



Australian Consumers' Association

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20th January, 2006

Mr Scott Gregson
The General Manager
Adjudication Branch
Australian Competition and Consumer Commission (ACCC)
PO Box 1199
Dickson ACT 2602

**Re: Application A90994-6 by Medicines Australia re revised Code of
Conduct [15th Ed]**

Dear Mr Gregson,

I refer to your letter dated 5th December 2005, regarding authorisation of version 15 of the Medicines Australia (MA) Code of Conduct (the Code). The Australian Consumers' Association (ACA) is opposed to the authorisation of the proposed Code for the reasons outlined in this submission.

Experience from other countries shows the detrimental impact of advertising of pharmaceutical drugs. For example, US spending on drugs rose by \$42.7 billion in the 5 years from 1993 to 1998 and 22% of this increase was for the 10 most heavily advertised drugs.¹ It would be detrimental to the Pharmaceutical Benefits Scheme (PBS) if Australia was to follow this path. This experience demonstrates the importance of effectively regulating the advertising of pharmaceuticals. In our submission, the MA Code is not effective for the reasons set out below. It should not be authorised.

The Australian Consumers' Association (ACA)

ACA is an independent not-for-profit, non-party-political organisation established to provide consumers with information and advice on goods and services, health and personal finances, and to help maintain and enhance the quality of life for consumers. ACA provides consumer education, conducts surveys into consumer attitudes, lobbies for improved conditions for consumers and distributes unbiased consumer advice.

The ACA is opposed to the authorization of the proposed Code because it is ineffective in achieving its aims. It ineffectively monitors advertisements, lacks transparency, the sanctions are nominal and do not deter repeat offenders and MA does not adequately consult with consumers. These deficiencies result in pharmaceutical companies targeting both consumers and doctors in their advertising campaigns without real sanctions or penalties. Neither does the Code require evidence to support advertising claims nor effectively regulate advertising in software. The bottom line is that pharmaceutical companies are concerned about their 'bottom line' and not about consumer safety

¹ Coulter, A. (2001) 'Information or Advertising', Health Expectations, pp 203-4
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and the MA Code of conduct enables them to appear to be meeting guidelines, when in fact they are free to market their drugs in ways which should be prohibited.

1. Ineffective monitoring

While the MA monitoring committee claims to actively seek misleading claims, it is vague in defining the monitoring procedures. The monitoring committee documents state that it will "monitor selected promotional material...on a regular and ongoing basis"², but does not include specific information about how this will be carried out.³ The monitoring committee is ineffective in monitoring the advertisements of pharmaceutical companies.

Furthermore, the monitoring committee requires its members to submit some advertisements for monitoring but does not seek to monitor advertisements randomly. It is a concern that companies can pick and chose which advertisements they will submit.

In the financial year 2004/2005, MA received 51 complaints, 30 of which were lodged by member companies.⁴ No complaints were listed to have arisen from the 'monitoring committee'. The Code of conduct committee decided that 35% of the 51 complaints were in breach of the Code and that a further 20% were not in breach. 8% of the complaints were withdrawn, but no explanation was given for this. The annual report which appears to be the reporting mechanism of the MA Code of conduct omits a lot of information.

None of the complaints were lodged by consumers. One complaint was lodged by a consumer health organisation and one complaint was listed in the 'other category', though it was not explained who this actually referred to. An obvious deficiency of the Code is highlighted here. It is not 'consumer friendly, most consumers are unaware of its existence.

MA has given presentations to varied stakeholders including consumers to inform them about the Code, but these presentations appear to be tokenistic. They have obviously been ineffective in informing consumers about the Code because there were no complaints lodged by consumers in the last financial year despite the high incidence of advertisements which are in fact in breach of code provisions⁵.

2. Lacking transparency

The process established by the Code is not transparent. For example, while MA makes information about the number of complaints available online and in its annual report, it will not release information before the relevant company is contacted. The Code does not outline what will happen if the company refuses to allow the information to be released.^{6 7}

² MA Code of Conduct, V14

³ Lexchin, 2003

⁴ MA, 2005 Code of Conduct Annual Report

⁵ Harvey et al 2005

⁶ Lexchin, 2003

⁷ MA Code of Conduct, V14

Related to the issue of transparency is the lack of detail required in regards to disclosure. For example, the Code does not oblige companies to disclose sponsorship programs or commercial relations with speakers.⁸ Furthermore, companies are free to distribute their promotional materials at such events and companies are under no obligation to name the generic equivalent of their brand new drug.⁹

3. Lack of effective sanctions

The Code lacks effective sanctions. The nominal fines which are imposed inadequately deter repeat breaches of the Code. For example, the maximum fine is \$200,000 which is insignificant for an industry which has an annual turnover of \$14.5 billion.^{10 11} Furthermore, most of the fines imposed by the Code Committee were under \$25,000 and only 1 fine was in the \$100,000 to \$150,000 range. No company was fined the maximum amount.¹² The nominal fines do not deter repeat offenders, for example Pfizer Australia was fined a total of \$20,000 in 2003 for two breaches of the Code.¹³

Complaints can take up to 90 days to resolve.¹⁴ This is ample time for a company to promote its new drug as much as possible. These mechanisms of the Code needs to be further strengthened.

4. Advertising targeting consumers

The Code does not deter pharmaceutical companies from avoiding the prohibition on direct to consumer marketing. Many trade association codes, including the MA Code of Conduct, are deliberately vague and do not cover certain aspects of promotion because misleading advertising tactics are good for business.¹⁵ As one academic, Diana Zuckerman has stated "they [pharmaceutical companies] sell medical products just like any other products...just like toys and cars and deodorant. The goal is to make us want them".¹⁶ The quote was made in the context of describing the system in the US but could equally be applied here. The only difference in Australia is that direct to consumer advertising is illegal; yet still occurs in less obvious ways which the Code does not adequately address.

Companies advertise to consumers in a number of ways, for example:

- by masquerading advertising as education campaigns such as the Xenical (for weight loss) advertisements which advised consumers to 'ask their doctors'.¹⁷
- through stories in the media which are presented as 'medical breakthroughs' such as Concerta for ADHD or Travatan for glaucoma.¹⁸

⁸ Lexchin, 2003

⁹ Lexchin, 2003

¹⁰ Pharmaceutical Industry Factsheet, Department of Industry, Tourism and Resources

¹¹ Ruff, T. Haikal-Mukhtar, H. (2005) 'Doctors, Drugs, Information and Ethics: A Never Ebbing Story', Medical Journal of Australia, v183, n2

¹² MA, 2005 Code of Conduct Annual Report

¹³ Burton, B. (2005) 'Pfizer Australia is Fined for Misleading Promotion of Celecoxib', British medical journal, v330

¹⁴ MA, 2005 Code of Conduct Annual Report

¹⁵ Lexchin, J. (2003) 'Voluntary Self Regulatory Codes: What Should We Expect?', The American Journal of Bioethics, Summer 2003, v3, n3

¹⁶ Vastag, B (2005) 'FDA Considers Tightening Regulations for Direct to Consumer Advertising', Journal of the National Cancer Institute, v97, n24

¹⁷ Moynihan et al 2005

¹⁸ Ballenden, N. (2004) Drug Advertising, *Choice Online*, www.choice.com.au

- by sponsoring high profile support groups such as the Healthy Weight Task Force which was sponsored by Roche.¹⁹
- by subsidising academics to provide their 'expert' opinions about particular drugs or by sponsoring prizes for journalist awards.²⁰

5. Lack of effective regulation of pharmaceutical representatives

The number of pharmaceutical representatives is increasing. These representatives attempt to influence doctors' prescribing patterns in non-rational ways which have negative outcomes for consumers. It is the main way in which doctors receive information and it is a concern because the information is biased. The Code has proved ineffective in regulating this important pharmaceutical marketing channel.

Advertising is mostly targeted at prescribing physicians.²¹ Doctors are key targets because, "they are the decision makers because of their power to prescribe".²² There is a strong need to regulate pharmaceutical representatives.

Although pharmaceutical representatives undergo training, a two year part time course consisting of five modules, they are company representatives and give biased information. Little is known about the course as ACA was unable to obtain information about the cost of the course or to obtain a copy of the training manual when speaking to an MA official.²³ This further highlights the lack of transparency within MA.

Pharmaceutical representatives play an important role in this burgeoning industry, "referred as 'detail' men and women. Industry representatives are the most beautiful, friendliest, helpful, persistent, flattering group anyone meets".²⁴ Detailing exists and continues to grow because it obviously produces favourable results for companies. Data confirms that there is a high level of interaction between the pharmaceutical industry and medical organisations in Australia.²⁵ This participation is common and takes many forms as the industry provides support for a wide range of activities including for: education, research, conferences, equipment and journal publications.²⁶

¹⁹ Ballenden 2004

²⁰ Ballenden 2004

²¹ Brekke, K. Kuhn, M. (2005) 'Direct to Consumer Advertising in Pharmaceutical Markets', Journal of Health Economics, v25

²² PIAA 2001

²³ Telephone conversation with Deborah Monk (Director, Scientific and Technical Affairs), 19/01/06

²⁴ Grant, D. Iserson, K. (2005) 'Who's Buying Lunch: Are Gifts to Surgeons from Industry Bad for Patients?', Thoracic Surgery Clinics, v15, p533

²⁵ Kerridge, I. Maguire, J. Newby, D. McNeil, P. Henry, D. Hill, S. Day, R., Macdonald, G. Stokes, B. Henderson, K. (2005) 'Cooperative Partnerships or Conflict of Interest? A National Survey of Interaction Between the Pharmaceutical Industry and Medical Organisation', Internal Medicine Journal, v35

²⁶ Kerridge, I. et al, 2005

Pharmaceutical representatives have more influence on prescribing practices than all other promotional modalities and should be monitored carefully.²⁷ The representatives give oral presentations and may not always be accurate or comply with standards.

Regulating pharmaceutical representatives is also important because even though medical practitioners voice concern about the quality of information pharmaceutical representatives provide, they remain reliant on them for much of their information.²⁸ It should be the goal of the regulator to introduce independent detailers to provide independent information to doctors.

These conflicts of interest can be potentially extremely dangerous because human lives are at stake. This kind of interaction between pharmaceutical representatives and physicians currently serves a commercial rather than scientific or community purpose.²⁹

The ACA believes information should be made available to doctors which uses patients' questions as the starting point, ensures common concerns are addressed and refers to all relevant treatment options.³⁰ The disseminated information should hold the consumers' health as the main priority.

Further regulation is required on pharmaceutical representatives because they play an important role in advertising products to doctors. This has been confirmed in several studies which have shown that it is indeed "naïve to suppose that pharmaceutical representatives are passive resources for drug information".³¹ It is vital that information given to doctors is educational and not simply "thinly veiled as an educational document".³²

6. Lack of evidence to support many advertising claims

The Code does not consider the evidence used in advertisements. For example, absolute risk reductions (ARR) and numbers needed to treat (NNT) are not mandated in the Code.³³ Indeed, because there is no requirement, none of the ads (over 1000) examined in a study looking at pharmaceutical advertisements in medical journals provided data on AAR or NNT. Furthermore the study found that only 28% of claims were unambiguous.³⁴ Companies are therefore more likely to be able to make misleading or false claims and for these claims to be undetected.

7. Advertising in software

There is a lack of effective control over advertising in pharmaceutical software. A study carried out by Harvey et al found that the majority of the advertisements displayed in Medical Director, a

²⁷ Roughead, E. Gilbert, A. Harvey, K. (1998) 'Self regulatory Codes of Conduct: Are They Effective in Controlling Pharmaceutical Representatives' Presentations to General Medical Practitioners?', International Journal of Health Sciences, v28, n2

²⁸ Roughead, E. Harvey, K. Gilbert, A. (1998) 'Commercial Detailing Techniques Used by Pharmaceutical Representatives to Influence Prescribing', Australian New Zealand Medical Journal, v28

²⁹ Kerridge, I. et al, 2005

³⁰ Coulter, A. (2001) 'Information or Advertising', Health Expectations, pp 203-4

³¹ Somerset, M. Weiss, M. Fahey, T. (2001) 'Dramaturgical Study of Meetings Between General Practitioners and Representatives of Pharmaceutical Companies', British Medical Journal, v323

³² Haque (2005) 'Letters to the Editor- Pharmaceutical Advertising', Canadian Medical Journal, v173, n9

³³ Lexchin, 2003

³⁴ Loke, T. Koh, F. Ward, J. (2002) 'Pharmaceutical Advertising Claims in Australian Medical Publications', Medical Journal of Australia, v177

prescribing software commonly used by GPs, were in breach if the Code.³⁵ The Code is obviously ineffective in relation to prescribing software which is seen by both doctors and patients in the doctors' surgery.

8. The bottom line

An Australian study which looked at 174 advertisements for pharmaceuticals in six Australian medical publications found that the majority of the ads were for new and expensive drugs. Increased use of these drugs due to promotion will contribute to upward pressure on the Pharmaceutical Benefits Scheme (PBS).^{36 37} The main finding of the study was that greater diligence must be employed both by pharmaceutical companies in substantiating their claims and by clinicians when reading them. The problem is however that pharmaceutical companies have no incentive to substantiate their claims and clinicians have limited time to review the claims. There is a need therefore to ensure that the information provided to clinicians by companies is accurate, relevant and comprehensive. The market has failed to ensure this, and so have the various iterations of the MA Code.

Current regulation supports the interests of shareholders at the expense of consumers. Self regulatory codes such as this one are primarily designed in the interests of the shareholders and not consumers. "Codes that would genuinely restrict the ability to make money simply do not fit into this commercial ethic".³⁸

A parallel can be drawn between the methods employed by the pharmaceutical industry now and those that were employed by the tobacco industry. Voluntary Codes provide an appearance of self regulation in the absence of actual self regulation.³⁹

Questions answered

Your letter asked those submitting to answer several specific questions. To answer the first question, the Code is ineffective in regulating both:

- (i) the marketing of prescription drugs to health professionals AND
- (ii) the pharmaceutical industry and the general public

as outlined earlier in this letter.

Secondly, the Code is ineffective in its current form and it is unlikely that minor changes, such as those suggested in edition 15, will improve this self regulatory code in any meaningful way. The ACA does not support the approval of this Code as:

- it lacks transparency
- the monitoring committee is ineffective

³⁵ Harvey, K, Vitry, A, Roughead, E, Aroni, R, Ballenden, N, Faggotter, F (2005) 'Pharmaceutical Advertisements in Prescribing Software: An Analysis', *Medical Journal of Australia*, 183 (2): 75-9

³⁶ Newby, D, Henry, D. (2002) 'Letter: Drug Advertising: truths, Half-Truths and Few Statistics', *Medical Journal of Australia*, v177

³⁷ Loke, T, Koh, F, Ward, J. (2002) 'Pharmaceutical Advertising Claims in Australian Medical Publications', *Medical Journal of Australia*, v177

³⁸ Lexchin, 2003

³⁹ Chapman, S. (1980) 'A David and Goliath Story: Tobacco Advertising and Self Regulation in Australia', *British medical Journal*, v281

- the sanctions are nominal and do not deter repeat offenders
- there is a lack of consumer consultation and involvement
- there is insufficient regulation of marketing to consumers and physicians, especially the role of pharmaceutical representatives.
- there is no requirement to support claims in advertising
- it is ineffective in regulating medical software

Thirdly, we do not believe there are any public benefits associated with the Code. The Code provides an appearance of regulation but operates so as to permit a range of practices harmful to the public interest.

To answer the final question, there will be detriment to the public if the Code is approved. False advertising claims can negatively impact on consumers' health. The Code in its current form has a negative impact on the viability of the PBS. If doctors are prescribing newer more expensive drugs when older less expensive ones are available on the market with the same efficacy, the cost of the PBS will increase. This will impact consumers because the increase will be passed on to them through higher PBS co-payments.

Period of the Code

The ACA is also concerned that MA is applying for application for five years, instead of three as it has done in the past. If the Code is to be approved, it needs to be monitored and improved on a regular basis and for this reason should certainly not be approved for five years.

ACA would like:

A more effective independent regulator. In the absence of a new regulator, ACA would like the following fundamental changes to be made to the Code:

- wider consumer consultation,
- a more transparent enforcement body which makes more information available to the public,
- the requirement that the monitoring committee determine an effective program of monitoring the various forms of advertising,
- higher sanctions which will deter repeat breaches,
- stricter regulation surrounding pharmaceutical representatives (independent detailers would be the best option)
- prohibition of advertising in prescribing software, and
- a requirement that advertisement claims are backed by evidence.

Australian consumers need an effective regulator of pharmaceutical advertising, rather than the appearance of a regulator as is currently the case.

Please do not hesitate to contact me should you require further information or have any questions on 02 9577 3374 or 0411 788 076.

Yours Sincerely,
Viola Korczak
Policy Officer