**CASE AUTH/1852/6/06** *NO BREACH OF THE CODE*

# GENERAL PRACTITIONER v PFIZER

## Alleged disguised promotion of Lipitor

**A general practitioner alleged that Pfizer's electronic response, which appeared in the BMJ's 'Rapid Responses', was disguised promotion of Lipitor (atorvastatin). Pfizer's response had been prompted by an editorial in the BMJ entitled 'Switching statins'. The subtitle of the editorial read 'Using generic simvastatin as first line could save £2bn over five years in England'.**

**The complainant stated that, as far as he knew, BMJ 'Rapid Responses' were not 'peer reviewed' and as such any information provided by a pharmaceutical company in support of its products could be said to be promotional. Given that the response referred to atorvastatin and made claims in support of it, surely it required prescribing information and advice about the need to report adverse events? Also this forum was not restricted to health professionals and was open to the public.**

**The complainant did not consider that the response constituted a genuine medical information letter from Pfizer's medical information department to a specific enquiry regarding the issue of switching.**

**The Panel noted that the term promotion in the Code did not include replies made in response to individual enquiries from members of the health professions or appropriate administrative staff or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature.**

**The Panel did not consider that Pfizer's response to the editorial was promotional in nature; it provided information on Lipitor in a scientific, factual style. The response did not go beyond the topic of switching statins and included reasons as to why Pfizer disagreed with the proposal to change all patients taking 10mg and 20mg of atorvastatin to 40mg simvastatin.**

**The response was signed by Pfizer's medical director and would be read in that context. There was no allegation that Pfizer's response was misleading or inaccurate. The Panel considered that the response met the requirements of the Code. The response was not disguised promotion nor was it promotion that required prescribing information or a reference to reporting adverse events as alleged. Thus the Panel ruled no breach of the Code.**

A general practitioner complained about the response from the medical director of Pfizer Limited to an editorial in the BMJ on 10 June entitled 'Switching statins' (Moon and Bogle 2006). The subtitle of the editorial read 'Using generic simvastatin as first line could save £2bn over five years in England'.

### COMPLAINT

The complainant stated that, as far as he knew, the BMJ's 'Rapid Responses' were not 'peer reviewed' in any strict sense and as such any information provided by a pharmaceutical company in support of its products could be said to be a promotional activity. Given that this article referred to atorvastatin (Pfizer's product Lipitor) and made claims in support of it surely it required prescribing information and advice about the need to report adverse events? Also this forum was not restricted to health professionals and was open to the public and any other interested parties such as consumer journalists.

The complainant did not consider that Pfizer's response constituted a genuine medical information letter from the company's medical information department to a specific enquiry regarding the particular issue of switching. Indeed if this was of concern, Pfizer's medical director could have issued a 'Dear Doctor' letter as had often been done in the recent past or indeed subjected the views expressed in the response to the rigours of a formal peer review process. This was disguised promotion of Lipitor albeit not a 'blatant advertisement' which was prohibited by the BMJ's Rapid Responses guidelines. Surely if this was allowed, without the necessary requirements laid out in the Code for all promotional materials, what was there to advise the unsuspecting reader of what was in fact a genuine peer-to-peer discourse and simple promotion in the guise of an electronic blog?

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 4.1, 4.10 and 10.1 of the Code.

### RESPONSE

Pfizer noted that the complainant accused it of disguised promotion in sending a fully referenced

scientifically balanced response to correct the errors of fact in the BMJ's editorial. Pfizer strongly disagreed with the suggestion that the response was promotional.

The Code definition of promotion (Clause 1.2) specifically excluded 'replies made in response to … specific communications from them [health professionals] , including letters published in professional journals, but only if they relate solely to the subject matter of the letter of enquiry, are accurate and do not mislead and are not promotional in nature'. There seemed to be no difference in principle between responding to a letter and responding to an article.

The complainant's suggestion that this was not a medical information letter in response to an enquiry was correct in that there was no such enquiry, however the lack of an enquiry did not render the rebuttal of scientific error any the less important or appropriate. A medical information letter would not have been the appropriate manner in which to respond. Medical information letters were issued in response to a specific request or enquiry by a health professional and were therefore particular to that enquiry.

If a health professional requested information about switching from atorvastatin to simvastatin or *vice versa*, or to clarify the literature misquoted by Moon and Bogle, Pfizer's response would be likely to draw on the same references used to support the BMJ response.

The complainant seemed to misunderstand the basis of the letters page of the BMJ. Neither this, nor any other journal letters page was peer reviewed in the same way as original articles. The editor of the BMJ selected, and sometimes also edited letters for publication in the journal's letters page. The journal required that all letters submitted were first posted to its website and publication in the printed journal was by selection from letters posted there.

Pfizer submitted its response to correct the misrepresentation of the literature on statins (not just atorvastatin) by Moon and Bogle. The response was scientifically balanced, and correctly reported the literature it quoted. Clauses 4.1, 4.10 and 10.1 did not apply. Promotional material requirements such as adverse event reporting statements and prescribing information were therefore not applicable.

The complainant suggested that a 'Dear Doctor letter' should have been sent, but also misunderstood the purpose of such a communication. A 'Dear Doctor letter' was issued by a marketing authorisation holder, following approval of the content by the Medicines and Healthcare products Regulatory Agency (MHRA), to communicate something specific about the safety profile of a medicine. The editorial by Moon and Bogle was not concerned with safety information on atorvastatin.

To deal with the complaint of open access to the webpage a discussion took place with the BMJ. It was clear that the BMJ regarded the rapid responses webpage as part of the journal and not separate from it. The BMJ had not had any other complaint about a pharmaceutical company scientific response submitted to the journal. The BMJ positively welcomed Pfizer's response, and did not regard it as promotional; had this been the case it would not have been selected for publication in the paper journal. The BMJ's view was that the response, like others from the scientific staff in industry, encouraged appropriate debate on items of scientific interest and it would invite the authors of the original article to respond to Pfizer's response. Fulfilling the requirement for total transparency on the potential conflict of interest as an industry employee, the journal saw this as welcome input to an important dialogue that it wished to encourage.

In summary, Pfizer disagreed with the suggestion that its response was promotional, and regretted that a health professional should apparently aim to stifle a legitimate response from senior medical staff of a company. The response sought to correct the erroneous representation of the published literature on a whole class of medicines, not just Lipitor.

It would seem to be quite strange if anyone could make whatever erroneous remarks they chose about any medicine as long as they were outside the industry, and the scientific and medical response from the industry were then to be disallowed. Pfizer hoped the Authority would therefore agree that submitting its response to the BMJ was an appropriate element of scientific debate and was not promotional.

**PANEL RULING**

The Panel noted that Clause 1.2 stated that the term promotion did not include replies made in response to individual enquiries from members of the health professions or appropriate administrative staff or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they related solely to the subject matter of the letter or enquiry, were accurate and did not mislead and were not promotional in nature.

The Panel did not consider that Pfizer's response to Moon and Bogle's editorial 'Switching statins' was promotional in nature; it provided information on Pfizer's product Lipitor in a scientific, factual style. The response did not go beyond the topic of switching statins and included reasons as to why Pfizer disagreed with Moon and Bogle's proposal to change all patients taking 10mg and 20mg of atorvastatin to 40mg simvastatin.

The response was signed by Pfizer's medical director and would be read in that context. There was no allegation that Pfizer's response was misleading or inaccurate. The Panel considered that the response met the requirements of Clause 1.2 of the Code. The response was not disguised promotion nor was it promotion that required prescribing information or a reference to reporting adverse events as alleged. Thus the Panel ruled no breach of Clauses 4.1, 4.10 and 10.1 of the Code.

**Complaint received** **26 June 2006**

**Case completed** **21 August 2006**