

**Australian Competition
&
Consumer Commission**

PRE-DECISION CONFERENCE

Minutes

**Applications for revocation and substitution A91150, A91155-56
and applications for authorisation A91183-84
lodged by Medicines Australia Limited**

17 November 2009

The information and submissions contained in this minute are not intended to be a verbatim record of the pre-determination conference but a summary of the matters raised. A copy of this document will be placed on the ACCC's public register.

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Australian Competition and Consumer Commission Offices located in Brisbane, Sydney, Canberra, Adelaide and Melbourne by video conference facilities

Attendees:

Australian Competition and Consumer Commission

Peter Kell, Deputy Chair (in Canberra)

Richard Chadwick, General Manager, Adjudication Branch (in Sydney)

Joanne Palisi, Director, Adjudication Branch (in Canberra)

Monica Bourke, Senior Project Officer, Adjudication Branch (in Brisbane)

Medicines Australia Limited (in Sydney)

Mr Brendan Shaw, Acting Chief Executive

Ms Deborah Monk, Director, Innovation and Industry Policy

Ms Fiona Crosbie, Partner, Allens Arthur Robinson

Professor Philip Morris (in Brisbane)

Quintiles Pty Ltd (in Sydney)

Ms Lesley Borgo Caratti, Manager, Global Regulatory Affairs

PricewaterhouseCoopers Australia (in Sydney)

Mr Michael Daniel, Partner

Pfizer Australia (in Sydney)

Dr Bill Ketelbey, Country Medical Director

Ms Loretta Marron (in Canberra)

Generic Medicines Industry Association (in Canberra)

Ms Kate Lynch, CEO

Department of Health and Ageing (in Canberra)

Mr Adrian White, Director, Intellectual Property and Trade Policy

Ms Jenny Bartley, Assistant Director, Regulatory Policy Section

Dr Ken Harvey, Adjunct Senior Research Fellow, School of Public Health, La Trobe University (in Melbourne)

Dr Agnes Vitry, Quality Use of Medicines and Pharmacy Research Centre, University of South Australia (in Adelaide)

Conference commenced: 3 pm AEST

Deputy Chair Peter Kell welcomed attendees, made some introductory remarks outlining the purpose of the conference, declared the pre-decision conference open and invited the party that called the conference, Professor Philip Morris, to make an opening statement.

Professor Philip Morris opened by providing some information about his background within the industry. Professor Morris noted that he recognised that there can be a productive relationship between the medical profession and pharmaceutical companies provided there is adequate transparency and accountability of the gifts and benefits provided to medical professionals by pharmaceutical companies.

Professor Morris made the following comments throughout the conference:

- The monetary value of the sponsorships provided by pharmaceutical companies should be disclosed. Sponsorship is usually targeted at opinion leaders and is generally extensive, including overseas travel and accommodation, and can be up to the value of \$30 000.
- Sponsorship carries a greater influence on the behaviour of healthcare professionals compared to the receipt of various brand name reminders. Professor Morris submits public disclosure of such sponsorship should form part of the Code.
- Pharmaceutical companies should provide unrestricted and untied grants for the education of medical professionals and such educational events should be run independently of pharmaceutical companies.
- Public disclosure of the names of the recipients of sponsorship would increase transparency. Professor Morris submits that the medical profession should be made aware of any monetary ties a speaker has with a pharmaceutical company and the value of these ties. Professor Morris submits that keeping such information hidden may bring the industry into disrepute.
- Professor Morris submits that new section 9.7.4 of edition 16 of the Code supports the idea that pharmaceutical companies should disclose sponsorships of healthcare professionals when speaking at an event.

Deputy Chair Peter Kell invited Deborah Monk, on behalf of Medicines Australia, to address the conference.

Deborah Monk made the following introductory and general comments throughout the conference:

- Edition 16 of the Code was developed following extensive public consultation and is an improvement on previous versions. Medicines Australia submits that the Code results in a public benefit.
- It is important to appropriately balance the needs of various stakeholders to ensure that the Code remains robust and continues to be complied with. This is particularly challenging in the self-regulatory system to ensure that the Code continues to be accepted by members. Medicines Australia submitted that any

further reporting requirements would widen the gap in the standards of conduct required of Medicines Australia members and non-members.

- Sponsorships provided by pharmaceutical companies should not be seen as a gift to the particular healthcare professional as the sponsorship is not for personal gain. The scientific and medical program at the event is organised independently of the pharmaceutical company providing the sponsorship.
- It is Medicines Australia's experience that the value of sponsorship provided to attend a conference in North America for example is in the range of \$10,000 to \$12,000.
- Ms Monk noted that section 9.7.4 of edition 16 of the Code implies an expectation that a pharmaceutical company's sponsorship will be disclosed in certain situations, but does not go so far as to require the monetary amount of that sponsorship to be disclosed, or the individual healthcare professional to be named.
- Medicines Australia would be concerned with publishing the names of individual doctors who are either recipients of sponsorship or who attend educational events. In particular:
 - there are concerns around the privacy of doctors
 - Medicines Australia considers that educational events and conferences are important for healthcare professionals to attend. The requirement to publish the names of individual doctors might deter some from attending the event or accepting the sponsorship and therefore gaining the knowledge and experience
 - disclosing the amount of sponsorship a healthcare professional receives may be misconstrued in the media.
- Ms Monk noted that the Code 'regulates' the conduct of pharmaceutical companies and it cannot require doctors to undertake such disclosure.
- The new provisions in the Code relating to the relationship between pharmaceutical companies and Health Consumer Organisations (HCOs) provide greater transparency around this relationship and mirror the provisions of the European Federation of Pharmaceutical Industries and Associations Code (EFPIA).
- The provisions relating to disease education programs have been strengthened to clearly state what is appropriate/allowed when conducting such a program. Ms Monk noted that Australian legislation prohibits the promotion of prescription products to consumers and the Code is not able to supersede this prohibition.
- The intention of section 9.7.2 of the Code is that any person is able to request access to a pharmaceutical company's guidelines for awarding sponsorship. Further, the Code of Conduct Committee would also be able to request a copy

of the guidelines should it receive a complaint regarding sponsorship by a pharmaceutical company.

Deputy Chair Peter Kell opened the conference for discussion and invited questions in relation to the issues raised. The following attendees made comments.

Ms Loretta Marron submitted that from a consumer perspective, edition 16 of the Code results in an improvement to previous editions of the Code. Ms Marron would like Medicines Australia to consider the following points when developing the 17th edition of the Code:

- how complimentary medicines and other areas of the industry more broadly could be required to comply with the same standards of conduct as required by the Code and
- how a streamlined complaints process across the entire industry could be implemented.

Dr Ken Harvey submitted that edition 16 of the Code results in a substantial improvement in the Code. Dr Harvey made the following comments:

- The pharmaceutical industry is going through unprecedented change in terms of acceptance of the need for transparency. Dr Harvey submitted that sponsorship of healthcare professionals in terms of paying expenses to travel overseas to attend an event creates a reciprocal relationship.
- The industry would benefit from an industry wide standard of conduct.
- The level of fines remain relatively small in comparison to the income a pharmaceutical company may gain from misleading advertising and the recent fines imposed in the USA.
- Educational events should be run independently from pharmaceutical companies and the public reporting requirements in the Code should be developed further to include disclosure of any benefits/monies speakers receive.
- It would be of benefit if the costing information currently reported on Medicines Australia's website could be provided in a more user-friendly manner, such as in database format.

Dr Agnes Vitry recognised the improvements made in edition 16 of the Code however noted her support for pharmaceutical companies to fully disclose all financial gifts provided to medical professionals. Dr Vitry made the following comments:

- Sponsorship of healthcare professionals may create a reciprocal obligation on the healthcare professional with the pharmaceutical company and should be disclosed. Dr Vitry submitted that pharmaceutical companies will only sponsor a healthcare professional where they consider they will receive a return.
- The relationship between pharmaceutical companies and HCOs should be more transparent and pharmaceutical companies should be required to publicly disclose the type of support, whether financial or other, to HCOs.

- Dr Vitry considers that the new requirements in the Code relating to disease education activities legitimises such programs, and argued that such programs could be inconsistent with the provisions in legislation which prohibit direct advertising of prescription products to consumers. Dr Vitry submitted that a public panel could be established to determine whether a disease education program being run by a pharmaceutical company is a genuine campaign.

Dr Bill Ketelbey, Pfizer, submitted that disease education programs are important in terms of public health. For example, Pfizer's smoking cessation campaign does not mention a particular drug and encourages consumers to see a doctor which is a good outcome. There are many treatments available for the doctor to suggest once the consumer sees the doctor. Dr Ketelbey noted that Pfizer's programs ensure that they meet the standards set out in the Code and do not advertise a prescription product to consumers.

Dr Ketelbey noted concern about a table provided in Dr Harvey's submission recording Pfizer's previous breaches under the Code, and noted that Pfizer is committed to complying with the Code. Dr Ketelbey also noted that:

- The sanctions and public reporting of breaches in Medicines Australia's annual and quarterly reports ensure that the Code is working effectively. Specific to Pfizer's experience, Dr Ketelbey noted that in the previous 18 months Pfizer has not had any fines imposed on it and it takes breaches of the Code seriously.
- In terms of the sanctions for Code breaches, fines reflect only part of the cost to the pharmaceutical company. Companies place great weight on the public shaming which comes with a breach of the Code. Dr Ketelbey also noted that the corrective letters and corrective advertising bring the pharmaceutical company into unwanted disrepute with prescribers and are at a cost to the company involved.

Michael Daniel, PricewaterhouseCoopers, is on the Code of Conduct Committee and submitted that in his experience the Committee works well and the sanctions under edition 16 of the Code will adequately deter breaches of the Code as:

- for every breach, the alleged offending material is withdrawn
- the Committee considers whether corrective letters should be written. Mr Daniel noted that pharmaceutical companies do not like this to occur
- the level of fines have been further increased under edition 16 of the Code and
- the sanctions which the Code Committee can impose are in addition to any other action or remedy which may be carried out by an individual or a regulator.

Deputy Chair Peter Kell confirmed that no party wished to make any further comments. The Deputy Chair closed the conference by noting that parties could provide further submissions to the ACCC by Friday 20 November 2009 and that the ACCC would provide participants with a record of the conference, which would also be placed on the ACCC's public register.

Conference closed: 4.50pm EST