



Date 13 July 2006

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From Fiona Crosbie / Emma Marsh

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Dear Mr Gregson

## Medicines Australia

### Applications for revocation and substitution

Medicines Australia (**MA**) wishes to thank Commissioner McNeill, you and your colleagues for meeting last Thursday to discuss authorisation of Edition 15 of the MA Code of Conduct.

#### 1. Summary

MA trusts the Commission now has a better understanding of MA's significant concerns about the Commission's proposal to amend the wording of Condition C1 as described in your letter of 7 June 2006 to require more detailed reporting by MA member companies (the **Amended Condition**).

MA understands that the Commission does not now propose to amend Condition C1 precisely as envisaged in your letter of 7 June 2006, but that the Commission is minded to impose a variant of Condition C1. MA would be grateful for the opportunity to discuss with the Commission this proposed variant and indeed believes that as a matter of procedural fairness it should be given the opportunity to consider the precise wording of Condition C1 prior to the Commission issuing its final determination in this matter.

#### 2. MA's submissions

In relation to the Amended Condition, to summarise, MA's key concerns are that it:

- will not increase public benefit in the manner envisaged by the Commission;

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- may have an anti-competitive effect by requiring the disclosure of commercially sensitive information;
- may cause companies to resign as members of MA thereby defeating the very purpose of the self-regulatory scheme;
- will create an unnecessary and unduly onerous administrative burden on member companies;
- has the potential to undermine confidence in the industry, specific member companies and their medicines; and
- is in all respects unreasonable, for reasons previously articulated.

MA also submits that the Commission does not have an unfettered discretion to impose conditions and that it is beyond the power of the Commission to impose conditions in this matter.

The Commission recognised in its draft determination dated 26 April 2006 that the Code will result in public benefit in a number of ways, including by:

- enhancing compliance with the legislative provisions on misleading or deceptive conduct;
- enhancing compliance with the legislative prohibition on direct-to-consumer advertising; and
- encouraging rational prescribing practices.

The Commission also concluded that the Code is likely to result in minimal public detriment (see paragraph 6.180).

MA submits that there are additional significant public benefits that have not been adequately taken into account by the Commission, including that the Code:

- attracts high levels of support from key stakeholders while maintaining the goodwill of the members and encouraging membership of MA;
- contributes to a culture which actively discourages inappropriate hospitality and/or sponsorship;
- provides prescribers with information on PBS restrictions, encouraging PBS compliance;
- provides for greater consumer involvement in Code matters, including through the inclusion of a permanent consumer member on both the Code of Conduct Appeals and Monitoring Committees;
- leaves responsibility for consideration of complaints and monitoring enforcement of the Code with the Code of Conduct Committee and the Monitoring Committee respectively, thereby reducing the need for taxpayer-funded investigations and enforcement action by the ACCC, the TGA or other government bodies; and
- encourages transparency and consistency in the operations of the pharmaceutical industry in an efficient and relatively simple framework, while avoiding the imposition of unduly onerous, complex, costly and/or unworkable obligations.

### 3. Conclusion

MA has indicated that it is willing to accept the imposition of Condition C1 as set out in the Commission's draft determination dated 26 April 2006 even though, for reasons discussed previously and above, MA does not believe the Commission has power to impose such a condition.

However, MA has explained to the Commission that it believes there is a real risk that if the Commission were to impose the Amended Condition, or something that closely resembles the Amended Condition, it will be unacceptable to some MA members. There is a significant potential that some existing members may decide to terminate their membership of MA.

As set out above, MA would be grateful for the opportunity to discuss with the Commission the proposed variant on Condition C1 and indeed believes that as a matter of procedural fairness it should be given the opportunity to consider the precise wording of Condition C1 prior to the Commission issuing its final determination in this matter.

We will contact you shortly to discuss this request.

Yours sincerely

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