CASE AUTH/2469/12/11

VOLUNTARY ADMISSION BY BAYER

Symposium invitation

Bayer advised the Authority that, in its view, an invitation to a company sponsored symposium was in breach of the Code. The invitation, which promoted Levitra (vardenafil), had been prepared and distributed by Bayer global. Bayer global had not regarded the invitation as promotional and had thus not followed the relevant standard operating procedure (SOP). As a consequence the invitation had not been certified for UK use. Some of the invitations had been sent to UK recipients.

Bayer submitted that the invitation did not include the prescribing information and other obligatory information as required by the Code. Further, a strapline 'First-line ED [erectile dysfunction] therapy he can take any time, anywhere' was included although this was not approved for use in the UK.

In addition Bayer noted that the invitation had been sent in transparent envelopes thus the public could see the brand name and the fact that the product was related to sexual medicine. Finally, the invitation had been sent to some people whom Bayer understood were not health professionals.

In accordance with the Constitution and Procedure, this matter was taken up as a complaint under the Code.

The detailed response from Bayer is set out below.

The Panel noted that the invitation to a symposium in Italy had been created and distributed by the Bayer global team. The Code required that activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities took place or the materials were used. The invitation in question was issued from a company based in Germany but insomuch as it was sent to UK recipients, the Panel considered that that aspect of its use came within the scope of the Code. As the invitation was promotional and had not been certified for use in the UK, the Panel ruled a breach of the Code.

As the non-proprietary name was not included next to the most prominent display of the brand name, there was no prescribing information and no statement regarding adverse event reporting, breaches of the Code were ruled.

With regard to the strapline, 'First-line ED therapy he can take anytime, anywhere', the Panel noted that the maximum dose of Levitra was one tablet daily. The Panel thus considered that, depending on when the last dose was taken, Levitra could not be taken 'anytime'. The Panel thus considered that the strapline was inconsistent with the particulars listed in the Levitra summary of product characteristics (SPC). A breach of the Code was ruled.

The Panel noted that the invitation was sent in a transparent envelope such that the public could see the Levitra product logo on the front cover of the invitation and enough additional information to assume that Levitra was a medicine used in sexual health. In that regard the Panel considered that Levitra had been advertised to the public. Breaches of the Code were ruled.

The Panel noted that some of the recipients of the invitation were employees of another pharmaceutical company and others were employed by an agency representing a pharmaceutical company. Bayer had submitted that none of these recipients were health professionals. The Panel noted that they could also not be considered to be appropriate administrative staff. The Panel considered that the invitation, which promoted Levitra, had thus been sent to a small number of members of the public. A breach of the Code was ruled.

The Panel noted that Bayer had acknowledged all of the above breaches of the Code.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that Bayer's global SOP relating to the review and approval of promotional material clearly referred to the need for material to be consistent with, *inter alia*, local codes and to the need for country material to be reviewed and approved by country medical affairs. There was thus a global SOP which should have prevented the invitation being used in the UK without being appropriately certified. The Panel considered that Bayer had been badly let down by global colleagues who failed to regard the invitation as promotional material and consequently failed to follow company procedures. Nonetheless the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was seen as a sign of particular censure and reserved for such. No breach of that clause was ruled.

Bayer Healthcare in the UK voluntarily advised the Authority that, in its view, an invitation to a Bayer sponsored satellite symposium organised by Bayer global headquarters, Berlin, was in breach of the Code.

The symposium, held at the European Society for Sexual Medicine (ESSM) Congress in Milan in December 2011, was entitled 'Men's changing sexuality, identity and behaviour'; it was conducted by a faculty of four non-UK clinicians. The invitations were sent by Bayer global to delegates registered for the ESSM. Seventy four invitations were sent to UK delegates.

The four page, A5 invitation featured the Levitra (vardenafil) orodispersible tablets (ODT) logo prominently on the front cover. The front cover stated the title of the symposium and gave details of the time and place. Page two gave brief details of the four speakers and page three outlined the meeting programme. The Levitra product logo appeared in the bottom right hand corner together with the strapline 'First-line ED [erectile dysfunction] therapy he can take anytime, anywhere'. The centre of the back page featured a roundel showing a photograph of Milan and the Bayer Healthcare logo appeared in the bottom left hand corner.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

COMPLAINT

In late November 2011, Bayer global informed Bayer Healthcare that the invitation to the symposium had been posted earlier that month without obtaining UK approval of the invitation as required by the Code.

The invitation was prepared by global strategic marketing and approved by global medical affairs at Bayer global headquarters in Berlin. The invitation and the content of the symposium promoted Levitra. However, Bayer Healthcare submitted that the invitation did not include prescribing information as it was mistakenly not regarded as promotional by those who prepared and approved it through the global approval system. Consequently Bayer Healthcare believed that this was in breach of Clause 4.1. The invitation did not include an adverse event reporting statement, in breach of Clause 4.10.

Bayer Healthcare submitted that the invitation also failed to include the non-proprietary name (vardenafil) adjacent to the most prominent display of the Levitra brand name on the front cover of the invitation in breach of Clause 4.3. The non-proprietary name was included next to the later inclusion of the brand name on the inside cover.

The inside cover of the invitation included the strapline 'First-line ED therapy he can take anytime, anywhere' beneath the Levitra logo. Bayer Healthcare noted that this claim was not approved for use in the UK as Levitra should only be taken as a maximum of 1 tablet per 24 hours and was a breach of Clause 3.2.

The review and approval processes for marketing and educational materials were defined by a Bayer global standard operating procedure (SOP) which Bayer Healthcare considered clearly stated the company's commitment to comply with the IFPMA and EFPIA Codes. This SOP required all materials to be reviewed and approved at a global, regional and local country level. However, in this instance, there was a failure to obtain UK review and approval of the invitation and mailing. As such the invitation and mailing for UK health professionals was not certified, in breach of Clause 14.1.

Bayer Healthcare noted that the invitation was sent in a transparent envelope to health professionals in several countries, including the UK. This meant that the public could see the brand name and, although the indication was not visible, that the product was related in some way to sexual medicine. This was a breach of Clause 9.8. The use of the transparent envelope arose through a lack of supervision of the third party contractor engaged by the Levitra global product manager and failure of the envelope to be submitted for approval into the global approval system.

The invitation was also sent directly to people in another pharmaceutical company and to others in an events agency. Bayer Healthcare understood that none of these individuals were health professionals. Consequently Bayer Healthcare considered this was a breach of Clause 22.1.

Bayer Healthcare submitted that it took this breach of internal procedure and failure to comply with the Code extremely seriously and was working with global colleagues in Berlin to ensure that similar circumstances did not arise again. In late December senior officers from Bayer global's compliance, medical affairs and legal departments met senior Bayer Healthcare medical, legal and compliance colleagues to discuss how to prevent such circumstances arising again. On the previous day, the men's health global marketing team in Berlin had been re-trained on compliance.

When writing to Bayer Healthcare the Authority asked it to provide any further comments in relation to Clauses 2, and 9.1 of the Code.

RESPONSE

In relation to the requirements of Clauses 2 and 9.1, Bayer Healthcare stated that the SOP set out a clearly defined procedure for the review and approval of marketing and educational materials. It clearly stated Bayer's commitment to comply with the IFPMA and EFPIA Codes and required global promotional materials, in addition to global review and approval, to be reviewed at a country level if such material was to be distributed to external persons in that country.

Bayer Healthcare submitted that the company therefore had a clear procedure and instructions in place to ensure that global material intended for UK distribution was reviewed in the UK for compliance with the Code. The incident at issue arose because two individuals from Bayer's headquarters failed to follow the SOP. The individuals concerned were last trained on the SOP in 2009.

Bayer Healthcare submitted that if the materials had been submitted for approval in the UK in accordance with the SOP, they would not have been approved, as the medical department in the UK, which subsequently became aware of the existence of the UK invitations, was itself responsible for the internal reporting and voluntary admission of the incident.

Consequently, Bayer Healthcare acknowledged that it

had failed to maintain high standards in breach of Clause 9.1.

With regard to Clause 2, Bayer Healthcare emphasised that immediately after internally being made aware of the incident, it began a thorough internal investigation. As soon as this detailed investigation was finished, and Bayer Healthcare was confident that all relevant information had been collated, a voluntary admission was sent to the PMCPA.

Bayer Healthcare submitted that it had initiated prompt corrective action by implementing compliance retraining of the global marketing team concerned in December 2011 and was organising compliance retraining of the men's health global medical team. In addition, the breaches outlined were discussed at a legal and compliance meeting with senior global colleagues in December 2011. As a consequence, the importance of local country approvals had been re-emphasised.

PANEL RULING

The Panel noted that the invitation to a symposium in Italy had been created and distributed by the Bayer global team. The supplementary information to Clause 1.8, Applicability of Codes, required that activities carried out and materials used by a pharmaceutical company located in a European country must comply with the national code of that European country as well as the national code of the country in which the activities took place or the materials were used. The invitation in question was issued from a company based in Germany but insomuch as it was sent to UK recipients, the Panel considered that that aspect of its use came within the scope of the Code. As the invitation was promotional and had not been certified for use in the UK, the Panel ruled a breach of Clause 14.1.

The Panel noted that the Levitra product logo featured prominently on the front cover of the invitation and was also included on page three. The Panel considered that, as submitted by Bayer Healthcare, the invitation promoted Levitra and it therefore needed to incorporate prescribing and other obligatory information as required by Clause 4 of the Code. The Panel noted that as the front cover of the invitation featured the most prominent display of the brand name, the non-proprietary name should have appeared immediately adjacent to it. As the non-proprietary name was not included next to the brand logo on the front cover the Panel ruled a breach of Clause 4.3. The Panel further noted that the invitation should have included the Levitra prescribing information and as it did not a breach of Clause 4.1 was ruled. The invitation also did not include a statement regarding adverse event reporting. A breach of Clause 4.10 was ruled.

With regard to the strapline which appeared under the product logo on page three of the invitation, 'First-line ED therapy he can take anytime, anywhere', the Panel noted that the maximum dose of Levitra ODT was one tablet daily. The Panel thus considered that, depending on when the last dose was taken, Levitra ODT could not be taken 'anytime'. The Panel thus considered that the strapline was inconsistent with the particulars listed in the Levitra summary of product characteristics (SPC). A breach of Clause 3.2 was ruled.

The Panel noted that the invitation was sent in a transparent envelope onto which was stuck an address label and a stamp. The transparency of the envelope meant that the public could see the Levitra product logo on the front cover of the invitation and an incomplete reference to the ESSM (from the example provided the public would only see 'European Society for Sexual Medic', the rest of the text was obscured by the address label). Clause 9.8 of the Code required that exposed mailings, envelopes or wrappers must not carry matter which might be regarded as advertising to the public, contrary to Clause 22.1. The Panel noted that from the information which could be seen through the envelope, members of the public would assume that Levitra was a medicine used in sexual health. In that regard the Panel considered that Levitra had been advertised to the public. Breaches of Clauses 9.8 and 22.1 were ruled.

The Panel noted that some of the recipients of the invitation were employees of another pharmaceutical company and others were employed by an agency representing a pharmaceutical company. Bayer Healthcare had submitted that none of these recipients were health professionals. The Panel noted that they could also not be considered to be appropriate administrative staff. The Panel considered that the invitation, which promoted Levitra, had thus been sent to a small number of members of the public. A breach of Clause 22.1 was ruled.

The Panel noted that Bayer Healthcare had acknowledged all of the above breaches of the Code.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that Bayer's global SOP relating to the review and approval of promotional material clearly referred to the need for material to be consistent with, *inter alia*, local codes. It stated that country promotional material must only be used upon review and approval by country medical affairs. The Panel noted that Bayer global thus had an SOP in place which should have prevented the invitation being used in the UK without being appropriately certified. The Panel considered that Bayer Healthcare had been badly let down by global colleagues who failed to regard the invitation as promotional material and consequently failed to follow the procedures laid out in the relevant SOP. Nonetheless the Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 which was seen as a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

Complaint received **22 December 2011**

Case completed **13 February 2012**