CASE AUTH/3309/2/20

COMPLAINANT v SINTETICA

Promotion of Ampres 20mg/ml solution for injection via LinkedIn

A complainant who described him/herself as a concerned UK health professional, alleged that a LinkedIn post, placed by a senior executive of Sintetica Limited, promoted Ampres 20mg/ml solution for injection (chloroprocaine hydrochloride) to the public.

The LinkedIn post stated that the company was excited to share the important announcement that Ampres 20mg/ml had been approved for peripheral nerve blocks in Europe and the UK. It was stated that peripheral nerve blocks and regional anaesthesia provided many benefits for patients and anaesthetists.

The complainant noted that Ampres 10mg/ml was only licensed for spinal anaesthesia not peripheral.

The complainant stated that there was no evidence that the item had been certified for use and he/she was concerned about Sintetica's understanding and the robustness of its processes given that a senior executive had posted the item at issue.

The detailed response from Sintetica is given below.

The Panel noted Sintetica's submission that the senior executive's personal LinkedIn status update announcing the approval of Ampres 20mg/ml in perineural anaesthesia was accessible to his/her personal LinkedIn connections which inevitably comprised the public. Thus, in the Panel's view, the executive's LinkedIn post promoted a prescription only medicine to the public and a breach of the Code was ruled. The Panel further decided, on balance, that the post would encourage members of the public to ask their health professional to prescribe such a product and that high standards had not been maintained. Breaches of the Code were ruled.

With regard to the complainant's concern that Ampres 10mg/ml was only licensed for spinal anaesthesia not peripheral, the Panel noted that the post referred to Ampres 20mg/ml. According to the company Ampres 10mg/ml had different indications to Ampres 20mg/ml. Ampres 20mg/ml was indicated for perineural anaesthesia (peripheral nerve block) in adults for short-duration surgeries (not exceeding 60 minutes). The Panel noted Sintetica's submission that the marketing authorisation for Ampres 20mg/ml was granted on 12 February 2020, four days before the LinkedIn post was published; that the complainant was unable to immediately view the SPC for Ampres 20mg/ml was due to delays of up to 6 weeks with the eMC at times of high demand. The Panel did not consider that the LinkedIn post promoted Ampres 20mg/ml for an unlicensed indication as alleged. No breach of the Code was ruled.

The content of the post in question had not been certified for use, by the senior executive, on his/her LinkedIn account and a breach of the Code was ruled.

The Panel considered that junior employees were often keen to link to senior employees' and/or corporate accounts and/or like their postings and thus all employees should be mindful of the impression given by their social media activities. In the Panel's view, companies should give unambiguous guidance to help ensure that employees did not use social media forums in a way that was potentially within the scope of, and inconsistent with, the Code. The Panel noted Sintetica's submission that its Communications Policy was being reviewed and rewritten with a planned implementation in December 2020.

The Panel noted its comments and rulings above and considered that a senior executive placing an uncertified post on his/her LinkedIn account, thereby promoting a prescription only medicine to the public, meant that Sintetica had brought discredit upon and reduced confidence in the pharmaceutical industry; a breach of Clause 2 was ruled.

A complainant who described him/herself as a concerned UK health professional, complained about the promotion, via LinkedIn of Ampres 20mg/ml solution for injection (chloroprocaine hydrochloride) by Sintetica Limited.

The LinkedIn post at issue had been placed by a senior executive of Sintetica and stated that the company was excited to share the important announcement that Ampres 20mg/ml had been approved for peripheral nerve blocks in Europe and the UK. The post stated that peripheral nerve blocks and regional anaesthesia provided many benefits for patients and anaesthetists. The post ended with a quotation from Albert Einstein 'Any intelligent fool can make things bigger and more complex ... it takes a touch of genius and a lot of courage to move in the opposite direction'.

COMPLAINT

The complainant provided a copy of the LinkedIn post at issue, which he/she received on his/her LinkedIn page, and alleged that it promoted Ampres to the general public.

The complainant noted that, according to the Electronic Medicines Compendium (eMC) website and with reference to the summary of product characteristics (SPC) for Ampres 10mg/ml, the product was only licensed for spinal anaesthesia not peripheral.

The complainant stated that there was no evidence that the item had been certified for use (or checked and then not used since it was inappropriate for LinkedIn).

The complainant was concerned about the understanding and robustness of the processes that existed within Sintetica given that a senior executive of the UK company had posted the item at issue.

When writing to Sintetica, the Authority asked it to consider the requirements of Clauses 2, 14.2, 26.1, 26.2, 9.1 and 2 of the Code.

RESPONSE

Sintetica provided a brief background to the company and submitted that Clause 9.1 and maintaining the high standards of the British pharmaceutical industry was very important to it. The company used an established job bag system to certify promotional materials, educational materials and those intended for disease awareness campaigns.

Upholding Clause 14 was also very important. Led by a named senior employee Sintetica had a robust job bag system which was augmented by suitably qualified external consultants who provided advice and guidance from time to time. A named third party compliance consultancy had advised Sintetica since its formation in the UK and had helped the company to navigate some of its everyday challenges and remain Code compliant.

The senior employee who led the job bag system was an experienced senior employee and practising NHS clinician and was therefore able to advise on the appropriate use of medicines; he/she sat, or had sat, on a number of influential committees (details were provided).

Sintetica stated that the LinkedIn post at issue was not a corporate LinkedIn status update, but the senior executive's personal LinkedIn status update which was accessible to his/her personal LinkedIn connections. Sintetica stated that the senior executive made one LinkedIn status update to his/her personal LinkedIn connections announcing the approval of Ampres 20mg/ml solution for injection in perineural anaesthesia on 16 February 2020.

Sintetica noted that Clause 26.1 prohibited the advertising of medicines to the public. Despite the post at issue being a personal status update, it could have been liked, shared or commented upon by any of the senior executive's LinkedIn connections. Therefore, it was with deep regret that the senior executive sincerely apologised for bringing his/her personal LinkedIn status update announcing the approval of Ampres 20mg/ml solution for injection in perineural anaesthesia within the scope of Clause 26.1, because his/her personal network of connections inevitably comprised the public. This was not the senior executive's intention and he/she was deeply sorry for inadvertently enabling the dissemination of material that was not intended for the public.

Sintetica stated that before the senior executive's personal LinkedIn status update, the Medicines and Healthcare products Regulatory Agency (MHRA) granted the Marketing Authorisation for Ampres 20mg/ml solution for injection on 12 February 2020. The SPC for Ampres 20mg/ml solution for injection was provided. Ampres 20mg/ml was indicated for perineural anaesthesia (peripheral nerve block) in adults for short-duration surgeries (not exceeding 60 minutes). Ampres 10mg/ml had different therapeutic indications to Ampres 20mg/ml solution for injection.

At times of high demand, Sintetica had observed delays of up to 6 weeks with the eMC, which was normal. This explained why the complainant was unable to immediately view the SPC for Ampres 20mg/ml solution for injection.

Sintetica stated that the senior executive did not intend to disseminate information to the public or do anything to discredit, or reduce confidence in, the pharmaceutical industry. Maintaining the high standards of the industry was a fundament of Sintetica and the senior executive.

Sintetica stated that in February 2020, the senior executive crafted the wording that would be adapted in his/her personal LinkedIn status update (copy provided). Sintetica had considered

issuing a press release but chose not to do so. It was this wording that was written in the senior executive's personal LinkedIn status update.

Sintetica stated that this wording was discussed with the senior employee who led the job bag system and the company's Quality Management Team at a sign-off meeting and details were provided.

Sintetica submitted that it had not promoted Ampres 20mg/ml. The decision was taken to wait until elective surgical procedures returned to normal due to the coronavirus pandemic severely disrupting elective surgery.

Sintetica stated that, as a consequence of this complaint, its Communications Policy, including social media, originally written in June 2018, was being reviewed and rewritten; implementation of the revised policy was planned for December 2020. The company was also in discussions with a third party compliance consultancy to deliver bespoke Code compliance training and support to its senior leadership team, head office staff and in-field staff. The training would be logged.

Sintetica stated that taking corrective action and preventative action was very important to the company and it was fully committed to remedying this and taking remedial action to prevent anything like this happening again. Details of the internal reporting process was given.

PANEL RULING

The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. LinkedIn was a business and employment-oriented network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment interests. The Panel considered that company employees ought to be cautious when using social media in areas which impinged on their professional role or the commercial interests of their company. In the Panel's view, pharmaceutical companies needed to be mindful that employees use of personal LinkedIn accounts might potentially come within the scope of the Code. The Code would not automatically apply to all activity on a personal LinkedIn account; whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, *inter alia*, content, dissemination and who had posted the material. Companies' social medial policies should address such matters.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 stated that information about prescription only medicines which was made available either directly or indirectly to the public must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted Sintetica's submission that the senior executive's personal LinkedIn status update announcing the approval of Ampres 20mg/ml solution for injection in perineural anaesthesia was accessible to his/her personal LinkedIn connections which inevitably comprised the public. Thus, in the Panel's view, that employee's LinkedIn post promoted a prescription only medicine to the public and a breach of Clause 26.1 was ruled. The Panel considered that the type of medicine might be relevant when deciding whether there was a breach of Clause 26.2 and decided on balance that the post in question would encourage

members of the public to ask their health professional to prescribe such a product; a breach of Clause 26.2 was ruled. The Panel considered that this meant that Sintetica had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted the complainant's concern that according to the Ampres 10mg/ml SPC on the eMC website the product was only licensed for spinal anaesthesia not peripheral.

The Panel noted that the post referred to Ampres 20mg/ml and noted Sintetica's submission that Ampres 10mg/ml solution for injection had different therapeutic indications to Ampres 20mg/ml solution for injection. Ampres 20mg/ml solution for injection was indicated for perineural anaesthesia (peripheral nerve block) in adults for short-duration surgeries (not exceeding 60 minutes). The Panel noted Sintetica's submission that the marketing authorisation for Ampres 20mg/ml was granted on 12 February 2020 which was four days before the LinkedIn post was published but the complainant was unable to immediately view the SPC for Ampres 20mg/ml due to delays of up to 6 weeks with the eMC at times of high demand. The Panel did not consider that the LinkedIn post regarding Ampres 20mg/ml solution for injection promoted it for an unlicensed indication as alleged. The Panel noted that Sintetica had not been asked to respond to Clause 3.2 of the Code and thus the Panel considered this matter under Clause 9.1. No breach of Clause 9.1 was ruled in this regard.

The Panel noted Sintetica's submission that wording crafted by the senior executive that would be adapted in his/her personal LinkedIn status was discussed at a sign-off meeting with the senior employee who led the job bag system and the company's Quality Management Team. Sintetica had considered issuing a press release but chose not to do so and it was this wording that was written in the senior executive's personal LinkedIn status update. The Panel noted that Clause 14.2 had been raised which covered the certification of meetings involving travel outside the UK. The Panel did not consider that this clause was relevant in relation to the matters alleged and it therefore ruled no breach of Clause 14.2. The Panel, however, did not consider that the content of the post in question had been certified for use, by the senior executive, on his/her LinkedIn account and the Panel therefore ruled a breach of Clause 9.1.

The Panel considered that junior employees were often keen to link to senior employees' and/or corporate accounts and/or like their postings and thus all employees should be mindful of the impression given by their social media activities. In the Panel's view, companies should give unambiguous guidance to help ensure that employees did not use social media forums in a way that was potentially within the scope of, and inconsistent with, the Code, particularly Clause 26. The Panel noted Sintetica's submission that its Communications Policy, including social media, originally written in June 2018, was being reviewed and rewritten; implementation of the revised policy was planned for December 2020.

The Panel noted its comments and rulings above and considered that a senior executive placing an uncertified post on his/her LinkedIn account, thereby promoting a prescription only medicine to the public, meant that Sintetica had brought discredit upon and reduced confidence in the pharmaceutical industry; a breach of Clause 2 was ruled.

Complaint received **16 February 2020**

Case completed **19 November 2020**