

Code of Conduct complaints relating to activities directed at the general public July – November 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 July and November 2005.

Content

Complaint	Page
Levitra (810)	1

Levitra (810)

Materials provided to healthcare professionals and members of the general public in relation to a disease awareness campaign including a list of doctors with an interest in men's health on a website

Complaint

A complaint was received from a healthcare professional alleging that Bayer Australia Limited (Bayer) was in breach of the Medicines Australia Code of Conduct. Medicines Australia had requested that Bayer respond to the complaint under Sections 1.9, 3.9, 3.9.1, 3.9.3, 9.4, 9.5, 9.7, 9.8 and the introductory paragraphs of Section 10 of the Code.

Response

A letter of response was received from Bayer denying any breach of the Code. Bayer maintained that the purpose of this program was to facilitate communication between men and their doctor and to provide educational material about erectile dysfunction to men.

Committee Ruling

Register of Healthcare Professionals

Some healthcare professional members of the Code Committee expressed concern about directing patients to specific doctors listed on a company website or via a call centre. Several considered that if a patient did not find their own GP's name on the list there may be an assumption that he/she was not interested in men's health issues and thereby a negative reflection on those doctors not listed. However, the Committee accepted that some men may choose to make an appointment with another GP rather than face the embarrassment of going to their family GP to discuss erectile dysfunction.

The healthcare professional members of the Committee regarded the Levitra program as a form of duress to have doctors' names included on the list of doctors who have an interest in men's health. Members of the Committee commented that there was no doubt that some men may benefit from accessing a GP and reading the information about erectile dysfunction however it was important that this was undertaken responsibly.

While acknowledging the healthcare professional's concerns that some patients may not disclose their complete medical and medication history to another GP, this was outside the parameters of the Code. The Committee was of the view that healthcare professionals would try to elicit a complete medical history from each patient.

In relation to an implied link through the program to a specific company and endorsement of a specific prescription medicine, Members were of the view that it is always the role of a healthcare professional to prescribe, if treatment is necessary, the most appropriate medicine for each patient. However, the "When – Now" campaign raised a possible conflict between duty of care to a patient and engagement in promotion on behalf of a company which was an issue that should be discussed with an organisation such as the AMA Ethical Standards Committee.

The question of medico-legal responsibility was also raised in regard to two matters. Firstly, if a GP received a letter addressed to a patient but disposed of the materials as they (or their Practice Manager) thought it was only more promotional material and secondly, what is the responsibility of a GP to follow up with the person who requested the information but does not make an appointment within a reasonable period of time. The Committee requested that Medicines Australia discuss this issue with the peak GP and Medical Defence organisations.

Section 1.9

As discussed previously, members of the Committee were concerned about the use of doctors' names on the website or provided via the call centre. Members also questioned whether all doctors had received an invitation to be listed as interested in men's health or only selected doctors, thereby not giving each healthcare professional access to the program. By a majority the Committee found a breach of Section 1.9 of the Code as members considered the information to healthcare professionals did not make the individual doctor aware of the full scope of the campaign or all the materials to be used in the campaign prior to a doctor enrolling. Further, Bayer did not inform doctors of the potential ethical implications of this program and possible medico-legal issues, including that there may be an implication that the identified doctors supported the marketing of Bayer's product for erectile dysfunction; and that Bayer was promoting certain doctors to members of the public.

Section 9.4

The Committee was of the view that the materials (website and performance pack) combined education with promotion. While acknowledging that there was reference to possible factors leading to erectile dysfunction, the emphasis in the information was on getting a treatment, particularly an oral medication that can be taken with alcohol.

The materials also used the terms "one step away from enjoying a spontaneous love life" and by asking for the performance pack to be sent to a doctor the consultation will be "faster and easier" which imply that all you have to do is go to the doctor and they will write a prescription. It was noted that the website stated "ensure you get the medication that meets your needs" rather than a more educative statement about talking to your doctor about your health and underlying causes of erectile dysfunction and the full range of options that may be available if there are no underlying health concerns or risks. In addition, the Committee was of the view that there should be a reminder on the website and performance pack brochure that it is important to tell the doctor about other medications the patient may be taking.

There was no information other than a reference to 'general health checks' to other types of tests such as blood tests that a doctor may consider when the patient makes an appointment – to investigate the underlying cause for the erectile dysfunction.

The Committee was concerned by the lack of balance in the information in the materials provided to a member of the general public encouraging men to ask for a prescription medicine that was a 'quick fix' to what may be more complicated health issues.

The Committee by a majority found a breach of Section 9.4 of the Code as the "when – Now" campaign encouraged a patient to seek a prescription for a specific prescription-only medicine. Whilst there was no mention of the name of a specific medicine, all of the activities provided connections directing to a specific medicine – emphasis on the treatment being a tablet, that works quickly (as Levitra is promoted to the doctor), that can be taken with alcohol (which is bolded in the brochure). In addition the materials were not balanced and went directly to encourage a 'quick fix' solution.

Section 3.9 and 3.9.1

For the reasons outlined in relation to Section 9.4 above, that the information provided was not balanced and did not refer to addressing possible underlying causes for erectile dysfunction but rather went directly to discussing treatment with a medication "that meets your needs", the Committee by a majority found a breach of Sections 3.9 and 3.9.1 of the Code.

Section 3.9.3

The Committee was of the view that this section did not apply.

Section 9.5

The Committee considered that Sections 9.5.1 and 9.5.5 were applicable to this complaint rather than all provisions within the Section.

For the reasons outlined in relation to Section 9.4, above in relation to the lack of balance of the information and that the information was intended to encourage a patient to ask their doctor to prescribe a product; the Committee unanimously found a breach of Section 9.5.1 and 9.5.5 of the Code.

Section 9.7

The Committee was of the view that this section did not apply.

Section 9.8

The Committee did not agree that this material or campaign would bring discredit upon the industry and found no breach of section 9.8 of the Code.

Section 10

The Committee considered that this program would not successfully withstand public and professional scrutiny or conform to professional and community standards of ethics and good taste. In addition the Committee was of the view that the material did not enhance the quality use of medicines as the material implied a 'quick fix' medication option was available without considering all other aspects of a patient's lifestyle and health. The Committee unanimously found a breach of Section 10 of the Code.

Sanction

Having found a breach of the Code, the Committee considered an appropriate sanction.

The Committee resolved that Bayer should take immediate action for the prompt withdrawal of the material found in breach (the website and patient brochure) and should permit no further appearance of it in its current form.

The Committee was of the view that there was no potential for patient harm but resolved that a corrective letter should be sent by Bayer to all doctors on the register of doctors interested in men's health and who had received the invitation to join the program, advising them of the breaches found in relation to the materials forming part of the "When – Now" campaign.

The Committee considered whether a fine should also be imposed but resolved not to do so.

In addition, Medicines Australia should write to the AMA, ADGP, RACGP and Medical Defense Union to seek their advice on this type of activity to enlist doctors to identify themselves as having an interest in a particular field and the implications from an ethical and medico-legal perspective.