CASE AUTH/2260/9/09

VOLUNTARY ADMISSION BY BOEHRINGER INGELHEIM

Conduct of representative

Boehringer Ingelheim voluntarily admitted that one of its representatives had emailed a health professional with potentially disparaging and misleading information on Bayer's product Xarelto (rivaroxaban). Xarelto and Boehringer Ingelheim's product Pradaxa (dabigatran) were both indicated for the prevention of venous thromboembolic events in adults who had undergone elective total hip or knee replacement surgery.

The action to be taken in relation to a voluntarily admission by a company was set out in of the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code. A representative providing potentially misleading and disparaging information about a competitor product was a serious matter and the admission was accordingly treated as a complaint.

The email read:

> **'As agreed at our last meeting just a brief reminder to you about checking the average length of bed stay for June/July with Rivaroxaban patients.**
>
> **Some additional information, over in [a named town] Rivaroxaban has been removed from the formulary. The orthopods had concerns about the bleeding rates with Rivaroxaban.'**

Boehringer Ingelheim submitted that the email contravened its company policies and standard operating procedures (SOPs). The representative had been immediately suspended and subsequently dismissed. He had not maintained a high standard of ethical conduct in the discharge of his duties in breach of the Code.

The company had reminded its field force personnel of their obligations and the requirements of the Code with respect to the use of email. There would be further training on the company's SOPs.

Boehringer Ingelheim was committed to abide by the spirit and letter of the Code. This isolated incident had been taken very seriously and the company would ensure that all the necessary steps were taken to prevent such an incident being repeated.

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that on 30 July the representative in question had sent twelve other emails similar to that at issue. The Panel was extremely concerned about the representative's behaviour. The emails, which should have been certified as they were promotional material, contained false information. It appeared from a later email sent by the representative that rivaroxaban had never been on the [named town] formulary. The email of 30 July was thus misleading and not capable of substantiation. Breaches of the Code were ruled as acknowledged by Boehringer Ingelheim. The information in the email related to claims regarding side effects for a competitor product. The Panel considered that the requirement in the Code that information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience applied to statements about competitor products. The Panel considered that the email was in breach and ruled accordingly. The email disparaged rivaroxaban and a breach was ruled as acknowledged by Boehringer Ingelheim. The representative had not maintained a high standard of ethical conduct or complied with all the requirements of the Code. A breach was ruled as acknowledged by Boehringer Ingelheim.

The Panel noted that on discovering the email Boehringer Ingelheim had suspended the representative in question. It was not clear how the email had come to light. The Panel was concerned about the number of emails sent. Companies were responsible for the conduct of their representatives. The Panel accepted that on discovering the problem Boehringer Ingelheim had taken action, however the fact that the representative had sent the emails in the first instance meant that high standards had not been maintained and a breach of the Code was ruled. The Panel did not consider that the circumstances amounted to a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

Boehringer Ingelheim Limited voluntarily admitted that one of its representatives had emailed a consultant orthopaedic surgeon with information on Bayer's product Xarelto (rivaroxaban) which could be seen as disparaging as well as potentially misleading. Boehringer Ingelheim marketed Pradaxa (dabigatran).

Pradaxa and Xarelto were both indicated for the prevention of venous thromboembolic events in adults who had undergone elective total hip or knee replacement surgery.

The action to be taken in relation to a voluntarily admission by a company was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter

as a complaint if it related to a potentially serious breach of the Code. A representative providing a health professional with potentially misleading and disparaging information about a competitor product was a serious matter and the admission was accordingly treated as a complaint.

COMPLAINT

Boehringer Ingelheim referred to an email which one of its representatives had sent to a consultant orthopaedic surgeon. The email read:

'As agreed at our last meeting just a brief reminder to you about checking the average length of bed stay for June/July with Rivaroxaban patients.

Some additional information, over in [a named town] Rivaroxaban has been removed from the formulary. The orthopods had concerns about the bleeding rates with Rivaroxaban.'

Boehringer Ingelheim submitted that the email contravened its company policies and standard operating procedures (SOPs). As a result the representative had been immediately suspended, subjected to a disciplinary hearing and subsequently dismissed.

Boehringer Ingelheim submitted that the representative had not maintained a high standard of ethical conduct in the discharge of his duties and so had breached Clauses 8.1 (disparaging), 7.2 (misleading information) and 15.2 (high standards of ethical conduct) of the Code.

The company had communicated directly with its field force personnel to remind them of their obligations and the requirements of the Code with respect to the use of email. Regional business managers would also undertake further training/briefings on the company's SOPs.

Boehringer Ingelheim submitted that it was committed to abide by the spirit and letter of the Code. This isolated incident had been taken very seriously and the company would ensure that all the necessary steps were taken to prevent such an incident being repeated.

When writing to Boehringer Ingelheim the Authority asked it to respond in relation to Clauses 2, 7.2, 7.3, 7.4, 7.9, 9.1 and 15.2.

RESPONSE

Boehringer Ingelheim stated that as set out above, the representative's conduct breached company policies and procedures and was initiated without the company's knowledge or sanction. The company was committed to maintaining the highest standard of conduct and to comply with all the requirements of the Code. It ensured that all employees were aware of these requirements and abided by them. On knowing of the unprompted action of the representative the company immediately suspended him while investigating the case and dismissed him at the conclusion of the investigation. This decisive action, together with the voluntary admission to the Authority, reflected Boehringer Ingelheim's commitment to not bring discredit to, or reduce confidence in the industry.

The information that the representative emailed to the consultant did not come from a company source, and was to Boehringer Ingelheim's knowledge not factually correct in that rivaroxaban was not removed from the [named town] formulary. The information could thus be seen as misleading and in breach of Clause 7.2. As the information could not be substantiated, the claim could potentially be in breach of Clause 7.4.

The email did not mention a brand name or make a comparison; Boehringer Ingelheim thus believed that Clause 7.3 had not been breached.

Boehringer Ingelheim had voluntarily admitted a breach of Clause 7.2 as the information that rivaroxaban had been removed from the formulary in question was incorrect and could therefore be misleading. Similarly, the reason mentioned as to why it allegedly had been taken off the formulary ('concerns over bleeding rates') could not be substantiated and Boehringer Ingelheim noted that it had admitted to a potential breach of Clause 8.1 in this regard. However, there were no claims about the safety of Boehringer Ingelheim's own product (dabigatran) and so there was no breach of Clause 7.9.

Boehringer Ingelheim accepted that the representative had not maintained a high standard of ethical conduct in the discharge of his duties and that his conduct amounted to a breach of Clause 15.2. Boehringer Ingelheim did not tolerate the representative's behaviour as evidenced by his dismissal. However, Boehringer Ingelheim believed that the rogue activity of this one representative did not reflect a failure of the company to maintain high standards and there was no breach of Clause 9.1.

During the meeting referred to in the email, held on 22 June to discuss the consultant's recent attendance at a conference, the consultant referred to the differences in length of bed stays between certain clinical trials. The consultant asked the representative to email him in early August to remind him to review the length of bed stays in June and July.

Boehringer Ingelheim did not believe that any materials had been used by the representative or that he had acted on any briefing materials.

It was not Boehringer Ingelheim's understanding that rivaroxaban had been removed from the formulary in question. The company did not issue or sanction any communication regarding this matter. The representative had acted on knowledge obtained through his own network of contacts. Boehringer Ingelheim emphasised that the

representative did not disclose the email either before or after it was sent. The representative did not follow internal SOPs and the email was not certified in accordance with Clause 14.1.

In completing the internal investigation of this case, Boehringer Ingelheim had uncovered similar emails sent by the representative to other customers, unprompted by and undisclosed to the company. Copies were provided.

PANEL RULING

The Panel noted that on 30 July the representative in question had sent twelve other emails similar to that at issue. The Panel was extremely concerned about the representative's behaviour. The emails, which should have been subject to the certification process as they were promotional material, contained false information. It appeared from an email sent by the representative on 5 August that rivaroxaban had never been on the [named town] formulary. The email of 30 July was thus misleading and not capable of substantiation. Breaches of Clauses 7.2 and 7.4 were ruled as acknowledged by Boehringer Ingelheim. The email was not a comparison and thus no breach of Clause 7.3 was ruled. The information in the email related to claims regarding side effects for a competitor product. The Panel considered that Clause 7.9 was not limited to claims about a company's own product. The requirement that information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience applied to statements about competitor products. The Panel considered that the email was in breach of Clause 7.9 and ruled accordingly. The email disparaged rivaroxaban and a breach of Clause 8.1 was ruled as acknowledged by Boehringer Ingelheim. The representative had not maintained a high standard of ethical conduct or complied with all the requirements of the Code. A breach of Clause 15.2 was ruled as acknowledged by Boehringer Ingelheim.

The Panel noted that on discovering the email Boehringer Ingelheim had suspended the representative in question. It was not clear how the email had come to light. The Panel was concerned about the number of emails sent. Companies were responsible for the conduct of their representatives. The Panel accepted that on discovering the problem Boehringer Ingelheim had taken action, however the fact that the representative had sent the emails in the first instance meant that high standards had not been maintained and a breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances amounted to a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

Complaint received **1 September 2009**

Case completed **1 October 2009**