CASE AUTH/2514/6/12

VOLUNTARY ADMISSION BY BAXTER

Failure to certify an advertisement

Baxter voluntarily admitted that an advertisement for FEIBA (Factor VIII inhibitor bypassing agent) had been published in the UK version of the international journal, Haemophilia, prior to certification.

The detailed response from Baxter is given below.

The Panel noted that the advertisement at issue was published in the March 2012 edition of Haemophilia, ie before it was certified in April 2012. A breach of the Code was ruled as acknowledged by Baxter. The Panel noted that a draft advertisement had been submitted to the publisher prior to certification and considered that this could lead to problems if the submitted draft differed from the final approved advertisement. The Panel queried whether providing a draft advertisement was in effect issuing it as set out in the Code. The Panel considered that failing to certify prior to publication meant that high standards had not been maintained. A breach 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 a sign of particular censure and reserved for such use. No breach of that clause was ruled.

Baxter Healthcare Limited made a voluntary admission to the Authority about an advertisement for its medicine FEIBA (Factor VIII inhibitor bypassing agent) published in the UK version of the international journal Haemophilia. FEIBA was indicated for the treatment of spontaneous or surgical bleeding in haemophilia and for prophylaxis in haemophiliacs with frequent joint bleeding.

COMPLAINT

Baxter submitted that earlier in 2012 it had reserved marketing space in Haemophilia for FEIBA following the publication of an important study.

In late January the publisher asked for draft artwork to allow it to begin typesetting and Baxter's agency supplied this. Baxter stated that the agency email made it very clear that this was a draft copy only and was not to be printed without written confirmation of approval from the agency or Baxter. Three days later the agency told the publishers that the copy was approved and that it could be released for publication which was not so; the advertisement was not finally approved by signatories until April.

Baxter submitted that as a draft copy was published prior to certification this was in breach of Clause 14.1.

Baxter stated that to prevent this from happening again it had reminded its marketing teams that the only acceptable evidence of material being released for use was the Code of Practice certificate complete with appropriate signatures. It was this and only this that should be supplied to agencies or publishers in order to release material.

When writing to Baxter the Authority asked it to respond in relation to the requirements of Clauses 9.1 and 2 as well as Clause 14.1 cited above.

RESPONSE

Baxter submitted that it had been a challenge to retrieve all correspondence in relation to this case; as its corporate email system automatically deleted messages after 90 days a number of emails were no longer available. While some communication was by email some took place by telephone and Baxter had to therefore rely on the memories of the individuals involved.

Baxter stated that concurrent with the review of the UK advertisement, its global team had paid for and created a separate FEIBA advertisement for the same journal. There were two versions of Haemophilia, for UK and international circulation. As the number of pages dedicated to one medicine in any issue of a journal was strictly limited by the Code, Baxter had insisted that the global advertisement should appear only in the international version of the journal. In addition the global advertisement would require UK approval as Haemophilia was a UK journal. This was agreed with the Baxter global team and its draft advertisement was submitted for review and approved, in accordance with UK policy, in late December 2011.

Baxter submitted that it was unable to definitively state why the agency informed the publisher that the advertisement at issue was approved. In Baxter's view, although it was difficult to provide evidence to support it, the issue arose due to human error and confusion around the submission of the two advertisements for the same medicine for different versions of the same journal with different areas of circulation.

Baxter stated that when it became aware of the error in early April 2012, key personnel were on leave and so it took until the middle of May for members of the medical team to investigate and establish exactly what happened; the team recommended that the company make a voluntary admission regarding a breach of Clause 14.1.

Baxter submitted that guidance to the marketing team referred to earlier had, to date, been verbal but it would be communicated in writing shortly.

Baxter considered that it was clear from its willingness to make this error public, and the

emphasis that it put on local approval of materials such as this by its European and global teams, that it was committed to high standards in all its activities. By acting in this way Baxter considered that it had upheld the reputation of, and increased confidence in, the pharmaceutical industry. The company denied a breach of Clauses 9.1 and 2.

PANEL RULING

The Panel noted that emails provided by Baxter appeared to show that the advertisement at issue was published in the March 2012 edition of Haemophilia, ie before it was certified in April 2012. A breach of Clause 14.1 was ruled as acknowledged by Baxter. The Panel considered that submitting a draft advertisement to the publisher prior to certification could lead to problems if the submitted draft differed from the final approved advertisement. The Panel queried whether providing a draft advertisement was in effect issuing it as set out in Clause 14.1 of the Code. Taking all the circumstances into account the Panel considered that failing to certify prior to publication meant that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that although it first knew of the error in early April, it took Baxter until the middle of May to establish what had happened. The Panel noted that Baxter's investigation had not been helped by key personnel being on leave. The Panel further noted that in its response to the Authority in July, Baxter had submitted that although it had verbally reminded marketing teams that material could only be released with a Code of Practice certificate complete with appropriate signatures, no written guidance had yet been issued. In the Panel's view Baxter should have acted more quickly and decisively to ensure that its own staff and those of its agency had no doubt as to the correct procedures regarding the approval and certification of advertisements and their subsequent release for publication.

The Panel noted its comments above, however, it did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use. No breach of that clause was ruled.

Complaint received **13 June 2012**

Case completed **30 July 2012**