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Dr Richard Chadwick
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By Email

Dear Dr Chadwick

Applications for Revocation and Substitution - A91150 & A91155 & A91156 & A91183 & A91184

We act for Medicines Australia (***MA***) in respect of its application for authorisation of Edition 16 of the Medicines Australia Code of Conduct (*the* ***Code***).

The purpose of this letter is to address the principal issues raised at the pre-decision conference. These matters fall into a number of categories:

- reporting of sponsorship of individual doctors to attend third party conferences overseas;
- reporting of speakers at educational events;
- reporting of relationships with health consumer organisations (***HCOs***);
- the level of fines that can be imposed by MA;
- disease awareness campaigns; and
- development of an industry-wide code of conduct.

We address each of these below but first make a number of general comments.

1. General Comments

It is not controversial that very significant public benefit flows from the Code. This was the finding of the Australian Competition Tribunal (***Tribunal***) in respect of edition 15 of the Code, and the ACCC recognises this in its Draft Determination regarding edition 16. This view was also expressed by attendees at the pre-decision conference.

In creating a voluntary industry code there is always a tension in seeking to accommodate the different interests of parties. Edition 16 of the Code incorporates industry and consumer input gathered during an extensive review process. As part of that process MA wrote to 161 organisations and received 46 submissions over an eight month period from September 2008 to April 2009.

The Code has evolved over 16 editions. It is now detailed, prescriptive and the most rigorous it has ever been. These improvements have not involved merely incremental steps. The reporting requirements imposed by the Tribunal upon the

ACCC's application on the last occasion, involved a very significant step for Members.

It is widely acknowledged that MA Members have complied with the letter and spirit of the reporting requirements in edition 15 of the Code. This has involved Members expending significant effort, time and expense to gather the information required and generate the reports. MA has worked hard to retain Members but some have expressed disquiet about these obligations in circumstances where some of their competitors are not subject to comparable burdens.

MA acknowledges the concerns that have been raised by Professor Morris and others. However, MA considers there is a real risk that if the Code is seen to move any more quickly than is occurring now, the gap between Members and non-members will widen and support for the Code through membership of MA will be threatened.

2. Reporting of Sponsored Doctors

Professor Morris contends that the Code should require MA to report the names of doctors sponsored by pharmaceutical companies to attend overseas conferences where those conferences are not held or sponsored by that company. He asks that the amount associated with their sponsorship i.e. value of registration, flights to and from the conference and conference accommodation be 'monetarised' and published.

The elements of sponsorship which Professor Morris raises - travel, accommodation, registration fees and social programs are subject to specific restrictions in the Code:

- the class of travel for sponsored doctors is restricted: section 9.7.5;
- entertainment as a component of sponsorship is prohibited: section 9.7.10;
- level of accommodation is prescribed: section 9.7.6; and
- sponsored doctors who address their peers on matters the subject of the conference are required to disclose the fact of the sponsorship: section 9.7.4.

MA considers the reporting of the names of individual doctors takes the reporting requirements too far. There are a number of significant issues associated with this step which are yet to be the subject of detailed consultation with those likely to be affected, including issues of privacy, media distortion[1] including possible targeting of individual doctors and a decline in the number of doctors attending leading international forums which address new clinical developments.

Professor Morris suggested that the fact Members do not now report such information is the result of a drafting oversight. MA disagrees. The current reporting condition was designed to address discretionary expenditure by pharmaceutical companies on hospitality provided in relation to the events held or sponsored by the company. Sponsorship of attendance at medical conferences held by third parties does not involve any discretion on the part of the Member. The registration fee and accommodation are matters determined by the third party organiser. Flights to conferences in Australia and New Zealand must be

[1] See transcript of Tribunal proceedings where Professor David Henry acknowledged the proclivity of the media to distort reported data of this nature.

economy class and long haul flights to Europe or North America must be economy or business.

The Draft Determination acknowledges that edition 16 of the Code fully incorporates the public reporting requirements stipulated by the ACCC and the Tribunal in respect of edition 15 of the Code. MA considers that the current formulation of the condition strikes the right balance between transparency through reporting and the risks associated with imposing further requirements on Members. The Code has never been more rigorous. It can only continue to be effective if MA retains a broad based membership. MA is concerned that requiring reporting of names of individual doctors is the step that will widen, to an unacceptable degree, the gap between those prepared to submit to the Code and those who are not so prepared.

3. Reporting of Speakers at Educational Events

Drs Harvey and Vitry suggest that the current educational event reporting requirements should be expanded to indicate whether the event was organised by:

(a) the company, with a company determined speaker, such as a drug representative or key opinion leader; or

(b) an independent organisation such as a Royal College who also independently selected the speakers.

They also propose that reporting indicate any benefits or remuneration received by the speaker.

In MA's view, these matters are already addressed by the Code. If an educational meeting is organised by an independent organisation, that organisation should independently determine the educational content, select the speakers and invite the attendees: section 9.5.2.

Members are required to provide a report to MA on all educational meetings and symposia held or sponsored by that company by completing the table set out at Appendix 3 of the Code: section 35.4. The table at Appendix 3 requires the company to provide a detailed description of the function. In practice this means that the nature of the event, whether the speaker was organised by the company and any payment to the speaker is usually apparent from the description. In addition, the Code of Conduct Guidelines provide examples of meeting reports which include appropriate descriptions for both company and independently organised events.

4. Reporting of Relationships with Health Consumer Organisations

Dr Vitry considers Member companies should provide a report to MA on all relationships with HCOs and all patient support programs.

The Code requires each Member to make publicly available on its website a list of HCOs to which it provides financial support and/or significant direct/indirect non-financial support: section 35.4. The list must include a description of the nature of the support and be

updated on an annual basis. These arrangements are consistent with equivalent requirements in the EU.

Dr Vitry's concerns about patient support programs appear to proceed from a false premise. Such programs are not an arrangement between a pharmaceutical company and a health consumer organisation. Patient support programs are generally provided to patients via their health professional without the involvement of a HCO.

5. Fines

Dr Harvey and Loretta Marron suggest that fines for contraventions of the Code should be increased. Edition 16 substantially increases fines for moderate, severe and repeat contraventions by 50%, 100% and 100% respectively. In addition, the Code of Conduct Committee has the power to, and does regularly, impose a range of additional sanctions, including publication of corrective notices and withdrawal of offending materials.

As Dr Bill Ketelbey from Pfizer noted in the pre-decision conference, companies take these additional sanctions very seriously. Further, sanctions imposed by MA are in addition to any action that a regulator may wish to take.

6. Disease Education Activities

Dr Vitry considers disease awareness campaigns should be prohibited unless the pharmaceutical company has no financial interest in treatment for the disease the subject of the campaign.

Australian legislation prohibits direct to consumer advertising of prescription medicines. In the United States and New Zealand there is no such prohibition. In those countries there is widespread advertising by pharmaceutical companies in a variety of media about the products they provide.

The provisions of the Code relating to disease education activities have been strengthened in edition 16 to ensure that these activities cannot circumvent the Australian prohibition on direct to consumer advertising.

In an increasingly stretched healthcare environment, disease education activities play an important role in educating consumers and encouraging them to seek medical advice. Many health problems go undetected and untreated because people do not consult their doctors, either because they do not recognise the symptoms or they are embarrassed to do so. Approaching a doctor is particularly important for conditions where early intervention is critical. Disease education activities assist consumers to recognise symptoms and to overcome perceived stigma associated with them. Important examples include depression, other mental illnesses and Alzheimer's disease. The fundamental message of these campaigns is 'talk to your doctor'. The doctor is best placed to diagnose and choose an appropriate treatment, which may or may not include prescribing a medicine.

Dr Vitry suggests that pharmaceutical companies would not engage in this activity unless they directly benefited from it. The fact there is a link between such activities and the potential for financial gain by the pharmaceutical company is an inadequate basis to call for

the prohibition of disease education activities. In MA's view there is overwhelming evidence that considerable public benefit flows from such activities particularly given the related guidance provided by the Code.

7. Application of the Code

Implicit in the calls for an industry-wide code reflecting the standards in the Code is a recognition that the Code is effective. Of course MA would like to see all participants in the prescription medicines industry comply with the standards reflected in the Code, but this issue does not go to the question whether the Code in its current form should be authorised.

Yours sincerely

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