

# VOLUNTARY ADMISSION BY ROCHE

## Failure to certify an advertisement

Roche voluntarily admitted that due to a misunderstanding of its certification procedure, an advertisement for Avastin (bevacizumab) was published in the BMJ before it had been fully certified.

The detailed response from Roche is given below.

The Authority's Constitution and Procedure provided that a voluntary admission should be treated as a complaint if it related to a serious breach of the Code. Failure to certify was a serious matter and the Director decided to take the matter up as a complaint.

The Panel noted that the advertisement had been published prior to certification. A breach of the Code was ruled as acknowledged by Roche. The Panel considered that the failure to certify prior to publication meant that high standards had not been maintained. A breach of the Code was ruled. The Panel noted that once it knew of the error Roche had taken action both with the individual concerned and more widely with the marketing teams as a whole, to ensure that journal advertisements were not published before final certification.

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.

Roche Products Limited voluntarily admitted that a journal advertisement for Avastin (bevacizumab) (AVAB00055a) had not been certified before publication.

Paragraph 5.4 of the Authority's Constitution and Procedure provided that a voluntary admission should be treated as a complaint if it related to a serious breach of the Code. Failure to certify was a serious matter and the Director decided to take the matter up as a complaint.

### COMPLAINT

Roche noted an error in final certification of a journal advertisement which had appeared in the BMJ throughout September. The advertisement was not finally certified prior to publication because a single employee misunderstood the process.

A line manager identified the error when she was asked to sign the job bag containing the published advertisement. The manager explained to the individual concerned that in the case of a journal

advertisement a colour pdf of the proof sent to the printers, including cutter guide and exact dimensions, and not the actual final journal, should be finally certified. The journal itself should then be placed in the job bag once published.

The individual, who returned from a leave of absence earlier in 2009, had since received full ABPI standard operating procedure (SOP) training, thought that the final article itself, ie the journal, needed to be certified, as was the case with other promotional items. The identified training need had been addressed by means of the manager's explanation and the individual was now fully aware of the process. The advertisement had been finally certified, and the certification form and the file note added to the job bag.

Roche submitted that the matter was reported to the compliance team and to the head of medical affairs as soon as it was discovered. The company apologised for the error.

The Authority asked Roche to provide it with any further comments that the company might have in relation to Clauses 2, 9.1 and 14.1 of the Code.

### RESPONSE

Roche repeated its explanation above and stated that it did not believe that the misunderstanding identified was widespread. Nonetheless a marketing manager presented the case at a recent marketing team meeting to highlight this issue. Additionally, the medical director had emailed all of the marketing teams detailing the correct process. There were plans to develop a journal advertising guideline in conjunction with Roche's advertising and media buying agencies and these along with the message from the medical director would further ensure that this would not occur again.

Roche accepted that there was a breach of Clause 14.1 and expressed its regret. Immediate action was taken, and subsequent insertions of the advertisement were certified ahead of use with no amendments required. The advertisement was therefore certifiable in the form in which it appeared, having been through several prior rounds of approval.

Roche took adherence to the Code and maintenance of high standards very seriously, however in this instance it did not consider that high standards had not been maintained, and thus submitted that a breach of Clause 9.1 should not be ruled. The advertisement in question complied with the Code as detailed above – the issue was a failure to finally

certify. The issue, once identified, was rectified immediately through certification, and was brought to the Authority's attention in a timely manner.

Although Roche appreciated the critical importance of finally certifying items as detailed under Clause 14.1, it strongly believed that this particular case did not deserve the particular censure of a breach of Clause 2. Failure to certify, in this case, neither discredited nor reduced confidence in the pharmaceutical industry. As detailed above, following a rigorous review process prior to final certification, the advertisement was appropriate and complied with the Code. As soon as the issue was identified the advertisement was certified and no amendments were made.

#### **PANEL RULING**

The Panel noted that the advertisement had been published prior to certification. A breach of Clause

14.1 was ruled as acknowledged by Roche. The Panel considered that the failure 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 once it knew of the error Roche had taken action both with the individual concerned and more widely with the marketing teams as a whole, to ensure that journal advertisements were not published before final certification.

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.

**Complaint received**      **2 October 2009**

**Case completed**        **4 November 2009**

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