CASE AUTH/2326/6/10

CONSULTANT HAEMATOLOGIST v BAYER SCHERING PHARMA

Envelope for Kogenate mailing

A consultant haematologist complained about an envelope used by Bayer Schering Pharma to send a Kogenate (recombinant coagulation factor VIII) mailing to patients. The envelope stated 'Good news. A new way to mix your clotting factor'. The letter and leaflet inside were about a new reconstitution kit for Kogenate.

The complainant was concerned that promotional material had been posted to patients with haemophilia A. Some patients who received Kogenate by a home delivery service had received direct mailings from Bayer Schering. In particular, the complainant knew about one patient who felt a gross breach of confidentiality in that he had received a letter through the post with information on the outside that clearly indicated that he was receiving clotting factors and thereby was a haemophiliac. Having discussed this issue with the home delivery company, the complainant realised that Bayer Schering had sent the marketing material in blank (unaddressed) envelopes to the home delivery service company which had then labelled them and posted them to the patients. The complainant was sure that Bayer Schering and the home delivery service realised that was grossly inappropriate. The patient wrote to complain about possible use of his personal details and was concerned that these details were stored at Bayer Schering.

The complainant was concerned that patients' confidentiality had been breached and that Bayer Schering had sought to send promotional information to patients, although the complainant realised that this was probably to inform them of perceived improvements in the product. However, a cynic would suggest that Bayer Schering was also seeking to raise brand awareness. The complainant suggested that Bayer Schering stopped communicating directly with patients about its product. Information about the administration of clotting factors could be given by the medical team looking after the patient.

The detailed response from Bayer Schering Pharma is given below.

The Panel noted that Bayer Schering did not have access to patient details. Patient confidentiality was extremely important and it appeared that this was well understood by Bayer Schering. The mailing in question had been certified for the home delivery service to hand deliver to patients who would be using the new presentation of Kogenate. The home delivery service had mailed the letters following instructions from a Bayer Schering employee that the letters should be sent before the patient received the new presentation. The individual concerned had failed to ensure that the mailing was sent in an (outer) plain envelope.

The Panel noted that the Code permitted pharmaceutical companies to provide information to patients and/or the public about prescription only medicines. Such medicines could not be advertised to the public. The mailing was intended to inform patients already taking Kogenate about changes to its presentation and reconstitution. The Panel queried why it was necessary to refer to such changes as good news on the envelope.

The Panel considered that the claim 'Good news. A new way to mix your clotting factor' was unacceptable for use on an envelope mailed to patients. It put information in the public domain that the addressee was receiving treatment for a medical condition. Patients would have cause to be concerned that a pharmaceutical company had their details. The Panel did not know whether the patients had agreed to receive mailings from Bayer Schering. The Panel considered that high standards had not been maintained and a breach of the Code was ruled as acknowledged by Bayer Schering.

The Panel noted Bayer Schering's submission that the mailing was approved for delivery by the home delivery service, to be delivered by hand with the product pack. The Panel noted that the certificate did not refer to the method of delivery. The Panel noted that such details might appear elsewhere in the job bag. The Panel considered that Bayer Schering had been badly let down by its employee. The Panel decided that the matter was covered adequately by its ruling of a breach of the Code above. On balance the Panel decided to rule no breach of Clause 2 which was reserved to indicate particular censure.

Bayer Schering Pharma made a voluntary admission regarding an envelope (ref UK.PH.HN.KOG 2010.15) containing a mailing to patients about the presentation of Kogenate (recombinant coagulation factor VIII). The envelope stated 'Good news. A new way to mix your clotting factor'. The letter and leaflet inside gave information about a new reconstitution kit for Kogenate. Before deciding whether to treat the matter as a complaint, in accordance with Paragraph 5.4 of the Constitution and Procedure, the Director asked Bayer Schering for additional information.

On receipt of the additional information, it became clear that a consultant haematologist had complained to Bayer Schering about the mailing and copied that complaint to the ABPI. The PMCPA was unable to trace a copy of the letter to the ABPI. A copy was provided by Bayer Schering. Given the circumstances, the Director decided the matter should be considered as a complaint from the consultant. Bayer Schering was so informed.

COMPLAINT

The complainant was concerned that promotional material had been posted to patients with haemophilia A. Some patients, who received Kogenate by a home delivery service, had received direct mailings from Bayer Schering with information about Kogenate. In particular, the complainant had received a specific complaint from a patient who received such promotional material in an envelope with his name and address on the outside and information indicating that he was on clotting factors. Having discussed this issue with the home delivery company, the complainant realised that Bayer Schering had sent the marketing material in blank [unaddressed] envelopes to the delivering company which had then labelled them and posted them to the patient. The complainant was sure that Bayer Schering and the home delivery service realised that was grossly inappropriate. The patient wrote to complain about possible use of his personal details and was concerned that these details were stored at Bayer Schering. Additionally, the patient felt a gross breach of confidentiality in that he had received a letter through the post with information on the outside that clearly indicated that he was receiving clotting factors and thereby was a haemophiliac.

The complainant was concerned that the patients' confidentiality had been breached and that Bayer Schering had sought to send promotional information to patients, although the complainant realised that this was probably to inform them of perceived improvements in the product. However, a cynic would suggest that Bayer Schering was also seeking to raise brand awareness which would be commercially advantageous given that recombinant clotting factors were currently subject to a tendering process.

The complainant wanted assurance from Bayer Schering and the home delivery company that such a breach would not happen again and suggested that Bayer Schering stopped communicating directly with patients about its product. Information about the administration of clotting factors could be given by the medical team looking after the patient.

When writing to Bayer Schering, the Authority asked it to respond in relation to Clauses 2 and 9.1 of the Code.

RESPONSE

Bayer Schering stated that 173 patients were sent a user guide in an envelope with the declaration 'Good News – A new way to mix your clotting factor' on the external face as an open mailer. Subsequently two patients telephoned Bayer Schering directly to bring this most regrettable of incidents to its attention. As a result, Bayer Schering made a voluntary admission to the Authority on 10 June 2010. It then became apparent that the company had been overtaken by events when, on 11 June, it received a letter of complaint from a consultant. The letter followed a specific complaint from a patient.

Bayer Schering submitted that the patient should never have received a letter through the post with information on the envelope indicating that he was receiving clotting factor. It was no wonder that he complained and felt a 'gross breach of confidentiality'. Consequently, Bayer Schering replied to the doctor to express its most sincere apologies and to explain how this unfortunate event occurred. Bayer Schering hoped that the doctor would feel able to convey its apologies to his patient.

The letter contained a user guide ('How to prepare Kogenate Bayer for injection') for patients with instructions for reconstituting their clotting factor.

Clearly, information about the administration of clotting factor should be given by the medical team looking after the patient. However, in this case Bayer Schering consulted centres as to whether there should be an additional communication. Two people at the complainant's centre were contacted regarding the use of the home delivery company. The consensus of all of the centres was that this was appropriate and that it should be delivered to patients by hand by the home delivery service when delivering their clotting factor. Consequently, the envelope and user guide were intended to be, and approved for, delivery by the home delivery companies, not by post as an open mailing.

Unfortunately, but for the best of intentions, one of Bayer Schering's employees considered it was important that patients were made aware of the relevant information prior to delivery of their clotting factor so that they were prepared for the change. The individual concerned believed that patients should be informed of the change to their treatment as soon as possible. As a result the delivery company was instructed to send the mailer before delivering the clotting factor to patients. Unhappily, as the company was acutely aware, the individual did not emphasize the need to enclose the mailing in a [outer] plain envelope.

As part of the tendering process there was user testing of the reconstitution devices provided by the different companies. It was a condition of the contract that a specific reconstitution device was used. The letter was sent by the delivery service to patients because Bayer Schering had been requested to change the reconstitution device for its clotting factor. It was not an attempt to send

promotional information to patients or to communicate directly with them.

It could not be over-emphasised that Bayer Schering did not store, or wish to store, personal details of patients. Patient details were only held by the delivery companies which were engaged by the centres and instructed by them as to which patients should receive clotting factor. The delivery companies were not third party service providers to Bayer Schering.

The letter was sent after contracts had been awarded and only to those patients whom the centres had decided would receive Kogenate.

In summary, the envelope and enclosed letter and user guide were intended, and as such approved, to be delivered by the home delivery service and not sent through the post as an open mailing. In other words it was certified for delivery by hand with the product pack.

Regrettably this unacceptable event was a consequence of an individual not following the instructions for how the mailing was to be used. Having instructed the delivery services to send the mailing prior to delivery of the product, this was compounded by the failure to ensure that all of the delivery companies understood that it was inappropriate to send a letter through the post with information on the outside indicating that patients were receiving clotting factor.

Bayer Schering hoped that it was accepted that this regrettable incident was the consequence of an unwitting failure on the part of an individual whose only intention was to do what they thought was best for the patients, that was to inform them of the change to reconstitution of their clotting factor as soon as possible.

A number of actions were taken when this most unfortunate of events came to light. All the delivery companies were contacted in order to draw the matter to their attention and request that no further open mailings should be sent. There had been an investigation as to how this happened together with a full and frank discussion with the individual concerned. Bayer Schering's medical governance function subsequently sent an internal communication requiring senior managers to reinforce awareness within their teams that the delivery of items should be in accordance with the instructions provided in the certified job bag.

This incident was a failure to maintain high standards, hence Bayer Schering's voluntary admission. Having conveyed its most sincere apologies to the complainant, Bayer Schering now extended them to the Authority.

PANEL RULING

The Panel noted that Bayer Schering did not have access to patient details. Patient confidentiality was extremely important and it appeared that this was well understood by Bayer Schering. The mailing in question had been certified under Clause 14 for the home delivery service to hand deliver to patients who would be using the new presentation of Kogenate. The home delivery service had mailed the letters following instructions from a Bayer Schering employee that the letters should be sent before the patient received the new presentation. The individual concerned had failed to ensure that the mailing was sent in an [outer] plain envelope.

The Panel noted that Clause 22 permitted pharmaceutical companies to provide information to patients and/or the public about prescription only medicines. Such medicines could not be advertised to the public. The mailing was intended to inform patients already taking the medicine about changes to the presentation and reconstitution of Kogenate. The patient would already be aware of the product. However the Panel queried why it was necessary to refer to the changes as good news on the envelope.

The Panel considered that the claim 'Good news. A new way to mix your clotting factor' was unacceptable for use on an envelope mailed to patients. It put information in the public domain that the addressee was receiving treatment for a medical condition. It would also cause patients to be concerned that a pharmaceutical company had their details. The Panel did not know whether the patients had agreed to receive mailings from Bayer Schering. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled as acknowledged by Bayer Schering.

The Panel noted Bayer Schering's submission that the mailing was approved to be delivered by the home delivery service. It was certified for delivery by hand with the product pack. The Panel noted that the certificate recorded the intended use/purpose/distribution as 'To inform patients about the new reconstitution kit'. There was no reference to the method of delivery. The Panel noted that such details might appear elsewhere in the job bag. The Panel considered that Bayer Schering had been badly let down by its employee. The Panel decided that the matter was covered adequately by its ruling of a breach of Clause 9.1 above. On balance the Panel decided to rule no breach of Clause 2 which was reserved to indicate particular censure.

Complaint received **22 June 2010**

Case completed **3 August 2010**