

CASE AUTH/2098/2/08

VOLUNTARY ADMISSION BY ROCHE

Promotion of Herceptin and Avastin to the public

As a result of inter-company dialogue, Roche voluntarily admitted that it had promoted prescription only medicines to the public in that a one page article which it placed in the 2007 edition of In The Pink magazine referred to Herceptin (trastuzumab) and Avastin (bevacizumab). The article faced a one page corporate advertisement for Roche oncology.

In The Pink magazine was an annual consumer publication available in September/October to support Breast Cancer Awareness Month.

The Constitution and Procedure provided that the Director should treat a voluntary admission as a complaint if, inter alia, it related to a potentially serious breach of the Code. Advertising prescription only medicines to the public was regarded as a serious matter and the admission was accordingly treated as a complaint.

The Panel noted that in January 2007 Roche had been offered a chance to buy space for an advertisement and an article by the In The Pink editor. The Panel considered that at the outset these should have been seen by Roche as a single corporate package; instead the company viewed the two components as individual items which could be dealt with separately under the Code. In the Panel's view this initial failure to recognise that the article was paid-for space for which Roche would be responsible under the Code, together with the lack of formality and clear written agreements at the outset, led to the errors which occurred. An internal Roche email dated 30 January described the process. The advertisement was required by August and the article copy was required by July and '...we get to input and influence this (basically we can put an overview forward of key areas we'd like them to consider covering) and sign off on final copy'. An email from Roche to the publishers dated 31 January asked for confirmation of the exact process around the article. It did not appear that this point had been answered other than that the editor would be in touch soon regarding the article but in the meantime press releases could be forwarded to the editor. In August the magazine editor asked for press releases so as to decide what to cover in the article.

Roche sent the breast portfolio and relevant press releases on Avastin, Bondronat and Xeloda. This email stated that the article and advertisement were commissioned by Roche. In September Roche provided a number of press releases and backgrounders and asked to see the article before it went to print if this were possible. Roche submitted that it did not see the final article.

Of the two pages that were published in the In The Pink magazine, one simply stated 'Roche oncology working together to fight cancer'. This was the corporate advertisement submitted by Roche and had the company logo in the top right hand corner. The facing page was headed 'Pioneering an era of unprecedented benefit for women with breast cancer'. The Roche company logo appeared at the end of the heading. The article referred to Herceptin and Avastin as a new generation of medicines which transformed the outlook for women with breast cancer. It went on to discuss the positive effects of Herceptin and Avastin including on progression free survival which it described as unprecedented.

The Panel considered that the second page was an advertisement for Herceptin and Avastin, prescription only medicines. It was not an independent article; Roche had paid for the space and provided the information. Although the article had been written by a third party, Roche was nonetheless responsible for it. A breach of the Code was ruled. It thus followed that the advertisement also contained statements which would encourage members of the public to ask their health professionals to prescribe a specific prescription only medicine. A further breach was ruled.

The Panel considered that the generation of the advertisement demonstrated a lack of control and poor knowledge of the requirements of the Code. High standards had not been maintained. A breach was ruled. The Panel considered that companies should take particular care when producing material for the public. Roche had failed to exercise due diligence. On balance the Panel considered the conduct of company employees was such that they had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Roche Products Limited voluntarily admitted that a one page article which it placed in the 2007 edition of In The Pink magazine promoted Herceptin (trastuzumab) and Avastin (bevacizumab), both prescription only medicines, to the public. The article was next to a one page corporate advertisement for Roche oncology. Together the advertisement and the article formed a double page spread.

In The Pink magazine was an annual consumer publication with a potential circulation of about 75,000. The 2007 edition was available for six weeks over September and October to support Breast Cancer Awareness Month, and could be purchased in supermarkets and newsagents. Correspondence between Roche and the publisher outlining distribution and intended audience was provided.

COMPLAINT

Roche stated that as a result of a complaint from GlaxoSmithKline UK Limited about an advertisement and article in the 2007 edition of *In The Pink* it now voluntarily admitted of a breach of Clause 20 of the Code, with regard to promotion to the public.

Roche stated that regrettably, communication between it and the publishing company was not completely effective and as a result the article contained some promotional messages to the public. A copy of the article was provided.

Roche fully supported the Code and although unintentional and factually correct the article was clearly a breach of the Code and thus it decided to bring it to the Authority's attention.

The Constitution and Procedure provided 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 appropriate action to address the matter. Advertising prescription only medicines to the public was regarded as a serious matter and the admission was accordingly treated as a complaint.

When writing to Roche, the company was asked to respond in relation to Clauses 2, 9.1, 20.1 and 20.2.

RESPONSE

Roche did not contest breaches of Clauses 2, 9.1, 20.1 and 20.2.

Roche had undertaken a thorough investigation into the activities and communications leading up to the publication of the article. To allow a transparent view of these events Roche provided details of all events in chronological order and summarised them as follows:

Details of the article's production;

- The publishers approached Roche on 23 January 2007 regarding, a full page advertisement and article package.
- Roche agreed the funding on the understanding that the advertisement would be a corporate one and include no product branding. Roche requested approval of the article in correspondence with the publisher at this stage. However no formal agreement for Roche approval was written into the agreement.

Roche noted that the corporate advertisement in the magazine complied with the Code and was certified in accordance with Clause 14.3. However, although the article was requested for approval when the project was set up, the lead individual was on sick leave when it was developed, so final approval was not sought.

- Payment for the package was sent in March 2007 upon receipt of an invoice from the publisher.

- No further action was taken until August.
- The lead individual on the article and main contact with the publisher was on unexpected sick leave when the publisher requested Roche's latest press releases relating to breast cancer upon which to base the article. At this point the project was managed by people who had no prior knowledge of the nature of the article and the fact that it was a paid-for article.
- Certified press releases (provided) for Roche oncology products licensed for use in breast cancer were sent to the publication upon request.

The provision of the press releases occurred in two emails, offering a spectrum of information on all Roche breast cancer products. The second batch contained a 'targeted therapies' backgrounder which appeared to have formed the basis for the majority of the final article.

Roche submitted that the publisher then produced the article. Regrettably, due to a lack of continuity in the management of this project and no robust process to approve both advertisement and article together, the article was not requested for full copy approval and was incorrectly treated as responding to an independent article request, rather than a paid-for article.

Action already taken;

- When it realised the error Roche undertook an in-depth investigation to identify the events that might have led to this occurring.
- Roche also immediately contacted the publishing company to ensure that no unsold copies of the magazine were still in circulation (gaining written confirmation that all copies had been destroyed) and that no further copies could be made available to the public.

Compounding circumstances;

Roche submitted that its investigation showed no deliberate intent to breach the Code and promote to the public. Therefore, although Roche did not contest breaches of Clauses 2, 9.1, 20.1 and 20.2, it was important to explain the circumstances that led to the breach.

- Internal process training

Roche submitted that the training at Roche when the project was undertaken did not sufficiently highlight the need for a formal contract to ensure full copy approval of paid-for articles. Therefore, although copy review was initially requested by Roche this was not chased or requested in a formal manner as it should have been.

- Inconsistent project management

Unfortunately the Roche lead on this article was unexpectedly off sick in late August for two weeks

and in late September for around ten days. Therefore the press releases provided to the publisher were sent by people who did not know about the original agreement, or that the article had been paid for. However, an informal request to review the article was made again at this stage.

- Approval process

Roche submitted that it currently had two separate processes for the approval of marketing led activities (such as advertisements) and PR activities. Had there been a system to approve the corporate advertisement and the article together as one item this error might have been averted. With the future compliance development plan this was being addressed as a priority.

- Agreement, payment, set up and delivery of package

Roche submitted that the item was agreed with the publisher in January 2007 and paid for in March 2007 but nothing more happened until August 2007 when the advertisement and press releases were requested. This time delay, combined with the lead Roche contact being on sick leave, contributed to the series of events.

Roche fully understood that the above circumstances did not mitigate the breaches of the Code however it took this issue very seriously. A detailed overhaul of the company's standard operation procedures had been initiated to ensure that it had ongoing robust processes to ensure full compliance with the Code. These improvements would significantly reduce the risk of such incidents happening again in the future. Furthermore, as part of its ongoing partnership with the ABPI Roche was implementing a comprehensive compliance programme (provided).

PANEL RULING

The Panel noted that Roche had been offered an advertisement and an article by the In The Pink editor. An email from the publisher dated 23 January referred to the Roche brand fitting perfectly with the magazine which was described as a glossy annual magazine dedicated to Breast Cancer Awareness Month. The email made it clear that Roche was being offered the chance to buy space for an advertisement and an article. The Panel considered that at the outset the advertisement and article should have been seen by Roche as a single corporate package; instead the company viewed the two components as individual items which could be dealt with separately under the Code. In the Panel's view this initial failure to recognise that the article was paid-for space for which Roche would be responsible under the Code, together with the lack of formality and clear written agreements at the outset, led to the errors which occurred. In that regard the Panel did not accept that the passage of time and the change of personnel had contributed to the series of events. An internal Roche email dated 30 January described the process. The advertisement was required by August and the article copy was required by July and '...we get to input and influence this (basically we

can put an overview forward of key areas we'd like them to consider covering) and sign off on final copy'. An email from Roche to the publishers dated 31 January asked for confirmation of the exact process around the article. It did not appear that this point had been answered other than that the editor would be in touch soon regarding the article but in the meantime press releases could be forwarded to the editor. In August the magazine editor asked for press releases for the article page so that the editor could decide what to cover in the article.

Roche decided to send the breast portfolio and relevant press releases on Avastin, Bondronat and Xeloda. This email stated that the article and advertisement were commissioned by Roche. In September Roche provided a number of press releases and backgrounders and asked to see the article before it went to print if this were possible. Roche submitted that it did not see the final article.

The Panel examined the two pages that were published in the In The Pink magazine. One simply stated 'Roche oncology working together to fight cancer'. This was the corporate advertisement submitted by Roche and had the company logo in the top right hand corner. The facing page was headed 'Pioneering an era of unprecedented benefit for women with breast cancer'. The Roche company logo appeared at the end of the heading. The article referred to Herceptin and Avastin as a new generation of medicines which transformed the outlook for women with breast cancer. It went on to discuss the positive effects of Herceptin and Avastin including on progression free survival which it described as unprecedented.

The Panel considered that the second page was an advertisement for Herceptin and Avastin, prescription only medicines. It was not an independent article; Roche had paid for the space and provided the information. Although the article had been written by a third party, Roche was nonetheless responsible for it. A breach of Clause 20.1 was ruled. It thus followed, that the advertisement also contained statements which would encourage members of the public to ask their health professionals to prescribe a specific prescription only medicine. A breach of Clause 20.2 was ruled.

The Panel considered that the generation of the advertisement demonstrated a lack of control and poor knowledge of the requirements of the Code. High standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel considered that companies should take particular care when producing material for the public. Roche had failed to exercise due diligence. On balance the Panel considered the conduct of company employees was such that they had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received	19 February 2008
Case completed	20 March 2008