

# INFORMATION PHARMACIST v UCB

## Keppra information on a nurses' website

An NHS medicines information pharmacist complained about information about Keppra (levetiracetam) on the Epilepsy Nurse Association (ESNA) website. The information was headed 'Data on Keppra v generic levetiracetam' and reproduced an email, the first paragraph of which stated 'Thank you for your request for information on the prescribing of branded Keppra (levetiracetam) vs. generic levetiracetam ...'. The letter was 'signed' by a medical information officer and a telephone number for further information was given. Keppra was marketed by UCB Pharma and was indicated for epilepsy.

The complainant queried whether it was appropriate and ethical for a company piece to be posted on an apparently independent website without being identified as such. It was only by cross-checking the telephone number that the source [ie UCB] was apparent. The material had been prepared by UCB's medical information department but was not credited to the company.

The detailed response from UCB is given below.

The Panel noted UCB's submission that the material was published without its knowledge or consent. It appeared that a UCB medical information response to what appeared to be an unsolicited enquiry from an epilepsy nurse in 2012 had been published by ENSA on its own website. The Panel noted that the request for information was originally sent to a UCB colleague who forwarded it to the author for reply. It appeared that the health professional and original UCB recipient had, at the very least, been in contact previously. It was not known whether the health professional had links with ESNA and/or intended to publish the response nor was it known whether the original UCB recipient knew of any such link/intention. However, the original recipient described the email as a medical information request from an epilepsy nurse specialist. Following a request from UCB, ENSA removed the material from its website.

The Panel considered that given the circumstances, UCB was not responsible for the publication of the information at issue and thus neither prescribing information nor a statement identifying the responsible pharmaceutical company were required. No breaches of the Code were ruled.

An NHS medicines information pharmacist complained about information he had seen about Keppra (levetiracetam) on the news page of the Epilepsy Nurse Association (ESNA) website. Keppra was marketed by UCB Pharma Ltd and was indicated for epilepsy. The information on the ESNA website was headed 'Data on Keppra v generic levetiracetam' and reproduced the body of an email, the first paragraph of which stated

'Thank you for your request for information on the prescribing of branded Keppra (levetiracetam) vs. generic levetiracetam ...'. The letter was 'signed' by a medical information officer and a telephone number for further information was given.

### COMPLAINT

The complainant queried whether it was appropriate for a company piece to be posted on an apparently independent website without being identified as such. The complainant noted that it was only by cross-checking the telephone number that the source of the document [ie UCB] was apparent. The complainant noted that the material at issue had been prepared by UCB's medical information department but was not credited to the company. The complainant did not consider that such conduct was ethical.

When writing to UCB, the Authority asked it to consider the requirements of Clauses 4.1, 9.1 and 9.10 of the Code.

### RESPONSE

UCB submitted that its records indicated that when the advice was given the medical information officer whose name appeared on the website text in question worked in the medical information team responding to unsolicited medical information queries on Keppra and generic versions. Based on the similarity of the text in UCB's medical information email response and that which appeared on the website, the text in question stemmed from an unsolicited email request for medical information from an epilepsy nurse specialist in March 2012, on switching from Keppra to generic levetiracetam. The medical information team responded the day after receiving the request. It appeared that, unknown to UCB, text from that response was subsequently extracted and published on the ESNA website without UCB's consent. The published extract from the medical information response was then read by the complainant and formed the basis of this complaint.

UCB noted that Clause 4.1 dealt with the provision of prescribing information in promotional materials. However, Clause 1.2 specifically excluded, replies made in response to individual enquires from members of the health professions from the definition of promotion. As UCB's response to an unsolicited medical information request, as evidenced by the opening statement of the text from the ESNA website and further evidenced by the job title of the responding UCB team member, fell within the exemption to Clause 1.2, UCB submitted that the email did not require prescribing information and so it denied a breach of Clause 4.1.

UCB further noted that the supplementary information to Clause 14.3 excluded written responses from medical information departments from the certification requirements. As such, the medical information response in March 2012 was not certified.

UCB noted that Clause 9.10 stated that materials relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which was sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company.

UCB stated that its response to the medical information request was sent via the company's email address and the medical information officer was clearly identified as such. Since the requester received the response the day after submitting the request to UCB, the company strongly believed that he/she was fully aware that the response was from UCB. Furthermore, UCB was not aware that the response had been extracted and posted on the ESNA website and it did not sponsor the content of this site. UCB denied a breach of Clause 9.10.

UCB noted that its response to the epilepsy nurse specialist was made in a timely manner, it was accurate at the time, did not mislead and was not promotional. The medical information officer was clearly identified and the email response was sent using UCB's email address. UCB submitted that it had maintained high standards and hence had not breached Clause 9.1.

UCB explained that on an average, it responded to between 400-500 medical information queries each month in the UK. In responding to such enquiries, it strove to adhere to compliance and other requirements as stipulated by the Code. This complaint had arisen because a medical information response addressed to an individual health professional had been published on an external website without the company's prior knowledge and consent.

UCB stated that it continued to review its processes to ensure the highest standards and since 2012, it included the following in all its responses: 'Please note that the attached literature is for your own personal use, and due to copyright may not be forwarded'. Although UCB firmly believed it was not in breach of the Code for the reasons stated above, based on this case, it had updated the statement, to read: 'Please note that UCB's response and any attached literature are for your own personal use, and due to copyright may not be forwarded/published'. Further, emailed responses were now sent as a pdf, instead of free text.

UCB noted that when it was notified of this complaint it contacted ESNA and asked it to remove the text in question from its website.

Based on the above, UCB contended that it would be unfair to rule it in breach of the Code for actions undertaken without its prior knowledge and consent.

Although UCB firmly believed it was not in breach of the Code as set out above, the additional actions undertaken after the receipt of the complaint strongly indicated that it always strove to maintain the highest standards.

## PANEL RULING

The Panel noted that the epilepsy nurse specialist's email in March 2012 asked for information or published papers on switching from Keppra to the generic version and noted that in one study 40% changed back to Keppra. In the Panel's view the email appeared to be an unsolicited request for medical information.

The Panel noted the supplementary information to Clause 1.2 Replies Intended for Use in Response to Individual Enquiries which stated, *inter alia*:

'The exemption to the definition of promotion for replies made in response to individual enquiries from members of the health professions or other relevant decision makers relates to unsolicited enquiries only. An unsolicited enquiry is one without any prompting from the company.'

The supplementary information to Clause 14.3 Examination of Other Material made it clear that such material did not need to be certified under Clause 14.

The Panel noted UCB's submission that the material on the ESNA website was published without UCB's knowledge or consent. It appeared that a UCB medical information response to what appeared to be an unsolicited enquiry in 2012 had been published by ENSA on its own website. The Panel noted that the request for information was originally sent not to the author of the response but to a UCB colleague who forwarded it to the author for reply. It appeared that the epilepsy nurse specialist and original UCB recipient had, at the very least, been in contact previously. It was not known whether the nurse had links with ESNA and/or intended to publish the response nor was it known whether the original UCB recipient knew of any such link/intention. However, the original recipient described the email as a medical information request from a health professional. Following a request from UCB, ENSA removed the material from its website.

The Panel considered that given the circumstances, UCB was not responsible for the publication of the information at issue and thus neither prescribing information nor a statement identifying the responsible pharmaceutical company were required. It ruled no breach of Clause 9.10. The Panel also ruled no breach of Clause 9.1 as UCB had not failed to maintain high standards. The Panel also ruled no breach of Clause 4.1 as there was not a specific allegation about the lack of prescribing information.

**Complaint received**      **6 August 2015**

**Case completed**        **7 September 2015**