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~~Confidential Email~~ *MS 10/4/06*

Dear Ms Davis

Medicines Australia - application for revocation and substitution

We understand that Healthy Skepticism Inc (*Healthy Skepticism*) has indicated that it wishes its submission to Medicines Australia's review of the Code of Conduct (conducted prior to Medicines Australia (**MA**) amending the Code in the form of Edition 15 and lodging the current applications for revocation and substitution) to be considered as a submission to the Commission. We set out below MA's responses in relation to a number of the comments included in the Healthy Skepticism submission.

A number of comments made in the Healthy Skepticism submission have also been made in submissions to the Commission by other interested parties and already addressed by MA in its previous submissions to the Commission dated 8 March 2006 and 9 January 2006.

1. Sanctions

Healthy Skepticism has made a number of comments in relation to the sanction provisions of the Code in paragraphs 10 to 13 of its submission. MA reiterates comments made in its previous submissions to the Commission that the Code of Conduct Committee has available to it a range of sanctions. If the Code of Conduct Committee imposes a sanction to issue corrective letters or corrective advertising, it outlines the elements that must be communicated in order to correct any misleading or incorrect promotion. In addition, the text of any corrective letter is reviewed and approved by the Code of Conduct Committee prior to publication. The Committee pays particular attention to ensure that corrective communications are not an opportunity for further promotion of any product.

Our Ref CYOS: EXMS:201287744

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The Code of Conduct Committee is effectively an independent panel of experts. MA submits that it would be time consuming, costly and impractical to have the corrective communication drafted by another independent panel of experts, because the panel would not be familiar with the complaint or the reasoning which led to the finding of a breach of the Code.

MA also reiterates that the Code includes higher sanctions for breach repetitions (repeating the same breach in promotion of any of the Company's products) and repeat of a previous breach (the same or similar breach in promotion of a particular product). Consequently, the Code of Conduct Committee has the ability to impose higher sanctions if it considers that a company has repeatedly failed to comply with the Code. As explained in our letter dated 8 March 2006, MA believes that the Committee's responses to complaints are appropriate.

MA does not believe that the suggestions made by Healthy Skepticism to extend the sanctions under the Code are appropriate. Again, as set out in previous submissions to the Commission, the level of fines provided for in Edition 15 and the alternative sanctions that can be imposed are comparable with penalties and sanctions that can be imposed under State fair trading laws and the *Trade Practices Act* for misleading conduct and other breaches. The Code is not legislation and provides an avenue, in addition to the avenues which are available by virtue of the above legislation, by which complaints can be resolved in relation to the conduct of pharmaceutical companies.

MA submits that the suggestion made by Healthy Skepticism that the Code of Conduct Committee should have the power to ban promotional activity for a period of time is not appropriate for a voluntary industry code. Further, such a sanction would be considerably more punitive than penalties and sanctions available for misleading conduct under the above-mentioned legislation.

Healthy Skepticism also suggested that the Code of Conduct Committee and the Code of Conduct Appeals Committee should have the power to find breaches of the Code beyond those raised in a complaint. MA submits that to impose a sanction for a breach of the Code which was not raised in the complaint would be contrary to natural justice, because the subject company would not have the opportunity to consider and prepare a response to any additional issues or complaints of which it is accused. However, both Committees may, through the minutes, inform a subject company of any issues beyond those complained of to which the subject company should give attention to ensure compliance with the Code.

Finally, Healthy Skepticism's comment that expulsion from membership of MA is an ineffective sanction that may exacerbate non-compliant behaviour overlooks the fact that the Code applies both to member and non-member companies. If a company is expelled from membership of MA, it is still required to comply with the Code.

2. Promotion of pharmaceutical products

MA submits that the suggestion contained in paragraph 18 of Healthy Skepticism's submission is too prescriptive for inclusion in a voluntary industry code and, if anything, this

is more of a legislative issue. However, a fundamental tenet of the Code, as expressed in Sections 1.1 and 1.3, is that all promotional and medical claims must be balanced.

In paragraph 19 of the submission, Healthy Skepticism comments that qualification of claims is in some cases inadequate. However, MA submits that clear requirements in this regard are set out in Section 1.3 of the Code, Explanatory Note 1.3(g), Section 1.7 and Explanatory Note 1.7.

MA further submits that the suggestion set out in paragraph 20 of the Healthy Skepticism submission is already addressed by the provisions of Section 1 of the Code.

3. Monitoring of promotional activities

Healthy Skepticism comments in paragraph 22 that the Code should contract an external organisation to provide monitoring of promotional activities in order to identify best practices, refine the Code and improve practices within pharmaceutical companies.

MA submits that this role is already appropriately assumed by the Monitoring Committee, whose role is described in Section 14 of the Code. The Monitoring Committee is an independent committee comprising GPs, a specialist in a relevant therapeutic area, company representatives who do not have a conflict in the therapeutic area and, when Edition 15 comes into effect, a consumer representative.

4. Complaints Process

Healthy Skepticism submits in paragraph 27 that both complainants and subject companies should be able to appeal against Code of Conduct Committee decisions. MA submits that this is addressed in Section 13.1 of Edition 15 of the Code whereby both subject companies and complainants may lodge an appeal against the findings of the Code of Conduct Committee.

Healthy Skepticism also submits in paragraphs 24 and 27 that non-industry complainants should be provided with the equivalent of free legal advice. MA submits that this issue is already adequately addressed in Appendix 1 of Edition 15 of the Code, under which MA will provide access to independent facilitators to assist external complainants with the submission of their complaints. This facility will be provided at all stages of the process, from complaint through to any appeal.

5. Reporting

Healthy Skepticism includes in paragraphs 25, 26 and 28 of its submission comments in relation to the reporting of Code of Conduct Committee and Code of Conduct Appeals Committee outcomes. Many of the suggested timeframes are impractical and could not reasonably be met.

In relation to Healthy Skepticism's comments about the Celebrex complaint, copies of the minutes were provided to the complainant promptly following the Appeal. They were then published in the Code of Conduct Annual Report.

MA also reiterates that improvements have been made to the reporting process in Edition 15 of the Code. MA will publish Code outcomes quarterly rather than 6 monthly on its website, which means that interested parties will be able to access information about complaints more quickly than at present. Information about consumer directed activities will continue to be published as soon as the complaint is finalised and in the Annual Report. These reports are virtually the full transcript of the minutes of the relevant Committees.

MA also repeats its submission that it would be an abuse of process to release information about a complaint before the complaint was finalised.

6. Continuing Education Program

Healthy Skepticism comments in paragraph 28 that all staff responsible for, and involved in, the creation and approval of promotional activities should be required to complete the CEP.

As explained previously, Section 4 of Edition 15 of the Code has been amended so that persons with responsibility for the development, review and approval of promotional materials are also now required to attend the Code of Conduct module of the CEP program (Section 4.14).

Please let us know if you have any queries in relation to any of the above.

Yours sincerely

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