

Code of Conduct complaints relating to activities directed at the general public July 2008

The Medicines Australia Code of Conduct (Section 16.3) provides for the publication on the website of information regarding complaints that involve activities directed towards members of the general public. Section 16.3 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.

- 870 AstraZeneca Heartburn Campaign
- 947 Cialis Media Release
- 948 Cialis Media Release

Two complaints (Cialis 947 and 948) were in relation to the same media release. The three complaints have been reviewed by the Code of Conduct Committee.

AstraZeneca Heartburn Campaign (870)

Subject Company: AstraZeneca

Complainant: CHOICE

Product: N/A

Complaint

The complainant stated that information about 'heartburn' available to the general public encouraged consumers to visit the

AstraZeneca website www.heartburn.com.au.

While the website does not name a drug it does mention several classes of drugs for heartburn which can only be prescribed by a doctor, including H2-receptor antagonists and proton pump inhibitors as well as antacids. The complainant maintained that this was a form of direct to consumer advertising and therefore in breach of the Code.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 9.4 Promotion to the general public

Response

AstraZeneca denied that the information available to the general public was encouraging a patient to seek a specific prescription only medicine. The website did not name a prescription medicine and mentioned several classes of drug for heartburn which can be prescribed by a doctor. AstraZeneca asserted that the website contained a large amount of helpful information about heartburn, its management and treatment as well as links to helpful websites such as the Gastroenterological Society of Australia's website.

Code Committee determination

In a unanimous decision the Code Committee found no breach of Section 9.4 of the Code.

Consideration of the complaint

The Committee noted that Section 9.4 states: *Prescription products may be promoted only to healthcare professionals. Any information provided to members of the general public must be educational. Any activity directed towards the general public which encourages a patient to seek a prescription for a specific prescription-only medicine is prohibited.*

It was also noted that the Code requires pharmaceutical companies to identify within disease state awareness material (both electronic and print) that the information is prepared by an identified company. It would be considered to be misleading if a company did not make this information available to a reader or viewer.

The Committee reviewed the information available on the www.heartburn.com.au website which was referred to on the poster that gave rise to the complaint. Members were of the view that the information on the website was informative and balanced. It was noted that the site included information on lifestyle issues and dietary tips before any reference to medications and recommended that readers discuss their condition with their doctor, which was appropriate. Members were also of the view that it is legitimate to make reference to all the therapeutic classes, both non- prescription and prescription, which are used to treat the condition. The website did not include the name of any particular medicine and did not compare or recommend any specific treatment.

The Committee was of the view that a patient would not link this website with any specific medicine. If a patient asked their doctor for the medicine that is supplied by AstraZeneca as the provider of the website, it would be the role of the healthcare professional to firstly assess whether the patient did have reflux, secondly whether they required any medication and if this was considered necessary which treatment was most appropriate for the particular patient.

Healthcare professional members of the Committee noted that there is a hierarchical treatment approach for reflux patients which were discussed appropriately in the materials.

The Committee did caution that it may not be possible for a pharmaceutical company to conduct a disease awareness campaign where there was only one available treatment for the medical condition where the campaign's message was to recommend to readers to 'talk to your doctor' or 'ask your doctor' as this could lead to a patient effectively asking for a prescription for a specific medicine.

In a unanimous decision the Committee found no breach of Section 9.4 of the Code in relation to the 'heartburn' information supplied by AstraZeneca.

Cialis Media Release (947) & (948)

Cialis Media Release 947

Subject Company: Eli Lilly Australia (ELA)

Complainant: Dr Ken Harvey

Product: Cialis

Complaint

The complainant stated that the press release issued by the subject company on 29 April 2008 was not bona fide 'news' but rather was promotion of a prescription medication to the general public. Dr Harvey also alleged that within this press release, ELA had quoted a health professional without revealing his association with the company.

The complainant was of the view that this conduct undermined Quality Use of Medicines activities, breached several sections of the Code and ultimately brought disrepute to the industry.

Sections of the Code

Media releases alleged to be in breach of the following Sections of the Code:

- 9.2 Product Specific Media Statements
- 9.4 Promotion to the General Public
- 10.8 Discredit to and reduction of confidence in the Industry

Cialis Media Release 948

Subject Company: Eli Lilly Australia (ELA)

Complainant: CHOICE

Product: Cialis

Complaint

The Complainant alleged that the media release issued by ELA on 29 April 2008, which had been presented as news, was not genuine news and did not educate the public about the use of the medicine. CHOICE asserted that the media release was intended to promote the medicine to the general public. CHOICE also asserted that, by highlighting the potential increase in the spontaneity and regularity of sex, this media release was intended to encourage consumers to seek a prescription for the medicine.

Sections of the Code

Materials alleged to be in breach of the following Sections of the Code:

- 9.2 Product Specific Media Statements
- 9.3 General Media Articles
- 9.4 Promotion to the General Public

Response

Eli Lilly Australia (ELA) responded that the media release was within the guidelines of the Code, providing factual and educational content to the consumer, which in no way brings discredit to the pharmaceutical industry. ELA stated that the product, 'Cialis Once-a-day' was defined as new, and as such, was announced to the press in accordance with Section 9.2.1 of the Code.

ELA noted that healthcare professionals including GPs, pharmacists and specialists had been advised about the product's availability prior to the media statement being released. ELA maintained it has stayed within the parameters defined by the Code of Conduct, and asserted that the complaints raised were without merit.

Code of Conduct Committee decision

In a unanimous decision the Committee found a breach of Sections 9.2 and 9.4 of the Code and no breach of Sections 9.3 or 10.8 of the Code.

Complaints 947 and 948 were considered together and only one sanction was applied.

Sanction

In a majority decision ELA shall

- withdraw the media release from all websites or other media within its control
- pay a fine of \$60,000.

Consideration of the complaint

The Committee raised a number of issues in relation to the national Galaxy poll referred to in the media release:

- The survey was commissioned by Eli Lilly and therefore there was the possibility that the survey could be seen as biased;

- no information on the survey was provided for example survey design, methodology and analysis. Further this information was not released in response to an enquiry by one Committee member. Therefore it was not possible on the evidence available to critically review whether the survey was adequate to support the claims made in the media release; and
- the survey results were timed for release with the announcement of the availability of Cialis once-a-day.

Members did not disagree with Eli Lilly that it is permissible to distribute a media release to announce a new product or indication. However members were of the view that the media release was promotional through the inclusion of the survey results and other statements about the positive attributes of the product. The Code permits a media release which may only be educational and not designed to promote particular treatments to the general public. The media release subject to complaint whilst announcing the approval of a new product included overtly positive statements about the benefits of a once-a-day treatment such as 'exciting news', 'important new option for men with ED' and 'a new option with 24/7 coverage will be most welcome as it will make them feel more like they did before they got the condition'.

Several healthcare professional members of the Committee commented that erectile dysfunction is an area where there is lots of embarrassment and it is a positive step to encourage men to talk to their doctor. Some general practitioners were concerned that they had not been aware of the new once-a-day treatment until patients came into their surgery after the stories had been run in the media. Members also noted that the media release did not make any reference to dosage precautions, especially cardiovascular risk factors, and did not include the most common side effect to the medicine which is headaches. It was also noted that the reference to the contraindication of using Cialis with nitrates would probably not be well understood by the media and therefore should be more clearly explained in any media statements, including the names of relevant medicines.

The Committee was of the view that the language used in the media release and reference to the survey were promotional and unanimously found a breach of Sections 9.2 and 9.4 of the Code. The Committee unanimously did not find a breach of Section 9.3 because although ELA had distributed a media release the company had not directly initiated a media article. Although members considered this to be a moderate breach it unanimously did not find a breach of Section 10.8 of the Code.

Whilst not relevant to, or taken into account when making its decision, the Committee noted that the statement on the second page of the media release 'Cialis is most appropriate for men who anticipate sexual activity at least twice a week and who have responded to the on-demand treatment regime' was referenced to the Cialis Product Information, however the PI did not reflect this statement. The approved indication is for the treatment of erectile dysfunction in adult males.

Sanction

Having found two breaches of the Code the Committee considered what sanction/s should be imposed.

In a majority decision the Committee determined that Eli Lilly Australia should withdraw the media release from all websites or other media within its control and pay a fine of \$60,000. There were some members who considered the fine should be higher and one member who was of the view that the fine should have been lower.

The Committee noted that it was not appropriate for corrective advertising to be undertaken as this would provide Eli Lilly with another opportunity to discuss the product with the general public.