

Code of Conduct complaints relating to activities directed at the general public January – June 2005

The Medicines Australia Code of Conduct (Section 16.2) provides for the publication on the website of information regarding complaints that involve activities directed towards members of the general public. Section 16.2 states that this information will include the following:

- a) The name of the company against which a complaint has been lodged
- b) The name of the complainant, where appropriate
- c) The product, behaviour, conduct and/or promotional material subject to complaint
- d) A summary of the complaint, response and deliberations of the Code of Conduct Committee
- e) The section of the Code, if any, which was breached and the reasons for finding the breach
- f) Any sanctions imposed for the breach

The information shall be released following the exhaustion of all appeals procedures and the outcome of any appeal is known.

The following provides information about complaints considered by the Code of Conduct Committee between January and June 2005.

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ABA (798)

Promotion to the general public via public media

Complaint

A letter from the Australian Broadcasting Authority (ABA) had been forwarded to Medicines Australia by the Complaints Resolution Panel. The Complaints Resolution Panel had determined that the products subject to complaint did not fall within their jurisdiction and that the matter should be referred to Medicines Australia. The ABA referral was in relation to a complaint from a healthcare professional alleging that several companies were promoting their products to members of the general public via television news or current affairs. Medicines Australia had asked Roche Products Pty Ltd (Roche), Abbott Australasia Pty Ltd (Abbott) and Merck Sharp & Dohme (Australia) Pty Ltd (MSD) to respond to the complaint in relation to Sections 9.2, 9.3, 9.4 and 9.5 of the Code.

Response

Letters of response were received from Roche, Abbott and MSD stating that they did not have any editorial rights over what information was broadcast and were concerned that they were being judged on a program that had been instigated and developed by the media. Each company denied that the materials they had supplied at the request of the broadcaster were in breach of the Code of Conduct.

Committee ruling

Members of the Committee agreed that each company's response should be considered individually.

Roche

Members of the Committee commented that it was the responsibility of companies to ensure that any material provided to media outlets is not promotional and is current, accurate and balanced. This also applied to materials supplied by agencies working on behalf of pharmaceutical companies. Members commented that as a company may not always be informed of what was going to be broadcast it was critical that any information provided was of the highest standard. The Committee acknowledged that this may leave a company vulnerable, but a company must ensure that its material is written in a manner which is balanced in terms of contraindications, precautions and adverse reactions. In particular, individual case studies of personal experience with a product are less likely to be balanced.

Members also commented on the ethics of nominating patients to speak to the media. While noting Roche's response that patients contact Roche to report positive experience with the weight loss product and give permission for their names to be provided to the media, members commented that this type of testimonial may be used by the media to discuss positive outcomes from a particular treatment and if the company provided the names of the patients, a link can be formed back to the company. Members also commented that even if a company provides accurate and balanced information in a written format to a media outlet, the provision of patient names to the media who could subsequently interview these people resulting in promotion of a particular prescription medicine was cause for concern.

In reviewing the material provided by the PR agency acting for Roche to Channel 7, members of the Committee were concerned that the information in Attachment 2 "*Healthcare Professionals and Weight Loss*" was not balanced and went beyond purely educational information. Members referred to the definition of promotion in the Code of Conduct glossary:

"Promotion", "Promotional" or "Promotional claim" means any statement made by a company or company's representative, whether verbal or written, which conveys the positive attributes of a product which extend beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication for the purpose of encouraging the usage of that product. It includes statements concerning efficacy, rate of adverse reactions or other cautionary aspects of the product and comparative information.

"Promotional material" means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product.

The Committee discussed whether the provision of the package of information by the PR Company on behalf of Roche was in compliance with the Code of Conduct. Whilst the information provided was probably correct and factual, members were of the view that the information provided to Channel 7 was promotional. It was selective and not balanced by appropriate information about precautions, side effects, contraindications etc. Although the approved PI was included in the package of information, Attachment 2, "*Healthcare Professionals and Weight Loss*", was not balanced.

Section 9.2

The Committee was of the view that the material provided to Channel 7 was not a media release and therefore no breach of Section 9.2 of the Code was found.

Section 9.3

The Committee discussed at length whether the material was in breach of Section 9.3 of the Code and whether this section applied to the material supplied by Roche. The Committee acknowledged that Roche had provided the written information and patient details in response to a request from Channel 7 and Roche did not have any editorial rights over what information was broadcast. The Committee also acknowledged that it was likely that Roche had been given a short time frame in which to respond to the request for information. By a majority no breach of Section 9.3 of the Code was found

The Committee expressed a number of concerns about companies providing details of individual patients to the media and asked the Secretariat to refer this matter to the Code Review Panel for its consideration of expanding the Explanatory Notes.

Section 9.4

The Committee unanimously found a breach of Section 9.4 of the Code as the material provided to Channel 7, particularly Attachment 2, was not balanced and went beyond a simple non-qualitative or quantitative description of the therapeutic category or approved indication. These materials in combination with the provision of contact details for a case study that had positive outcomes from use of the product could be viewed as encouraging the usage of that product.

Section 9.8

The Committee unanimously found no breach of Section 9.8 of the Code.

Sanction

The Committee considered that it was the responsibility of a company to do their best to ensure that the provisions of the Code are complied with and any materials that are provided to media are balanced and not promotional. It was insufficient defence to say that a company does not know what the media will do with the material or how they will interact with the patient contacts. Members acknowledged the lengthy process that had occurred with the ABA and Complaints Resolution Panel prior to the complaint being received by Medicines Australia.

Having found a breach of the Code in relation to these materials, Roche or their agencies must not provide this information package again.

The Committee also imposed a fine of \$20,000.

Abbott

Members of the Committee commented that it was the responsibility of companies to ensure that any material provided to media outlets is not promotional and is current, accurate and balanced. This also applied to materials supplied by agencies working on behalf of pharmaceutical companies. Members commented that as a company may not always be informed of what was going to be broadcast it was critical that any information provided was of the highest standard. The Committee acknowledged that this may leave a company vulnerable, but a company must ensure that its material is written in a manner which is balanced in terms of contraindications, precautions and adverse reactions. In particular, individual case studies of personal experience with a product are less likely to be balanced.

Members also commented on the ethics of identifying patients to speak to the media.

Section 9.2

As Abbott had not provided a media release to any media outlet, no breach of Section 9.2 of the Code was found.

Section 9.3

In their response Abbott claimed that they had not initiated any contact with or provided any information to the media outlet other than the name of a general practitioner. No breach of Section 9.3 of the Code was found.

Section 9.4

In their response Abbott claimed that they had not initiated any contact with or provided any information to the media outlet other than the name of a general practitioner. No breach of Section 9.4 of the Code was found.

Section 9.8

As no breach of Sections 9.2, 9.3 or 9.4 was found the Committee found no case to answer in relation to a breach of Section 9.8 of the Code.

MSD

Members of the Committee commented that it was the responsibility of companies to ensure that any material provided to media outlets is not promotional and is current, accurate and balanced. This also applied to materials supplied by agencies working on behalf of pharmaceutical companies. Members commented that as a company may not always be informed of what was going to be broadcast it was critical that any information provided was of the highest standard. The Committee acknowledged that this may leave a company vulnerable, but a company must ensure that its material is written in a manner which is balanced in terms of contraindications, precautions and adverse reactions. In particular, individual case studies of personal experience with a product are less likely to be balanced.

Section 9.2

As MSD had not provided a media release to any media outlet no breach of Section 9.2 of the Code was found.

Section 9.3

In their response MSD claimed that they had not initiated any contact with or provided any information to the media outlet other than the animated graphics showing the method of action of Ezetrol. No breach of Section 9.3 of the Code was found.

Section 9.4

In their response MSD claimed that they had not initiated any contact with or provided any information to the media outlet other than the animated graphics showing the method of action of Ezetrol. No breach of Section 9.4 of the Code was found.

Section 9.8

As no breach of Sections 9.2, 9.3 or 9.4 was found the Committee found no case to answer in relation to a breach of Section 9.8 of the Code.