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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

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Australian Consumers' Association