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Australian Consumers' Association
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22 May 2006

Mr Scott Gregson
The General Manager
Adjudication Branch
Australian Competition and Consumer Commission
PO Box 1199
DICKSON NSW 2602

Re: Medicines Australia
Applications for Revocation and Substitution A90994-A90996
Draft Determination

Dear Mr Gregson,

The Australian Consumers' Association (ACA) is concerned that the Australian Competition and Consumer Commission (ACCC) proposes to authorise version 15 of the Medicines Australia Code of Conduct (the Code).

We do not believe that the Commission should be satisfied in all the circumstances that the implementation of the Medicines Australia Code of Conduct Version 15 will result in a benefit to the public at all. If it does have any benefit this benefit does not outweigh the *prima facie* anti-competitive nature of the proposed Code. In particular:

- The Code does not have adequate provisions to detect breaches in relation to the marketing of pharmaceuticals.
- The Code does not have adequate (transparent, balanced) processes for determining whether a breach of the Code has occurred.
- The penalties specified in the Code are wholly inadequate to deter breaches of the Code.
- There are no adequate measures to monitor the effectiveness of the Code, to consult the public, consumer organisations or others on required changes to the Code or to review and improve the Code.
- The Code has significant gaps and does not adequately regulate all forms of advertising for example, advertisements appearing in prescribing software.

Overall the Code creates a false impression that there exists in Australia adequate protection for consumers, the medical profession and the public purse from the harm caused by inappropriate marketing of pharmaceuticals.

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We are concerned that the Commission proposes to authorise the Code *even though it has identified significant deficiencies in the Code*. We believe that the code is ineffective in detecting, evaluating and sanctioning the marketing and promotion of prescription drugs in Australia. Direct to Consumer Advertising (DTCA) continues to exist in Australia even though it is prohibited by the Therapeutic Goods Act. Our specific concerns with the Code are outlined in previous submissions.

In a letter sent to the Minister for Health MP Tony Abbott dated 2 may 2006 (attached), the ACA argued the focus of regulating the promotion of pharmaceutical products needs to shift to more direct regulation, as occurs in a range of other sectors of the economy. This should occur through legislation enforced by the appropriate regulator. Failing this preferred option, there should be a requirement that industry develop an effective Code of Conduct that meets certain policy objectives established by legislation.

The ACCC proposed draft authorisation of version 15 of the Code, subject to one condition. We believe a number of further conditions are required before it can be determined that no harm will result from the current self regulatory arrangement. We note that "the ACCC continues to have real concerns about whether the code is effectively enforced", further conditions should be imposed. Apart from the condition about monitoring, these could include the following:

- Imposing higher sanctions which reflect the serious and potential harm which can result from misleading advertising. Higher sanctions would also be more likely to deter repeat breaches of the Code.

- Prohibiting advertising in prescribing software.

- Simplifying the complaints process so that consumers can become more involved. None of the complaints in the financial year 2004/5 were raised by consumers because most consumers are not aware that such a mechanism exists.

- Making information about the training program which pharmaceutical representatives undergo more transparent. Members of the public who are not enrolled are currently unable to obtain any information about the course.

We believe that further changes need to be made to the Code because of the potential harm to consumers that can result from the ineffective regulation of the marketing and promotion of pharmaceutical products.

Yours Sincerely,

Viola Korczak
Health Policy Officer
Australian Consumers' Association

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2nd May 2006

The Hon. Tony Abbott MHR
Minister for Health and Ageing
Leader of the House of Representatives
Room MG 43
Parliament House
Canberra, ACT, 2600

Dear Minister,

Re: Pharmaceutical Advertising

I am writing to urge you to take action to improve the regulation of pharmaceutical advertising in Australia. As you know, the advertising of pharmaceuticals is governed by some general provisions in the Therapeutic Goods Act together with the Medicines Australia (MA) Code of Conduct (the Code).

The objective of the regulation of pharmaceutical marketing should be to achieve a balance between the interests of pharmaceutical companies in promoting their products, the need for consumers to receive accurate and comprehensive information about medicines, and minimising the risk of over prescribing or incorrect prescription.

The current MA Code is ineffective in regulating the advertising of pharmaceuticals in Australia. The Australian Competition and Consumer Commission (ACCC) approved interim authorisation of version 15 of the Code on the 26th of April 2006, *even though it identified significant deficiencies in the Code.* The ACCC stated that the law required it to approve the Code. The MA self regulatory code is ineffective and does not protect the interests of consumers.

The ACA is concerned about the way in which pharmaceutical companies target both consumers and doctors in their marketing practices.

While direct to consumer advertising (DTCA) is prohibited by the Therapeutic Goods Act, companies get around this in a number of ways. Neither the provisions of the Act nor the Code have proved effective in prohibiting forms of DTCA. Examples of activities which constitute DTCA include:

- advertising masquerading as education campaigns
- placing stories in the media which are presented as 'medical breakthroughs'
- sponsoring high profile support groups
- subsiding academics to provide their favourable 'expert' opinions, and
- sponsoring prizes for journalist awards

It is clear that many of these activities generate conflicts of interest that have contributed to the undermining of consumer confidence in this industry and that also impact upon the reputation of the medical profession.

In a submission to the ACCC about the MA Code (attached), the ACA outlined why it is an ineffective self regulatory code. The reasons include:

- The imposed sanctions are inadequate. The MA Code sanctions do not deter repeat offenders.

It is a fundamental requirement for any successful code that there are meaningful sanctions if it is breached. Yet most of the fines imposed by the Code Committee were under $25,000; only one was in the $100,000 to $150,000 range and none higher.

- There is a lack of consumer consultation and involvement in developing and appraising the Code.

Most consumers don't know about the Code. Of the 51 complaints in the financial year 2004/5, 30 complaints were lodged by other companies, none were brought forward by consumers

- There is insufficient regulation of the role of pharmaceutical representatives.

There are roughly 3000 pharmaceutical representatives marketing drugs to doctors and only 150 independent detailers providing independent drug information to doctors funded by the NPS. Little is known about the training course that the pharmaceutical representatives are required to do. MA has been unwilling to provide information about this course that would help doctors or consumer organisations understand the basis upon which pharmaceutical representatives recommend drugs.

- The Code is ineffective in regulating medical software

A study[1] found that the majority of the advertisements displayed in Medical Director, prescribing software commonly used by GPs, were in breach of the Code. This is a concern because patients can view advertisements on the GPs' screen.

- Code processes are ineffective in monitoring promotional material.

While a monitoring committee peruses some promotional material, it is ineffective in deterring repeat breaches because much of the material 'slips through the cracks'.

[1] [1] 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

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The current self regulatory system is detrimental to consumers in two main ways. First, the advertisements inflate the prevalence of certain conditions and encourage consumers to take medication which they may not in fact need. This has long term implications for their health. Second, the increased demand for new products when older versions with the same efficacy are available inflate the cost of the PBS. This puts pressure on both the Government and consumers as the increased cost is in part passed onto them in the form of higher co-payments.

On the 27th of January, the ACCC denied interim authorisation of version 15 of the Code. It asked MA to address some concerns and on the 28th of April 2006 issued a draft determination granting authorisation of the Code for three years subject to a condition related to monitoring.

In approving the Code, the ACCC stated that it "continues to have real concerns about whether the Code is effectively enforced". Further, the draft determination for approval states "the ACCC considers that it is difficult to precisely determine the magnitude of the public benefit and detriment". The ACCC concluded, however, that its role is "not to craft an ideal code". Despite these concerns, the ACCC granted interim authorisation with only one condition, which related to monitoring.

Ultimately the ACCC's code approval process has proven to be an inappropriate mechanism for managing this important public policy issue. Given this, the focus needs to shift to more direct regulation of advertising in this sector (as occurs in a range of other sectors in the market). This could take the form of:

- a requirement that industry develop an effective Code of Conduct that meets certain policy objectives established by legislation, or
- through legislation enforced by the appropriate regulator

ACA's experience in dealing with advertising codes suggests that the latter option is likely to produce better outcomes for consumers.

We would welcome the opportunity to discuss this issue with you or your office. Please contact Viola Korczak on 02 9577 3374 or 0411 788 076.

Yours Sincerely,

Peter Kell
CEO

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