

CASE AUTH/2055/10/07

VOLUNTARY ADMISSION BY UCB PHARMA

Promotion of prescription only medicine to the public

UCB Pharma stated that, with regret, it brought to the Authority's attention an advertisement placed in a Parkinson's Disease supplement distributed in The Times in September which referred to Keppra (levetiracetam) and Neupro (rotigotine), both prescription only medicines. This breach of the Code was brought to UCB's attention by GlaxoSmithKline.

UCB explained that in early August 2007 its media relations department was invited to contribute to the Parkinson's Disease supplement at issue. At this time, UCB was in the late stages of acquiring Schwarz Pharma which manufactured Neupro for the treatment of Parkinson's Disease. The enquiry and draft copy was hence referred to a brand manager in Schwarz.

The article copy and layout was amended through interactions with various departments. The article was released to the media agency without approval/certification in late August containing two brand names, Keppra and Neupro.

UCB explained that the copy was reviewed outside the approvals process by corporate, commercial and medical departments. Consistently the draft article was assumed to be a corporate press release and as such the opportunity to identify a potential breach was not identified.

Whilst it was intended that the article would raise the profile of the new company, UCB acknowledged that the effect might be considered promotional and as such represented a breach of the Code.

Whilst it did not lessen the nature of this breach, it was significant that the preparation of the advertisement immediately preceded the merger of the two organisations. The brand manager operated without direct supervision and failed to comply with relevant compliance guidelines.

To address the issues identified UCB had undertaken a number of actions. A new standard operating procedure (SOP) relating to media enquiries had been introduced. All media relations, marketing and medical employees would be trained on the new SOP. All Schwarz employees would undergo compliance training in accordance with UCB SOPs. Investigations under the UCB disciplinary procedure were being carried out.

This episode was deeply regrettable and UCB assured the Authority that it took its obligations to the Code very seriously and with utmost importance and would comply fully with the complaints procedure. Recognising that the organisation was

going through a period of transformation UCB had done much in the last year to ensure that compliance was at the heart of its culture - details of actions were provided.

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.

The Panel noted that The Times supplement on Parkinson's Disease contained an advertisement placed by UCB. The advertisement, written in the style of an advertorial, stated, *inter alia*, 'With UCB's expertise in CNS, and a market-leading anti-epileptic drug (Keppra), the combination with Schwarz has brought additional strength to UCB's neurology franchise which now includes Neupro, a transdermal patch for the treatment of Parkinson's disease. The patch was launched in the UK in April 2006'.

The Panel examined the emails and other materials provided by UCB and considered that there was a serious lack of understanding throughout the organisation as to the requirements of the Code particularly with regard to relations with the general public and the media. The draft copy for the advertisement was supplied by UCB media relations department which at the outset, despite acknowledging that the intended article was to appear in The Times, queried whether the suggested wording would be acceptable under the Code. The brand manager to whom the draft copy was sent gave his interpretation of what the Code allowed but stated that presumably the article would need to be signed off by corporate affairs and 'both of our medics' (presumably from UCB and Schwarz). The emails sent in July when the project was first discussed were headed 'Advertising proposal - Parkinson's Disease' supplement - The Times'. This became 'draft PD article', 'UCB [sic] Advertorial - first proof' and 'UCB Article the Times' in emails sent in August. In that regard the Panel considered that it should have been obvious that it was not draft text for a corporate press release.

The Panel noted that despite the requirements of the Code being queried several times with regard to the advertisement, each time the brand manager stated that he thought it was acceptable under the Code. No-one within the organisation, however, appeared to be prepared to confirm the brand manager's beliefs or challenge them. This demonstrated very poor control

and/or knowledge of the Code. The Panel noted UCB's submission that the brand manager had not complied with company SOPs. The brand manager however, had not acted in isolation. The material had been drafted by the media relations department and seen by the brand manager and members of the medical department. Some members of staff were away when the material was finalised. It was also seen by the managing director. UCB had been badly let down by several members of staff.

The advertisement was signed off on a Schwarz promotional material approval form. The Panel noted UCB's submission that the reviewers of the text were not told by the brand manager that payment was being made for the text to be included in The Times supplement. The Panel noted, however, that the copy approval form described the material as 'Draft article for Times PD [Parkinson's Disease] supplement', the product was 'Neupro' and the audience was 'Times readers'. In that regard the Panel considered that there was enough on the form to ring alarm bells for those reviewing the material. The form had been signed by a product manager and a member of the medical team. The Panel noted UCB's submission that 'incorrect assumptions were made in relation to [the material's] intended purpose'. This was unacceptable; no-one should review material on the basis of assumptions. The Panel considered that the advertisement promoted Keppra and Neupro to the public. 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 had demonstrated a lack of control and poor knowledge of the requirements of the Code throughout the company. High standards had not been maintained. A breach of the Code was ruled. The Panel considered that companies should take particular care when producing material for the public. UCB 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.

UCB Pharma Ltd voluntarily admitted that an advertisement which it placed in a Parkinson's Disease supplement distributed in The Times on 7 September referred to Keppra (levetiracetam) and Neupro (rotigotine), both prescription only medicines.

COMPLAINT

UCB stated that, with regret, it brought to the Authority's attention this advertisement which represented a breach of the Code. The breach was brought to UCB's attention by GlaxoSmithKline. UCB had subsequently investigated the specific circumstances leading to this breach.

UCB explained that in early August 2007, UCB media

relations department was invited to contribute to a Parkinson's Disease supplement in the Times. At this time, UCB was in the late stages of acquiring Schwarz Pharma which manufactured Neupro for the treatment of Parkinson's Disease. The enquiry and draft copy was hence referred from UCB media relations to a brand manager in Schwarz on 7 August.

The article copy and layout was amended between 7 and 28 August through interactions with various departments. The article was released to the media agency without approval/certification on 29 August containing two brand names, Keppra and Neupro. Major deficits leading to this breach included the fact that the copy was reviewed outside the approvals process by corporate, commercial and medical departments. Consistently the draft article was assumed to be a corporate press release and as such the opportunity to identify a potential Code breach was not identified.

Whilst it was intended that the article would raise the profile of the new company, UCB acknowledged that the effect might be considered promotional and as such represented a breach of Clause 20.1.

Most significantly the brand manager responsible did not comply with the standard operating procedures (SOPs) and approval processes of either Schwarz or UCB. Specifically the item was released without final approval and certification and as such breached Clause 14.1.

Whilst it did not lessen the nature of this breach, it was significant that the preparation of the advertisement immediately preceded the merger of the two organisations which finally came into effect on 3 September. Notably the brand manager at this time operated without the direct supervision of a line manager. Nonetheless the individual concerned failed to comply with relevant compliance guidelines or with the terms of his contract of employment.

UCB submitted that it had taken the following actions to address the issues identified;

- Introduced a new SOP relating to media enquiries. Specifically this procedure would mandate the initiation of an approvals and certification procedure and origination of a 'job-bag' at the point of entry.
- The training of all media relations, marketing and medical employees on the above.
- All Schwarz employees would undergo compliance training in accordance with UCB SOPs. This programme had already commenced as part of integration training.
- The brand manager responsible for the item was currently being investigated under the UCB disciplinary procedure for breach of the Code and terms and conditions of employment.

Clearly this episode was deeply regrettable and UCB assured the Authority that it took its obligations to the Code very seriously and with utmost importance and would comply fully with the complaints procedure.

Recognising that the organisation was going through a period of transformation UCB had done much in the last year to ensure that compliance was at the heart of its culture - details of actions were provided.

Paragraph 5.4 of 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.

In addition to Clause 20.1 cited by UCB, the company was asked to respond in relation to Clauses 2, 9.1 and 20.2.

RESPONSE

With regard to Clause 20.1, UCB again stressed that the intention behind including the article in the supplement was to highlight the recent merger. UCB never intended to include prescription only medicines in the form of an advertisement to the public, but rather to raise the profile of the newly merged company. Nevertheless, UCB accepted that a section of the final article copy contained text inappropriate given the intended purpose.

With regard to Clause 20.1, the article included the paragraph: 'With UCB's expertise in CNS, a market leading anti-epileptic drug (Keppra), the combination with Schwarz has bought additional strength to UCB's neurology franchise which now includes Neupro, a transdermal patch for the treatment of Parkinson's disease. The patch was launched in the UK in April 2006'. UCB believed that these statements were factually correct, balanced and did not in themselves mislead. The statements did not include any medicinal claims or prejudice patient safety, they also were not made with the specific purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine. Nonetheless UCB understood that this section of the article might have had the unintended consequence of doing so.

With regard to Clause 9.1, UCB had always maintained high standards and had an excellent track record in this area and indeed with the Authority. Compliance was a top priority of UCB as evidenced by the action it had taken in the last year and as set out in the admission and its appendices. The breach identified in this instance had been treated seriously and UCB immediately embarked upon a corrective action plan which included staff training and an ongoing review of SOPs.

UCB accepted that, on this occasion, the relevant brand manager had failed to comply with existing UCB and Schwarz SOPs. However, UCB believed that this was an exceptional case and the relevant employee's conduct was being investigated. Notwithstanding this, UCB had always and continued to uphold and enforce the high standards demanded of the pharmaceutical industry and it believed that this incident, whilst

serious, was not of a distasteful or offensive nature which might be the case with other matters which usually fell to be considered under this clause of the Code.

With regard to Clause 2, UCB believed that this case should not bring discredit to or reduce confidence in the pharmaceutical industry. Whilst UCB acknowledged that one of its employees had departed from its high standards, UCB believed that this was exceptional. The company had established a strong compliance culture throughout the organisation and continued to dedicate resources to ensure that the appropriate training, systems and processes were in place to support this culture. A senior medical advisor had been appointed as compliance manager and UCB staff had participated in training events relating to awareness of the Code and an understanding of its provisions.

To summarise, UCB was confident that this transgression represented an isolated incident to be viewed against the background of a merger. UCB remained confident that this situation would not arise again and continued to take steps to develop compliance and staff training as outlined above. Moreover, on notification of the breach by GlaxoSmithKline, UCB acted promptly to identify the circumstances leading to this situation and executed measures that it believed were appropriate to the issues identified. GlaxoSmithKline had been informed of UCB's determination to disclose all findings to the Authority. The subsequent correspondence with GlaxoSmithKline was provided.

Finally with regard to the specific questions asked, UCB paid a media agency for the advertisement and front page corporate banner. The final copy submitted to the media agency was provided.

FURTHER RESPONSE

In response to a request from the Panel for further information UCB stated that its media department received regular unsolicited communications from a media agency. With regard to the Parkinson's Disease supplement, the agency was advised to contact Schwarz as the expertise resided in that organisation at that time.

A subsequent telephone discussion regarding The Times supplement took place between the relevant Schwarz brand manager and the agency. The call was initiated by the agency which then followed up its conversation by email to the brand manager. A copy of the original email and acceptance of the agency's offer was provided.

The brand manager then contacted the UCB media relations department as he considered that the contribution to the supplement should be written in the context of the impending integration of UCB and Schwarz. The email correspondence between UCB and Schwarz was provided.

The supplement was produced by the agency and

distributed in The Times. As such, there was no contact directly between UCB and The Times during this process.

The 'draft copy' referred to in the admission was draft text for a corporate press release relating initially to the UCB organisation. This was suggested by the UCB media relations department following the referral from the brand manager mentioned above. The 'draft copy' was then referred back to the brand manager for review and confirmation of information relating to Parkinson's Disease and Neupro.

The project was led by the brand manager because Schwarz and UCB were operating as separate organisations at the time and the supplement related to Parkinson's Disease, Schwarz's main therapeutic focus. A job bag was then initiated within Schwarz. The initial text drafted by UCB and the further versions after comment on the information relating to Parkinson's Disease and Neupro were provided.

In the review process the copy was commented upon by several departments between 7 and 28 August. In UCB the copy was reviewed outside a formal approval process and as a result incorrect assumptions were made in relation to its intended purpose.

The contents of the original job bag were provided. Importantly the brand manager did not tell the reviewers the company was paying for the text to be included in The Times supplement. Indeed, it was clear that the brand manager did not appreciate that paying for the article to be published meant that it should be treated as an advertisement rather than a press release. UCB believed that this was not intentional but accepted that reviewers did not identify the risk of potential breach.

The article together with the front page banner were paid for as mentioned in previous correspondence. In UCB's initial response, it referred to the 'advertisement'. This reference represented UCB's agreement that, on review of the actual published supplement, what was actually published was, in reality, an advertisement. However, as mentioned above, throughout the copy review process UCB reviewed the copy as a corporate press release and did not intentionally release it as an advertisement.

The copy was issued to the media agency initially as a text document. The agency converted this into a PDF and returned it to UCB; a copy was provided. This PDF was reviewed internally with further comments made. The amended document was then returned to the agency without further internal approval as required in the Schwarz approval process.

The brand manager from Schwarz arranged for both items to be released to the agency. As previously discussed the item was released without completion of the job bag and without certification.

According to Clause 14.3 of the Code, a press release should be examined to ensure that it did not contravene the Code or the relevant statutory

requirements. UCB and Schwarz policy was to review and certify all press releases. The brand manager acted against the existing Schwarz SOP at the time. As a result of this unfortunate and unforeseen event, UCB had updated its 'Relationship with the Media and Public SOP' and in future would be certifying all communications external to UCB. A copy of this SOP was provided.

PANEL RULING

The Panel noted that the supplement on Parkinson's Disease, distributed with The Times, 7 September 2007, contained an advertisement placed by UCB. The advertisement, written in the style of an advertorial, stated, *inter alia*, 'With UCB's expertise in CNS, and a market-leading anti-epileptic drug (Keppra), the combination with Schwarz has brought additional strength to UCB's neurology franchise which now includes Neupro, a transdermal patch for the treatment of Parkinson's disease. The patch was launched in the UK in April 2006'.

The Panel examined the emails and other materials provided by UCB and considered that there was a serious lack of understanding throughout the organisation as to the requirements of the Code particularly with regard to relations with the general public and the media (Clause 20). The draft copy for the advertisement was supplied by UCB media relations department which at the outset, despite acknowledging that the intended article was to appear in The Times, queried whether the suggested wording would be acceptable under the Code. The brand manager to whom the draft copy was sent gave his interpretation of what the Code allowed but stated that presumably the article would need to be signed off by corporate affairs and 'both of our medics' (presumably from UCB and Schwarz). The emails sent in July when the project was first discussed were headed 'Advertising proposal – Parkinson's Disease' supplement – The Times'. This became 'draft PD article', 'UBC [sic] Advertorial – first proof' and 'UCB Article the Times' in emails sent in August. In that regard the Panel considered that it should have been obvious that it was not draft text for a corporate press release.

The Panel noted that despite the requirements of the Code being queried several times with regard to the advertisement, each time the brand manager stated that he thought it was acceptable under the Code. No-one within the organisation, however, appeared to be prepared to confirm the brand manager's beliefs or challenge them. This demonstrated very poor control and/or knowledge of the Code. The Panel noted UCB's submission that the brand manager had not complied with company SOPs. The brand manager however, had not acted in isolation. The material had been drafted by the media relations department and seen by the brand manager and members of the medical department. Some members of staff were away when the material was finalised. It was also seen by the managing director. UCB had been badly let down by several members of staff.

The advertisement was signed off on a Schwarz

promotional material approval form. The Panel noted UCB's submission that the reviewers of the text were not told by the brand manager that payment was being made for the text to be included in The Times supplement. The Panel noted, however, that the copy approval form described the material as 'Draft article for Times PD [Parkinson's Disease] supplement', the product was 'Neupro' and the audience was 'Times readers'. In that regard the Panel considered that there was enough on the form to ring alarm bells for those reviewing the material. The form had been signed by a product manager and a member of the medical team. The Panel noted UCB's submission that 'incorrect assumptions were made in relation to [the material's] intended purpose'. This was unacceptable; no-one should review material on the basis of assumptions. The Panel considered that the advertisement promoted Keppra and Neupro to the public. 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 had demonstrated a lack of control and poor knowledge of the requirements of the Code throughout the company. 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. UCB 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.

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