MEMBER OF THE PUBLIC V ROCHE

Newspaper article about Avastin

An anonymous, contactable member of the public complained about an article entitled 'Young cancer patient forced to pay £2,000 a week for treatment drugs – after NHS refuses' which appeared in the Daily Mirror newspaper and in the Mirror online. The article referred to Avastin (bevacizumab) which was marketed by Roche and indicated in combination for the treatment of certain cancers. The complainant submitted that he/she was technically whistleblowing but had to do so anonymously because of fear of internal recriminations.

The complainant stated that it was clear that the article had been company-inspired and placed in the newspaper by Roche's agents. The article was extremely well informed and referred to highly technical issues such as the National Institute for Health and Care Excellence (NICE), overseas use of Avastin and clinical data. The story focused on the use of Avastin to treat a brain tumour when the medicine was not licensed for such use. The complainant stated that this was a very serious breach of the Code as it was off-label promotion of a medicine and to a lay audience. The article inferred that the medicine extended and improved quality of life when there was no data to prove this.

The complainant stated that he/she knew that the article was promoted by Roche through its public relations agents. The complainant alleged that Roche and its agents contacted the journalists concerned after getting a tip about the patient from the sales force. The complainant stated that the content of the article was agreed by Roche; any suggestion to the contrary would be revealed as false by the paper trail with Roche, its agent and the Daily Mirror.

The detailed response from Roche is given below.

The Panel noted that the complainant had provided little information and no documentation to support his/her complaint despite reference to a paper trail between Roche and its agents. A request for further information had gone unanswered. As with any complaint, the complainant had to prove his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The parties' accounts differed. The complainant alleged that Roche was involved with the newspaper story; Roche denied that this was so. The company was aware of the story in a local newspaper before it received the enquiry from the journalist. Although the company had interacted with the journalist, it had stated in writing that Avastin was not licensed in the UK for the treatment of brain tumours and in response to a query had verbally told him/her that the medicine was so

licensed in Japan. The company submitted that it had not tipped the newspaper off about the patient at issue. Roche provided written statements from its agents each stating that they had not been involved in the generation of the story.

The Panel considered that on the basis of the evidence provided by the parties, the complainant had not proven that, on the balance of probabilities, Roche or its agents had instigated or placed the newspaper article as alleged. No breaches of the Code were ruled including Clause 2.

An anonymous but contactable member of the public complained about an article entitled 'Young cancer patient forced to pay £2,000 a week for treatment drugs – after NHS refuses' which appeared in the Daily Mirror newspaper and in the Mirror online. The medicine which the patient had to fund was Avastin (bevacizumab) marketed by Roche Products Limited. Avastin was indicated, in combination with another therapy, for the treatment of certain cancers.

COMPLAINT

The complainant stated that it was clear that the article had been company-inspired and alleged that it breached the Code in several important ways and was placed in the newspaper by Roche's agents. The article was extremely well informed and included references to highly technical issues such as the National Institute for Health and Care Excellence (NICE), overseas use of Avastin and clinical data.

The complainant stated that because of his/her job (and he/she could not disclose this for fear of dismissal), he/she knew that the article was promoted by Roche through its public relations agents and that this was in breach, *inter alia*, of the Code. The complainant submitted that he/she was technically whistleblowing but had to do so anonymously because of fear of internal recriminations such was the climate of fear in the organisation.

The complainant alleged that the article fundamentally breached the Code in that:

- 1 Roche and its agents initiated the article by contacting the journalists concerned after getting a tip about this patient from the sales force. There would be records of these discussions that must be disclosed. The contents of the article and the specifics below were agreed by Roche and its agents with the journalists so any suggestion from Roche that this was nothing to do with it would be revealed as false by the paper trail with Roche, its agents and the Daily Mirror.
- 2 The article was in mainstream media and this was deliberately selected by Roche's agent at its request. Under the Code the pharmaceutical

company was responsible regardless of who pursued the activity.

- 3 The article promoted a brand name of a medicine to non-prescribers.
- 4 The story focused on the use of Avastin to treat a brain tumour when the medicine was not licensed for such use. This was off-label promotion of a medicine and to a lay audience.
- 5 The article inferred that the medicine extended and improved quality of life when there was no data to prove this.
- 6 The article referred to use in other countries without any explanation.

The complainant stated that he/she was very worried about the ethical behaviour of the company he/she worked for.

In response to a request for further information, the complainant did not reply.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 9.1, 23.1 and 23.2 of the Code.

RESPONSE

Roche explained that Avastin was licensed for the treatment of numerous advanced solid tumour cancers; it was, however, not licensed in the European Union (EU) for glioblastoma (GBM) and it was completely counter to Roche UK's strategy to promote Avastin for GBM or any other unlicensed indication.

Roche's named public affairs agency provided crossportfolio advice and supported Roche with respect to healthcare policy. The public affairs agency was not retained by Roche to provide any public relations or public affairs activities in respect of Avastin or any other specific Roche product. Specifically, Roche did not instruct the agency to act on its behalf in respect of the newspaper article in question.

Roche's named marketing and public relations agency provided support for the Avastin brand to the public relations team. Specifically, Roche did not instruct this agency to act on its behalf in relation to placing the Daily Mirror article, although it did instruct it to help prepare the reactive statement referred to below.

Roche explained that its global media relations team received an enquiry on Monday, 28 July, from a journalist, who stated that he/she was preparing a national story about a man with an inoperable brain tumour. Roche was asked to 'send across a statement asap (within the next few hours) detailing countries where Avastin is used as a treatment for this form of cancer and more details on the drug. Any details on successful trials of treatment as well as any reaction to this case'. Roche outlined the timeline of associated event:

On 17 July 2014, Roche was notified by a media monitoring company that a story had appeared

in a local newspaper about a named individual, whose family was fundraising to support his treatment. Avastin was mentioned within the article.

On 28 July 2014, a media enquiry was received by Roche global media relations team (in Basel, Switzerland) and passed to the UK public relations team. Roche initiated the creation of a written reactive statement to the story in conjunction with its marketing and public relations agency. Roche did not instruct its public affairs agency in relation to this response. The reactive statement was raised and reviewed within Roche's approval system. Roche telephoned the journalist and asked for clarification as to whether the patient had GBM. The journalist responded that he did. Roche responded verbally and stated that Avastin was not licensed for GBM. In response to the journalist's query regarding where Avastin was licensed in other countries for GBM, Roche stated that Avastin was licensed for GBM in Japan. Later that day the online version of the story was published.

On 29 July 2014, the Daily Mirror published the story in print.

On 31 July 2014, the reactive statement was signed-off by two final signatories in line with Roche's standard operating procedures.

Roche submitted that healthcare compliance and human resources led an internal investigation; they interviewed appropriate Roche UK head office, field medical staff and field sales staff, searched Roche's customer relationship management (CRM) systems for applicable entries by both field medical staff and field sales staff, reviewed emails sent/received by relevant field, marketing and communications staff and reviewed information provided by medical information in response to enquiries. This very thorough investigation, including the review of several thousand emails, failed to find anything to suggest that anyone at Roche contacted the Daily Mirror directly or indirectly (other than the reactive contact with the journalist referred to above), or provided any form of tip about the patient.

Roche also interviewed both its public affairs and marketing and public relations agencies. Both confirmed that they had had no involvement in the story and that they were not instructed by Roche to place the story.

Roche noted that it had also contacted the Daily Mirror which responded that its policy was to not reveal its sources for any article it published.

In conclusion, Roche submitted that its thorough investigation had found no evidence to support the complainant's allegations that Roche facilitated the interview with the patient in any way or that it was involved with the placement of the article in the Daily Mirror. Roche denied breaches of Clauses 2, 9.1, 23.1 and 23.2.

In response to a request for more information, Roche confirmed that its global team had had no involvement with either the journalist or with the enquiry other than its handling of the initial enquiry as stated above.

PANEL RULING

The Panel noted that the complainant had provided little information and no documentation to support his/her complaint despite reference to a paper trail between Roche, and two named agents. Although the anonymous complainant had provided email contact details, a request for further information had gone unanswered. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The Panel noted that the parties' accounts differed. The complainant had alleged that Roche was involved, directly or indirectly, with the story that had appeared in the Daily Mirror. Roche, following its investigation of the matter, denied that this was the case. The company was aware of the story in the

local newspaper before it received the enquiry from the journalist. Although the company had interacted with the journalist as a result of his enquiry, it had stated in writing that Avastin was not licensed in the UK for the treatment of brain tumours and submitted that in a verbal response to the journalist it had stated that the medicine was so licensed in Japan. The company submitted that it had not provided the newspaper with a tip off about the patient at issue. Roche provided written statements from both its named agents each stating that they had not been involved in the generation of the Daily Mirror story.

The Panel considered that on the basis of the evidence provided by the parties, the complainant had not proven that, on the balance of probabilities, Roche or agents working on its behalf had instigated or placed the Daily Mirror article as alleged. No breaches of Clauses 2, 9.1, 23.1 and 23.2 were ruled.

Complaint received 30 July 2014

Case completed 15 October 2014