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Monday, 9 January 2006

Mr Scott Gregson
General Manager, Adjudication Branch
Australian Competition and Consumer Commission
PO Box 1199
Dickson ACT 2602

Dear Mr Gregson,

Re: Application for revocation and substitution (A90994-6) lodged by Medicines Australia Inc
Revised Code of Conduct

I write as the President of ASCEPT (Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists). ASCEPT is pleased to support Medicines Australia's view that the new edition of the Code of Conduct should come into operation on 1 January 2006, which will be three years from the introduction of the current edition. In developing the new edition I can confirm that Medicines Australia has consulted widely with all interested stakeholders and has engaged in considerable dialogue with a broad range of organizations to ensure that the changes proposed will be supported.

ASCEPT supports the view that there are a number of important improvements to the Code in this revised edition and that these changes strengthen the Code in the interest of ensuring responsible promotion of prescription medicines.

Some of the important changes are:

- 1) detailed reference to the National Medicines Policy and QUM (quality use of medicines) in the Preface to the Code which sets the framework in which promotion must sit. QUM strategy is an important component of the National Medicines Policy
- 2) strengthening the regulation that restricts placement of advertisements in prescribing software to those areas that are only intended for prescribers. This was in response to a specific complaint as well as concerns expressed from a number of contributors to the Review. The restricted placement will assist companies to ensure that they meet their obligations not to advertise prescription medicines to consumers.
- 3) included new provisions regarding advisory boards, which was lacking in the current edition of the Code, to ensure that their functions are more clearly aligned to provision of clinical advice and that they are governed by clear statements of purpose and terms of reference.
- 4) made amendments to the requirements for Starter Packs, flowing from the Galbally Review. It is particularly important that these changes are implemented quickly in readiness for the States and Territories repealing their legislation in favour of relying on the Code of Conduct to regulate supply of starter packs
- 5) included the three advertising principles from the Therapeutic Products Advertising Code, which will be the overarching Code under the Trans-Tasman Joint Therapeutics Agency, which is scheduled to commence on 1 July 2006. This provides a strong link between the Medicines Australia self-regulatory Code and the overarching Code which will be underpinned in legislation.

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ASCEPT supports Medicines Australia (MA) desire that the new Code to be fully implemented in readiness for the commencement of the new Joint Agency. It would be unworkable for the implementation of new MA Code to be delayed until close to, or after, the commencement of the new Agency.

In summary, ASCEPT supports MA's application for interim authorization.

Yours sincerely,

Professor Andrew Somogyi
President, ASCEPT