

Medicines Australia Code of Conduct: breaches

The Medicines Australia Code of Conduct guides the promotion of prescription products by pharmaceutical companies.¹ Each year Medicines Australia publishes a report, from its Code of Conduct Committee, which details all the complaints that have been received about advertising and other promotional activities. Many of the complaints in this year's report² have resulted from monitoring of 'educational events'. Pharmaceutical companies that are members of Medicines Australia provide reports of these activities. Reviewing events which exceeded certain thresholds is one of the functions of the Medicines Australia Monitoring Committee. This committee can refer cases to the Code of Conduct Committee.

The Monitoring Committee was the source of most complaints where a breach of the Code of Conduct was found. Only four of the successful complaints were made by health professionals. About a quarter of all complaints arise from pharmaceutical companies criticising their competitors.

Anyone can make a complaint, and healthcare professionals and members of the public can ask to remain anonymous. This year two complaints came from consumer organisations and there was even a complaint from a drug company representative about their own employer. A breach of the Code was found in about half of the complaints made during the year.

Sanctions can be applied to companies which are found to have breached the Code of Conduct. These may take the form of fines in addition to the withdrawal of promotional material. In some cases the company is required to write a corrective letter to the health professionals who received the material.

When reaching a decision, on whether or not promotional material has breached the Code of Conduct, the Code of Conduct Committee has to consider the details of the complaint and the response of the advertiser. This may require looking at the evidence from clinical trials and how this has been presented.

This year's report included examples of selective citation of data, misleading graphical presentations and inappropriate comparisons between products. The Code of Conduct Committee also has to rule on sponsorship and media matters. This year some media releases were found to be promotion rather than news. While donating a proportion of sales to charities may be acceptable for groceries, the Code of Conduct Committee determined that offering to give 25 cents per prescription to a research institute was a breach of the Code.

For educational events the Code of Conduct Committee may have to decide if hospitality has been excessive. A degustation menu for specialists resulted in a \$20 000 fine for one company, while providing a \$120 bottle of wine cost another company \$15 000. Six companies were fined at least \$100 000 for their promotional activities. These included a meeting for specialists on

Hayman Island, a media release promoting a drug to the public, and producing misleading promotional materials. The largest fine of \$175 000 was for several breaches of the code including leaving an internal company document in a general practitioner's surgery. While these fines are large by Australian standards a company in the USA has recently agreed to pay US\$2.3 billion for misleading promotion.³

Table 1 shows the cases where at least one breach of the Code of Conduct was found. Detailed information about the complaints can be found in the annual report of the Code of Conduct Committee.² A new version of the Code of Conduct is scheduled to be implemented on 1 January 2010.⁴

References

1. Medicines Australia. Code of Conduct. 15th ed. 2006. Amended 2007. www.medicinesaustralia.com.au [cited 2009 Nov 12]
2. Medicines Australia. Code of Conduct Annual Report 2008–2009. Canberra: Medicines Australia; 2009. www.medicinesaustralia.com.au [cited 2009 Nov 12]
3. US Department of Justice. Justice Department announces largest health care fraud settlement in its history: Pfizer to pay \$2.3 billion for fraudulent marketing [media release]. 2009 Sep 2. www.justice.gov/opa/pr/2009/September/09-civ-900.html [cited 2009 Nov 12]
4. Medicines Australia. Code of Conduct review. www.medicinesaustralia.com.au/pages/page223.asp [cited 2009 Nov 12]

Table 1

Breaches of the Code of Conduct July 2008 – June 2009

Company	Brand (generic) name	Material or activity	Sanction imposed by Code of Conduct Committee
Actelion	–	Educational event	\$20 000 fine
AstraZeneca	Crestor (rosuvastatin)	Promotional material	\$100 000 fine withdraw material and cease use corrective letter
	Nexium (esomeprazole)	Promotional material	\$85 000 fine withdraw materials corrective advertisement
Bayer	Levitra (vardenafil)	Promotional material	\$40 000 fine withdraw materials corrective advertisement
Eli Lilly	Cialis (tadalafil)	Media releases	\$60 000 fine
Eli Lilly & Boehringer Ingelheim	Cymbalta (duloxetine)	Media release	\$100 000 fine withdraw and cease use
Gilead	Truvada (tenofovir with emtricitabine)	Promotional material	\$75 000 fine withdraw material corrective letter
GlaxoSmithKline	Seretide (salmeterol with fluticasone)	Promotional material	\$175 000 fine withdraw material corrective letter
	Avamys (fluticasone)	Promotional material	\$100 000 fine withdraw material corrective letter
Ipsen	Somatuline Autogel (lanreotide)	Promotional material	withdraw material corrective letter
Janssen-Cilag	–	Educational event	\$50 000 fine
	–	Educational event	\$20 000 fine
	–	Educational event	\$15 000 fine
	–	Educational event	\$10 000 fine
Merck Serono	–	Educational event	\$20 000 fine
Novartis	Exelon (rivastigmine)	Media release	\$15 000 fine
	–	Educational event	\$5 000 fine
	–	Educational event	\$20 000 fine
	Famvir (famciclovir)	Promotional material	\$5 000 fine
Nycomed	Somac (pantoprazole)	Promotional material	\$90 000 fine withdraw material corrective letter and advert
	–	Educational event	\$5 000 fine
Organon	–	Educational event	\$100 000 fine
Orphan	Salofalk (mesalazine)	Promotional material	\$10 000 fine withdraw material and cease use corrective letter
Pfizer	–	Educational event	\$5 000 fine
Sanofi Aventis	Plavix (clopidogrel)	Promotional material	\$25 000 fine withdraw material
	–	Educational event	\$60 000 fine
	Plavix (clopidogrel)	Sponsorship	\$25 000 fine cease promotion of sponsorship
Servier	Coversyl (perindopril)	Promotional activities	\$100 000 fine withdraw materials
Sigma	Various	Starter packs	\$15 000 fine
Solvay	Lipidil (fenofibrate)	Promotional material	\$75 000 fine withdraw material corrective letter/advert