

29 October 2009



Dr Richard Chadwick
General Manager
Adjudication Branch
Australian Competition &
Consumer Commission
GPO Box 3131
Canberra, ACT, 2601

School of Public Health
Faculty of Health Sciences

Dear Dr Chadwick,

Re: Pre-decision Conference; Medicines Australia Code Reauthorisation (A91150)

I should like to attend this video-conference. A Melbourne venue would be convenient.

My interest in these matters stems from my involvement in an expert committee that formulated the World Health Organization's, "*Ethical Criteria for Medicinal Drug Promotion*" and also from making a number of submissions to Medicines Australia Code of Conduct reviews and ACCC authorisation processes over the years. In addition, I am involved in post-graduate and continuing professional education through my university, the Victorian Medical Postgraduate Foundation and the National Prescribing Service.

It was suggested that I summarise the points I would like to make at this conference:

1. I (and others) have argued that fines for Code offences should be substantially increased on the grounds that existing sanctions do not appear to have deterred repeated offences (see appendix). The 16th Ed of Medicines Australia Code provides only a modest increase in fines; this is one area where the ACCC might consider a minor variation of the Code warranted.
2. I have provided the ACCC with a number of papers from the medical literature that argued for greater transparency in the relationship between health practitioners and the therapeutic goods industry.^{1,2,3} I have suggested that the ACCC should extend the current Educational Event Reporting by Medicines Australia by adding a condition that would specifically indicate whether the event was organised by:
 - (a) The company, with a company determined speaker, such as a drug representative or key opinion leader, or
 - (b) An independent organisation, such as a Royal College who also independently selected the speakers.
3. I have also provided the ACCC with information about the U.S. "*Physician Payments Sunshine Act (S.301)*", introduced by Senators Grassley and Kohl.⁴ This would require

1 McNeill PM, Kerridge IH, Henry DA, et al. Giving and receiving of gifts between pharmaceutical companies and medical specialists in Australia. *Internal Medicine Journal* 36 (2006) 571–578.

2 Haines IE, Olver IN. Are self-regulation and declaration of conflict of interest still the benchmark for relationships between physicians and industry? *MJA* 2008; 189: 263–266.
http://www.mja.com.au/public/issues/189_05_010908/hai10221_fm.html

3 Mitchell PB. Winds of change: growing demands for transparency in the relationship between doctors and the pharmaceutical industry. *MJA* 2009; 191 (5): 273-275.
http://www.mja.com.au/public/issues/191_05_070909/mit10538_fm.html

4 http://www.prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf

U.S. drug, biologic, and medical device manufacturers to report the dollar value of certain gifts and payments ("transfers of value") made to physicians.

The information will be registered in a national and publicly accessible online database. Required disclosure includes: compensation; food, entertainment or gifts; travel; consulting fees or honoraria; funding for research; funding for education; stocks or stock options and ownership or investment interests. Companies failing to report incur financial penalties.

Some U.S. States already report this information and there is evidence that this practice has sensitised both physicians and consumers to potential conflicts of interest.⁵ This is another area where the ACCC might consider adding an additional reporting condition to the 16th Ed of Medicines Australia Code.

4. Finally, I have pointed out that the continued improvement of Medicines Australia's Code has now resulted in an anti-competitive environment with respect to different sections of the Australian medicines industry: prescription products (innovator compared to generic), compared to over-the-counter and complementary medicines.⁶ However, I accept your advice that it is the government, not the ACCC, that has jurisdiction in this matter.

Yours sincerely,



Dr. Ken Harvey
Adjunct Senior Research Fellow
School of Public Health
E: ken.harvey@latrobe.edu.au | W: <http://www.medreach.com.au> | M: 0419 181910

Please send written correspondence to:
Dr Ken Harvey
35A Mary St.
Hawthorn, Vic, 3122

La Trobe University
Victoria 3086, Australia
Tel: +61 3 9479 1750
Fax: +61 3 9479 1783
Email: sph@latrobe.edu.au
Web: www.latrobe.edu.au
ABN 64 804 735 113

⁵ http://www.twincities.com/ci_12573822?

⁶ <http://www.theaustralian.news.com.au/story/0,25197,26245931-23289,00.html>

Appendix: Pfizer Code breaches 2005-09

Complaint no	Fine	Comment
756	\$50,000.00	appeal successful
765	\$20,000.00	
779	\$30,000.00	
783	\$25,000.00	
789	\$15,000.00	
801	\$0.00	revise only
805	\$100,000.00	repeat breach of Code
809	\$20,000.00	
860	\$100,000.00	several severe Code breaches
865	\$50,000.00	
866	\$100,000.00	flagrant disregard of the Code
886	\$50,000.00	
909	\$200,000.00	brought industry into disrepute
916	\$50,000.00	appeal successful
920	\$20,000.00	
921	\$25,000.00	
987	\$5,000.00	
Total	\$860,000.00	
Average fine	\$50,588.24	

From: <http://www.medicinesaustralia.com.au/pages/page30.asp>