a high affinity for carbonic anhydrase-II, the predominant form of the enzyme in the eye. After brinzolamide is instilled into the eye, some drug is absorbed into the circulation. It is mainly distributed to the red blood cells. As the half-life of brinzolamide in whole blood is 111 days, it takes 6–9 months for the drug concentrations to reach a steady state. These concentrations are not great enough to interfere with the normal functions of carbonic anhydrase in the body.

During short-term clinical trials a twice-daily dose of brinzolamide 1% has reduced intraocular pressure by approximately 3–5 mmHg. In an 18-month study the mean reductions in intraocular pressure were 2.7–3.9 mmHg with brinzolamide and 4.7–5.6 mmHg with timolol 0.5% (a topical beta blocker).[1] Another study compared brinzolamide 1% with dorzolamide 2%, and timolol 0.5% for three months. All three drugs had similar effects on intraocular pressure and there were no significant differences in the efficacy of the two carbonic anhydrase inhibitors.[2] Adding brinzolamide to treatment with timolol can produce further reductions in intraocular pressure.

Most of the adverse effects of brinzolamide are related to the instillation of the drops. Patients may develop blurring of vision, and sore or painful eyes. They may also complain of a bitter taste.

Although brinzolamide has been used as monotherapy, the carbonic anhydrase inhibitors are second-line drugs. A three-times daily dose was used in some clinical trials, but 76% of patients will respond adequately to a twice-daily dose of brinzolamide.[2] This may give the drug an advantage over dorzolamide which is instilled three times a day. Another