

DOCTOR v BOEHRINGER INGELHEIM

Journal 'Special Report'

A doctor complained about a four page supplement, 'Preventing Stroke Special Report; "Action or crisis"' which was 'paid for and sponsored by Boehringer Ingelheim' and appeared in the Health Service Journal, 3 June 2010. The complainant noted that supplementary information to the Code stated that 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter'. The complainant alleged that the supplement did resemble independent editorial matter in that, *inter alia*, the colour scheme, typeface, graphics, spacing, and number of columns were the same as those in the rest of the journal. The complainant alleged a breach of the Code.

The detailed response from Boehringer Ingelheim is give below.

The Panel noted that the article in question was not presented as a supplement. It was presented as a special report and each page included a tab 'Special Report'. The heading to the article 'Preventing Stroke' was followed by the Boehringer Ingelheim logo. Details of the editors and designers were followed by 'This article is paid for and sponsored by Boehringer Ingelheim. Boehringer Ingelheim have had no editorial input into this article'; this statement was repeated at the very end of the article.

In the Panel's view the first matter to be decided was whether or not the article was promotional. The Panel noted that the letter from the Health Service Journal to Boehringer Ingelheim stated that the special reports were not for the purpose of product promotion. It appeared that the article had been initiated by the Health Service Journal. Boehringer Ingelheim had not influenced the content of the article other than to check it for factual accuracy. The article referred to stroke prevention including the use of anticoagulants for people with recognised atrial fibrillation.

The Panel considered that given its content, and Boehringer Ingelheim's role in the arrangements, the article could not be considered promotional. As the article was not promotional it could not be disguised promotion and thus no breach of the Code was ruled.

Upon appeal by the complainant, the Appeal Board considered that the material raised the awareness of the disease area and heightened Boehringer Ingelheim's profile but did not promote its medicines. In that regard it was not promotional and so could not be disguised promotion. The Panel's ruling of no breach of the Code was upheld.

A doctor complained about a four page stroke supplement, 'Preventing Stroke Special Report; "Action or crisis"' that appeared in the Health Service Journal, 3 June 2010.

COMPLAINT

The complainant noted that the supplement was 'paid for and sponsored by Boehringer Ingelheim'. The complainant noted that the supplementary information to Clause 12.1 of the Code stated that 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter'. The complainant alleged that the supplement did resemble independent editorial matter because the colour scheme, typeface, graphics, spacing, justification, design of the text boxes, font size, call-outs, photograph captions, and number of columns were the same as those in the rest of the journal. The complainant alleged a breach of Clause 12.1.

RESPONSE

Boehringer Ingelheim explained that the article was not in a separate supplement of the Health Service Journal, but a special report in the main journal itself. This was not a promotional piece but an independent, educational editorial by the Health Service Journal. Boehringer Ingelheim provided financial support only towards the publication of this article and had no control of content, other than to check for factual inaccuracies. Sponsorship of this special report was not for the purpose of promotion of any product. The declaration of the sponsorship was mentioned at the outset of the article (page 23) and on page 26 of the Health Service Journal.

Boehringer Ingelheim submitted that the Health Service Journal published these educational reports on stroke prevention in atrial fibrillation because the NHS was very interested in this area via the NHS Heart and Stroke Improvement programme with its recent reports on Commissioning for Stroke: Prevention in Primary Care – The Role of Atrial Fibrillation. As Boehringer Ingelheim had undertaken research in this area, it offered the company an opportunity to support these special reports.

The detailed process for these special reports as agreed with and set out by the Health Service Journal was as follows:

'Grants and sponsorship to support Special Reports in the Health Service Journal are used

for:

- Health Service Journal to commission journalists to write the articles and interview chosen individuals
- Health Service Journal to source all illustrations
- Health Service Journal to clear copy with sponsor for factual corrections only
- Health Service Journal to layout and design the special reports.

Boehringer Ingelheim will have no editorial input or control of content, other than for checking for factual inaccuracies. Sponsorship of these Special Reports is not for the purpose of promotion of any product, and full disclosure of sponsorship to support the publication of these Special Reports will be clearly visible.'

Boehringer Ingelheim believed that the material and clarification it had provided clearly complied with the relevant requirements of the Code and did not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code. Therefore, it denied a breach of Clause 12.1.

PANEL RULING

The Panel noted that the article in question was not presented as a supplement. It was presented as a special report and each page included a tab 'Special Report'. The heading to the article 'Preventing Stroke' was followed by the Boehringer Ingelheim logo. Details of the editors and designers were followed by 'This article is paid for and sponsored by Boehringer Ingelheim. Boehringer Ingelheim have had no editorial input into this article'; this statement was repeated at the very end of the article.

In the Panel's view the first matter to be decided was whether or not the article was promotional. The Panel noted that the letter from the Health Service Journal to Boehringer Ingelheim stated that the special reports were not for the purpose of product promotion. It appeared that the article had been initiated by the Health Service Journal. Boehringer Ingelheim had not influenced the content of the article other than to check it for factual accuracy. The article referred to stroke prevention including the use of anticoagulants for people with recognised atrial fibrillation.

The Panel considered that given the content of the article and Boehringer Ingelheim's role in the arrangements, in that it had no involvement other than providing the sponsorship and checking for factual accuracy, the article in question could not be considered promotional. The article did not promote the prescription, supply, sale or administration of Boehringer Ingelheim's medicines. As the article was not promotional it could not be disguised promotion and thus no breach of Clause 12.1 was ruled.

APPEAL BY THE COMPLAINANT

The complainant noted that in Cases AUTH/2287/12/09 and AUTH/2288/12/09, the Appeal Board ruled a breach of Clause 12.1. The complainant alleged that the material facts were identical in both cases and that therefore the current case must also be ruled in breach of Clause 12.1.

The complainant noted that in both cases a pharmaceutical company paid for an article to appear as a supplement in the Health Service Journal (Boehringer Ingelheim submitted that the article it sponsored was not a supplement, but the front cover of the Health Service Journal described it as a 'Preventing stroke and cutting costs supplement'). In neither case had the pharmaceutical companies any stated input into the article other than to check it for factual accuracy and fund its production. In both cases the article was developed for educational purposes only and did not offer any overt commercial advantage to the pharmaceutical companies in question. Nevertheless both articles were clearly promotional because the pharmaceutical company paid for the publication of an article on a topic for which it had funded research, thereby leading to increased awareness amongst readers about that clinical condition relative to other clinical conditions and therefore increased awareness of treatments which the pharmaceutical company either already marketed or was researching.

The complainant noted that in both cases, the special report appeared as inside pages in the Health Service Journal. Although clear declarations of sponsorship were included at the beginning and end of both articles, readers flicking through the journal, often from back to front, might read one of the inside pages of the supplement without first seeing the declarations of sponsorship. In both cases the editorial style of the supplement was extremely similar if not identical to the standard editorial text of the journal, in that they shared a very similar or identical page layout, typeface, font, font size, colour scheme, number of columns, text boxes, call-outs and so on.

The supplementary information to Clause 12.1 of the Code stated that, 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter'. The complainant alleged that in both cases, the fact that the text had been sponsored by a pharmaceutical company was disguised to the reader and therefore both cases were in breach of Clause 12.1.

COMMENTS FROM BOEHRINGER INGELHEIM

Boehringer Ingelheim submitted that it had funded the special report after the Health Service Journal had sought financial support (as an unrestricted educational grant) to publish three four page special reports on stroke prevention in atrial fibrillation.

These reports were to focus on the current issues surrounding stroke prevention in atrial fibrillation in terms of cost, commissioning, risk factors and future proofing. Atrial fibrillation was of significant interest to the NHS following the recent reports on Commissioning for Stroke: Prevention in Primary Care – the Role of Atrial Fibrillation.

Boehringer Ingelheim submitted that it had not influenced the educational content of the article other than to check it for factual accuracy.

Boehringer Ingelheim noted that the complainant referred to Cases AUTH/2287/12/09 and AUTH/2288/12/09, however the material facts of that case were very different to the present case. Unlike the previous case, the material now at issue was not a promotional supplement but an independently written educational editorial ('special report') initiated by the Health Service Journal not by Boehringer Ingelheim. In the previous case, the two companies found in breach made a voluntary admission that their supplement should have appeared as a separate piece from the journal.

Boehringer Ingelheim refuted the complainant's allegation that the article was clearly promotional because a pharmaceutical company paid for the publication of an article on a topic for which it had funded research, thereby leading to increased awareness of treatments which the pharmaceutical company either already marketed or was researching. Although the article discussed current treatments (and the benefits thereof), there was no reference to potential future treatments for stroke prevention in atrial fibrillation. Further, the inference that discussion of a disease area would automatically lead to increased awareness of treatments a pharmaceutical company was researching was not substantiable. Equally the article did not promote the prescription, supply, sale, or administration of a medicine and therefore, by definition, was not promotional.

Boehringer Ingelheim noted that the Code did not preclude pharmaceutical companies funding educational, non-promotional articles in journals such as the Health Service Journal. The complainant also alleged that the editorial style of the supplement was extremely similar if not identical to the standard editorial text of the journal and later quoted the supplementary information for Clause 12.1 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter'. As already stated this was an independently written educational 'special report' initiated by the Health Service Journal; Boehringer Ingelheim's only involvement was to check it for factual accuracy. Therefore, as it was not a 'paid-for' supplement the editorial style of the article was similar to the standard editorial text of the Health Service Journal and appeared as pages 23-26 of the journal. However, it was clearly stated that the article was paid for and sponsored by Boehringer Ingelheim

and clearly marked 'Special Report' on pages 23, 25 and 26 of the journal.

Boehringer Ingelheim submitted that it had demonstrated that without doubt the Panel's ruling of no breach of Clause 12.1 was correct, and it strongly refuted the complainant's allegation of disguised promotion.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant alleged that the question of whether the journal first approached the pharmaceutical company, or vice versa did not alter the ultimate fact that Boehringer Ingelheim funded the supplement in question.

Nobody questioned the fact that atrial fibrillation (and rheumatoid arthritis - the topic of the supplement considered in Cases AUTH/2287/12/09 and AUTH/2288/12/09) was of significant interest to the NHS. The respondents in the previous case likewise had not influenced the educational content of their article other than to check it for factual accuracy.

The complainant noted that although Boehringer Ingelheim claimed that the material facts of Cases AUTH/2287/12/09 and AUTH/2288/12/09 were very different from the current case it offered no evidence to demonstrate how this was so. Both cases involved independently written, educational pieces. Whether or not the journal first approached the pharmaceutical company, or the pharmaceutical company first approached the journal, did not affect the nature of the material that appeared in print. Nor did the fact that the respondents in the previous case admitted culpability, whereas Boehringer Ingelheim chose to contest the complaint, affect the material facts of the cases. The rheumatology supplement likewise discussed current treatments (and the benefits thereof) but no potential future treatments were named.

The complainant noted that Boehringer Ingelheim had not stated why his claim that the publication of an article on a topic for which it had funded research would lead to increased awareness amongst readers about that clinical condition relative to other clinical conditions and therefore increased awareness of treatments which the pharmaceutical company either already marketed or was researching, could not be substantiated. There was a wealth of evidence that reading about a disease increased interest in treatments and potential treatments eg the references listed in the notes section in Moynihan and Cassels (2005), 'Selling Sickness: How the Worlds Biggest Pharmaceutical Companies Are Turning Us All Into Patients'.

Nobody doubted that the Code allowed the pharmaceutical industry to fund educational articles in journals such as the Health Service Journal. The crucial point was that such articles must not resemble independent editorial material, and that

the funding must not be disguised from the reader. The complainant alleged that a reader thumbing through the journal and opening the middle page spread (pages 24-25) would have no way of knowing that this was anything other than independent editorial material, and that the article was funded by a pharmaceutical company. The complainant noted that contrary to Boehringer Ingelheim's claim, there was no indication on pages 24 and 25 (the middle pages of the supplement) that the article was paid for and sponsored by the company or that this was anything other than independent editorial content.

The complainant noted that Boehringer Ingelheim did not question his assertion that the editorial style of the supplement was extremely similar, if not identical, to the standard editorial text of the journal.

The complainant noted that Boehringer Ingelheim stated that it paid for the supplement, but that it was not a 'paid-for' supplement. This was patently absurd.

The complainant alleged that he had established that Boehringer Ingelheim paid for the publication of an article in the Health Service Journal that closely resembled independent editorial matter in clear breach of Clause 12.1.

APPEAL BOARD RULING

The Appeal Board noted that Clause 12.1 required that *promotional* material and activities must not be disguised (emphasis added). The Appeal Board considered that it had first to decide whether the material at issue was promotional and in that regard it noted that Clause 1.2 of the Code defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines. The Appeal Board disagreed with the complainant's assertion that disease awareness material sponsored by pharmaceutical companies with a commercial or research interest in the therapy area was, ipso facto, promotional.

The Appeal Board noted that the article in question was referred to on the front cover of the Health Service Journal as 'Preventing stroke and cutting costs supplement'. Inside, however, the article was clearly presented as an integral part of the journal (pages 23-26). Pages 23, 25 and 26 included a tab labelled 'Special Report'. The heading to the article 'Preventing Stroke', was followed by the Boehringer Ingelheim logo. Details of the editors and designers were followed by the statement 'This article is paid for and sponsored by Boehringer Ingelheim. Boehringer Ingelheim have had no editorial input into this article'. That statement also appeared at the very end of the article.

The complainant referred to Cases AUTH/2287/12/09 and AUTH/2288/12/09, in which the Appeal Board had previously ruled a breach of Clause 12.1, and alleged that the material facts were identical to the current case. However, the Appeal Board noted that in the previous case the respondents had acknowledged that the 12 page supplement at issue was promotional; it had included on its back cover an advertisement for a medicine which they co-promoted and the companies had had full editorial control. The material now at issue, however, did not include an advertisement for any medicine. Anticoagulation with warfarin or aspirin was referred to in general terms only. Boehringer Ingelheim did not have editorial control other than checking for factual accuracy.

In the Appeal Board's view, the material raised the awareness of the disease area and heightened Boehringer Ingelheim's profile but did not promote Boehringer Ingelheim's specific medicines. In that regard it was not promotional as defined by Clause 1.2. Thus it could not be disguised promotion and so the Appeal Board upheld the Panel's ruling of no breach of Clause 12.1. The appeal was thus unsuccessful.

Complaint received	9 June 2010
Case completed	8 September 2010
