

VOLUNTARY ADMISSION BY LILLY

Articles in the lay press

Lilly advised the Authority that a freelance journalist whom it had sponsored to attend the European Society of Sexual Medicine (ESSM) Conference in December 2005, had written two articles about Cialis (tadalafil) in the lay press. An article in *Take a Break* magazine, March 2006, referred to Lilly's erectile dysfunction (ED) disease awareness campaign and also included a pack shot of Cialis. The second article, which appeared in the June 2006 edition of *Choice* magazine, also referred to Cialis and included a patient's history with regard to erectile dysfunction. Both articles featured quotations from a doctor. The Authority's Constitution and Procedure required the Director to treat a voluntary submission as a complaint if, *inter alia*, it related to a potentially serious breach of the Code.

The possible promotion of a prescription only medicine to the public was regarded as a serious matter and the Director thus decided that Lilly's voluntary admission must accordingly be treated as a complaint.

The Panel noted that the two articles discussed ED, its causes and treatment. The article in *Take a Break* focussed on the condition in younger men, the other featured a more detailed discussion of ED and Cialis trial data with particular emphasis on a continuous daily dosing regime which was currently strongly discouraged as the long-term side effects after prolonged use had yet to be studied. The article in *Choice* magazine specifically referred to the proceedings at ESSM.

The Panel noted that Lilly had invited the journalist to and sponsored her attendance at ESSM in December 2005. The itinerary provided to the journalist by Lilly described presentations about ED and general issues in sexual medicine as optional but the Lilly ICOS symposium 'ED and Beyond – Lessons to Learn from the Past for the Future' as compulsory. The symposium included a podium session on the unlicensed dosage regimen of Cialis once daily everyday. The media interview with the doctor (who was later quoted in the two articles) was listed as a compulsory event. The Panel noted that Lilly had arranged the interview at the journalist's request although she had run the interview. Whilst the Panel noted Lilly's submission that neither it nor its affiliates or PR agency had provided any material to the journalist, the company had, nonetheless, made attendance at the Cialis symposium compulsory. The Panel considered that irrespective of whether Lilly had provided any material to the journalist it should have satisfied itself that the content of the Lilly symposium was appropriate for the journalist in

relation to the Code. The Panel noted that the company had amended its SOPs to ensure that all such meetings held outside the UK would be certified.

The Panel noted that the journalist had contacted the doctor she had interviewed at the conference some time later with more questions about ED. Lilly had given the doctor general media advice. The conference had taken place in December 2005 and the first of the articles in question was published in March 2006.

The Panel considered that there was no evidence that Lilly had provided any information or material to the journalist which was inconsistent with the Code and accordingly ruled no breach of the Code. The Panel noted that Lilly had arranged for the journalist to attend a clinical symposium at which Cialis would be discussed; there was particular focus on the use of continuous once daily treatment. The article in *Choice* magazine had specifically referred to proceedings at ESSM. The Panel could not understand why Lilly had arranged for the journalist's attendance at ESSM, insisted that she attend the company sponsored symposium and then asked her not to write about it. On balance the Panel considered that Lilly had provided the journalist with information that would encourage patients to ask their doctor to prescribe Cialis. A breach of the Code was ruled.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2.

COMPLAINT

Lilly advised the Authority that a freelance journalist whom it had sponsored to attend the European Society of Sexual Medicine (ESSM) Conference in December 2005, had written two articles about Cialis (tadalafil) in the lay press. The first article appeared in *Take a Break* magazine March 2006 and referred to www.lovelifematters.co.uk, Lilly's erectile dysfunction (ED) disease awareness campaign and also included a pack shot of Cialis. The second article which appeared in the June 2006 edition of *Choice* magazine also referred to Cialis and included a patient's history with regard to ED. Both articles featured quotations from a doctor.

The Authority's Constitution and Procedure stated that the Director should treat a voluntary admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take action to address it.

The possible promotion of a prescription only medicine to the public was regarded as a serious matter and the Director thus decided that Lilly's voluntary admission must accordingly be treated as a complaint.

When writing to Lilly, the Authority asked it to respond in relation to Clauses 2, 20.1 and 20.2 of the Code.

RESPONSE

Lilly explained that it did not request, mandate or pay the journalist to write either article and had not approved their content. Once the company knew about these articles it asked the journalist not to write further articles about Cialis based on the information she had gathered at ESSM.

In line with the Code, Lilly had updated its standard operating procedures (SOPs) and now medically approved all meetings organised for or attended by journalists to ensure that they complied with Clause 19; furthermore all such meetings were certified, if held outside the UK. In future, and where appropriate, consumer journalists would be invited to attend only Lilly certified meetings.

The unapproved articles written by the journalist fell outside the controls set by Lilly's SOPs but the company considered that its more robust approval process would prevent the likelihood of a similar circumstance arising. Lilly regretted that this very unfortunate incident occurred and reiterated its commitment to adhere to both the spirit and tenets of the Code.

Lilly explained that during November 2005 its public relations (PR) agency verbally invited the journalist, at Lilly's request, to attend the ESSM and provided her with a proposed itinerary. No material (including the symposium booklet) or press pack was provided to the journalist in connection with her sponsorship or attendance at the conference by Lilly UK or its overseas affiliates. Neither Lilly nor its agency gave the journalist a packshot of Cialis. It was Lilly's standard practice not to give consumer journalists pack shots of any of its medicines.

The patient featured in one of the articles was not known to Lilly or its PR agency. The patient details and statements by the doctor referred to in the articles were not made available to journalists at the conference. The journalist interviewed the doctor at the conference. The meeting was set up by Lilly, at the journalist's request, and was run by the journalist. The doctor was not briefed or paid by Lilly for the interview.

Some time after the conference, the doctor informed Lilly that the journalist had asked him some follow-up questions to the interview conducted at the ESSM. Lilly had not arranged or facilitated this further contact. The journalist told the doctor that she was

writing articles about ED and he was concerned about her line of questioning which involved the connection between consumption of alcohol and erectile dysfunction. Lilly advised the doctor on how to handle such questions.

Lilly noted, however, that although there was one reference to Cialis and Viagra in the journalist's questions to the doctor, this question related to prevalence of ED and that the journalist told the doctor that she was writing articles on ED. The assistance offered to the doctor by Lilly concentrated on how to effectively deal with questions from the media and did not pertain to Cialis. Lilly did not believe or suspect that the articles were anything other than general disease articles, specifically because the journalist told the doctor that she was writing articles about ED and her questions to him related to ED in general. Moreover, in helping the doctor respond to the journalist's questions, Lilly did not refer to Cialis or include any Cialis messages but suggested responses relevant to the disease.

In respect of Clause 20.1 of the Code, Lilly accepted that it would have been good practice (although not stipulated by the Code) to tell the journalist about the provisions of the Code and to request that any articles that she might have wanted to write in the consumer press should either have been about ED as a disease (and not specifically about any treatment), or only have been allowed if approved by Lilly. Lilly furthermore accepted that arrangements for the journalist's attendance at ESSM should have been more closely controlled so that she understood Lilly's commitments under the Code. Lilly therefore accepted that it had failed to ensure that prescription only medicines were not advertised to the general public.

In respect of Clause 20.2 of the Code, Lilly did not accept that any of its actions in respect of the journalist's attendance at ESSM contravened this clause, as the information presented to the public was in the journalist's control and Lilly did not request, mandate or pay her for either article, nor did Lilly approve either article. Lilly, in helping the doctor to respond to the journalist's questions, clearly concentrated on ED as a disease and did not directly or indirectly provide the journalist with information on Cialis that could be interpreted as factually incorrect or unbalanced or as raising unfounded hopes or as statements that would encourage the public to ask for a specific medicine. The Code allowed information on diseases and non-promotional information on prescription only medicines to be provided to the general public and this was what Lilly anticipated it was doing when it helped the doctor to respond to the journalist's questions. Lilly could only be responsible for the information actually (directly or indirectly) provided to the journalist (ie at ESSM, which was a medical meeting of high standing, and in helping the doctor to respond to the journalist's questions, which all related to ED as a disease) and should not be held responsible for the actual content of the published articles.

In respect of Clause 2 of the Code, Lilly did not accept that any of its actions in respect of the journalist's attendance at ESSM contravened this clause. A ruling

of a breach of Clause 2 of the Code should be reserved for cases which required a sign of particular censure and Lilly believed that its actions in this case should not attract such censure. Lilly had supported the journalist (by way of travel and accommodation sponsorship) to attend ESSM. Lilly did not request, mandate or pay the journalist to write either article and had not approved their content. Once Lilly knew about these articles it asked the journalist not to write further articles about Cialis based on the information gathered due to her presence at ESSM. Prior to the articles being printed Lilly was under the impression that the journalist would be writing articles on ED, ie the disease of ED, and had helped the doctor to respond to her queries with general information about ED as a disease, which was acceptable under the Code. As a result of these articles being published, Lilly had further strengthened its SOPs to ensure that in future and where appropriate, consumer journalists would be invited to attend only Lilly certified meetings. Lilly therefore maintained that its actions had not brought discredit upon or reduced confidence in the pharmaceutical industry.

PANEL RULING

The Panel noted that the articles entitled 'Not tonight, darling' (Take a Break magazine) and 'New techniques in medicine. A new lease of love life for men' (Choice magazine) discussed ED, its causes and treatment. The article in Take a Break focussed on the condition in younger men, the other featured a more detailed discussion of ED and Cialis trial data with particular emphasis on a continuous daily dosing regime which was currently strongly discouraged as the long-term side effects after prolonged use had yet to be studied. The article in Choice magazine specifically referred to the proceedings at ESSM.

The Panel noted that complaints about articles in the press were judged on the information provided by the pharmaceutical company or its agent to the journalist and not on the content of the article itself. Clause 20.1 prohibited the advertising of prescription only medicines to the general public. Clause 20.2 permitted information to be supplied directly or indirectly to the general public but such information had to be factual and provided in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their doctor to prescribe a specific medicine.

The Panel noted that Lilly had invited the journalist to and sponsored her attendance at ESSM in December 2005 and provided her with a proposed itinerary.

Whilst the itinerary described presentations about ED

and general issues in sexual medicine as optional, the Lilly ICOS symposium 'ED and Beyond – Lessons to Learn from the Past for the Future' was compulsory. This included a podium session on the unlicensed dosage regimen of Cialis once daily everyday. The media interview with the doctor (who was later quoted in the two articles) was listed as a compulsory event. The Panel noted that Lilly had arranged the interview at the journalist's request although she had run the interview. Whilst the Panel noted Lilly's submission that neither it nor its affiliates or PR agency had provided any material, including a press pack to the journalist, Lilly had nonetheless made attendance at the Cialis symposium compulsory. The Panel considered that irrespective of whether Lilly had provided any material to the journalist it should nonetheless have satisfied itself that the content of the Lilly symposium was appropriate for the journalist in relation to the Code. The Panel noted that the company had amended its SOPs to ensure that all such meetings held outside the UK would be certified.

The Panel noted that the journalist had contacted the doctor she had interviewed at the conference some time later with more questions about ED. Lilly had given the doctor general media advice. The conference had taken place in December 2005 and the first of the articles in question was published in March 2006.

The Panel considered that there was no evidence that Lilly had provided any information or material to the journalist which was inconsistent with Clause 20.1 of the Code and accordingly ruled no breach of that clause. With regard to Clause 20.2 of the Code, the Panel noted that Lilly had arranged for the journalist to attend a clinical symposium at which Cialis would be discussed; there was particular focus on the use of continuous once daily treatment. The article in Choice magazine had specifically referred to proceedings at ESSM. The Panel could not understand why Lilly had arranged for the journalist's attendance at ESSM, insisted that she attend the company sponsored symposium and then asked her not to write about it. On balance the Panel considered that Lilly had provided the journalist with information that would encourage patients to ask their doctor to prescribe Cialis. A breach of Clause 20.2 of the Code was ruled.

The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used to indicate particular censure and was reserved for such circumstances.

Proceedings commenced 21 September 2006

Case completed

21 November 2006