

COMPLAINANT v SHIONOGI EUROPE

Promotion of Fetcroja on LinkedIn

A complainant who described him/herself as a concerned UK health professional, complained that two postings on LinkedIn by Shionogi Europe, a UK based company, promoted Fetcroja (cefiderocol).

The first posting, which the complainant alleged was pre-licence promotion and promotion to the public, was headed 'Great news for patients from the Committee for Medicinal Products for Human Use (CHMP). Please see the link'. Below a graphic was the statement 'Fetcroja Pending EC decision - European Medicines Agency'. The second posting, which the complainant alleged was promotion to the public, stated 'Fantastic news! We are pleased to announce that our new antibiotic Fetcroja (cefiderocol) has received a marketing authorization for the treatment of infections due to aerobic gram-negative bacteria in adults'. The complainant noted that both posts included hashtags which ensured that they would be seen by people who did not follow the company.

The complainant queried whether the advertisements had been appropriately reviewed; as, this was not a small oversight but either the absence of any internal controls and/or a complete lack of understanding of how to undertake activities in the UK.

The detailed response from Shionogi Europe is given below.

The Panel noted that both of the Shionogi Europe LinkedIn posts at issue referred positively ('Great news', 'Fantastic news!') to Fetcroja.

The Panel noted that the Shionogi Europe Social Media Policy applied to employees' use of social media whether for business or personal purposes. The policy set out some 'common-sense guidelines and recommendations for using social media responsibly and safely'. Readers were told to remember that posting certain information about Shionogi Europe's products might breach laws and regulations governing the promotion of medicines and such posts should be avoided unless he/she was an official Shionogi Europe spokesperson. There were no examples of what the 'certain information' might be. The Shionogi Europe IT Policy stated that nominated staff would be given permission to represent Shionogi Europe on certain social media platforms for business purposes and advised readers that if they were unsure about the appropriateness of any social media content, they should discuss it with their line manager etc before posting.

The job description of the relevant employee stated that he/she would be responsible for, *inter alia*, managing the company's presence on appropriate social media. The Panel noted Shionogi Europe's submission about the responsibilities, experience and competencies stated in the job description. There was, however, no requirement for that employee to know about industry codes of practice. Although both the employee who posted the LinkedIn material, and his/her line manager with whom he had/she had

discussed it, had been trained on the social media and IT policies, the Panel had no information before it as to whether they had been trained on the UK Code.

The Panel considered that the Shionogi Europe LinkedIn posts would be read by a wide range of people including members of the public. Both posts referred positively to Fetcroja. The Code prohibited the promotion of a prescription only medicine to the public and that statements must not be made to encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted, however, that when the CHMP Update was posted, Fetcroja was not licensed and so it was not classified as a prescription only medicine. The relevant clauses of the Code only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of the Code with regard to the first LinkedIn post. The Panel considered, however, that the marketing authorization update post with its announcement of 'Fantastic news!' promoted a prescription only medicine to members of the public and would encourage them to ask their health professional to prescribe it. Breaches of the Code were ruled as acknowledged by Shionogi Europe.

The Panel noted that the CHMP Update, which referred to 'Great news for patients', was posted before Fetcroja had received a marketing authorization and so in that regard it promoted a medicine prior to the grant of a marketing authorization; a breach of the Code was ruled as acknowledged by Shionogi Europe.

The Panel ruled a further breach as it considered that high standards had not been maintained as acknowledged by Shionogi Europe.

With regard to Clause 2, the Panel noted that the person who posted the material had, according to standard company process, permission to represent Shionogi Europe and use LinkedIn for business purposes and had discussed the matter with his/her line manager. The Panel was extremely concerned that, despite the use of a product name and language such as 'Great news' and 'Fantastic news!', Shionogi Europe had submitted that neither employee had considered the material in relation to the requirements of the Code; in the Panel's view this demonstrated either a complete lack of awareness of the Code or an extremely poor understanding of its application. The Panel noted its comments and concerns above and considered that Shionogi Europe 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 that postings on LinkedIn by Shionogi Europe, a UK based company, promoted Fetcroja (cefiderocol) (both unlicensed and licensed) to the public. The first posting was headed 'Great news for patients from the Committee for Medicinal Products for Human Use (CHMP). Please see the link'. There were hashtags for healthcare, patients, antibiotics, antibiotic resistance and antimicrobial resistance. Below a graphic was the statement 'Fetcroja Pending EC decision - European Medicines Agency'. The second posting stated 'Fantastic news! We are pleased to announce that our new antibiotic Fetcroja (cefiderocol) has received a marketing authorization for the treatment of infections due to aerobic gram-negative bacteria in adults.' and included hashtags such as antibiotic, antibiotic resistance, infection, infectious disease and bacteria.

Fetcroja was indicated in patients 18 years of age or older who had limited or no alternative treatment options for the treatment of complicated urinary tract infections.

COMPLAINT

The complainant alleged that the first post was pre-licence promotion and promotion to the general public and the second post was promotion to the general public. The complainant noted that both posts included hashtags which ensured that the posts would be seen by many people who had not even followed the company.

The complainant queried whether the advertisements had been appropriately reviewed and stated that, in his/her view, this was not a small oversight but either the absence of any internal controls and/or a complete lack of understanding of how to undertake activities in the UK.

When writing to Shionogi Europe, the Authority asked it to consider the requirements of Clauses 3.1, 9.1, 26.1, 26.2 and 2 of the Code.

RESPONSE

Shionogi Europe referred to the first post at issue on its EU LinkedIn account as the CHMP update and the second post as the marketing authorization update.

Shionogi explained that the Shionogi EU LinkedIn account was initially set up approximately 5 years ago to provide an on-line presence for Shionogi Europe as an employer within Europe and to attract candidates to the company's job opportunities. A limited number of members of staff had administrative rights to that account (details provided).

Shionogi Europe submitted that its social media policy (copy provided) was very clear on what was and what was not appropriate activity for LinkedIn. In relation to posts which referred to medicines, the policy clearly stated: 'Always remember that publicly posting certain information about Shionogi Europe's products might breach laws and regulations governing the promotion of medicines and such posts should therefore be avoided'. The Shionogi Europe IT policy (copy provided) further reinforced that individuals should adhere to legal and regulatory requirements and stated: 'if you are unsure about the appropriateness of any proposed social media content, refrain from posting it until you have discussed it with your line manager or [a specified senior executive]'.

Shionogi Europe stated that the Social Media Policy formed part of the mandatory induction training for all staff. The member of staff who posted the material completed training in the company's learning management system on the social media policy referred to above, as did his/her line manager. Details were provided including the dates of the posts in 2020. It was regrettable, therefore, that despite company policy to the contrary, the two updates at issue had been posted.

Shionogi Europe provided a copy of the job description for the employee who had posted the updates and noted that one of his/her responsibilities was management of relevant social media profiles and website pages and such experience was essential (details provided). Thus, it was very clear that the employee was expected to have significant experience in the use of social media within the pharmaceutical industry and to be capable of working independently as such.

Shionogi Europe understood that the intention of posting the information was to attract candidates to the LinkedIn page by re-posting company news that had already been shared on the Shionogi Europe corporate website and European Medicines Agency (EMA) website. The standard process for posting updates to this account was for the employee and his/her line manager to discuss whether the information was in the public domain and suitable to be posted to LinkedIn. Whilst it was made clear to the line manager that the intention was for the updates

to be posted on LinkedIn, it appeared that neither the line manager nor the employee considered the updates in relation to the requirements of the Code and so both posts were added to the Shionogi Europe LinkedIn account.

In conclusion, Shionogi Europe submitted that despite its swift action (as documented below), it recognised that the actions taken by certain individuals had resulted in breaches of the Code.

Post 1 – the CHMP Update. At the time of posting Fetroja did not have a marketing authorization, therefore this post constituted pre-licence promotion of a medicine, in breach of Clause 3.1. Shionogi Europe acknowledged that posting such information about a medicine on social media amounted to a failure to adhere to the company's social media policy and maintain high standards, in breach of Clause 9.1.

Post 2 – the marketing authorization update. At the time of posting, Fetroja had received a marketing authorization, thus Shionogi Europe acknowledged that the post promoted a prescription only medicine to the public, in breach of Clause 26.1 and might have encouraged members of the public to ask their health professional to prescribe a specific medicine, in breach of Clause 26.2.

Shionogi Europe stated that on being notified of this complaint, it immediately (on the same day) deleted the posts from LinkedIn and a company-wide communication was issued in relation to the matter (copy provided). As part of its investigation the company had discovered that a number of Shionogi Europe staff had liked/shared the posts (not all these staff members were based in the UK); deletion of the updates had also deleted them from each individual's LinkedIn feed.

Shionogi Europe stated that it was very disappointed that these actions were in direct contradiction to the company's social media policy, which was freely available to all staff on the company standard operating procedure repository. As part of preventative action, all relevant staff were retrained on social media and the Code requirements in May 2020. The company stated that it planned to review and revise the social media policy, taking into account the learnings from this case. That would be trained out to all staff with appropriate validation of knowledge in order to ensure their comprehensive understanding of how to appropriately use social media platforms.

In summary, Shionogi Europe accepted breaches of Clauses 3.1, 26.1 and 26.2. The company considered that the conduct of certain individuals amounted to a failure to maintain high standards, in breach of Clause 9.1. Given the circumstances, Shionogi Europe could also understand why the Panel might want to consider the requirements of Clause 2. However, Shionogi Europe noted the similarity with Case AUTH/2455/11/11. In that case, the Panel noted that the company had in place a policy that, had it been followed by a member of staff, would have prevented inappropriate use of social media, and ruled no breach of Clause 2.

PANEL RULING

The Panel noted that LinkedIn was a business and employment-oriented platform used mainly for professional networking. In the Panel's view, it was not unacceptable for pharmaceutical companies to use LinkedIn accounts although they needed to be mindful of the numerous compliance issues that might arise. The Panel considered that companies should assume that the Code would apply to all of its LinkedIn posts unless, for very clear reasons, it could be shown otherwise; whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances. The content of posted material would be a crucial

factor. The Panel noted that both of the Shionogi Europe LinkedIn posts at issue referred positively ('Great news', 'Fantastic news!') to Fetcroja.

The Panel noted that the Shionogi Europe Social Media Policy applied to employees' use of social media whether for business or personal purposes. Section 5 of the policy set out some 'common-sense guidelines and recommendations for using social media responsibly and safely'. Readers were told to 'always remember that publicly posting certain information about Shionogi Europe's products might breach laws and regulations governing the promotion of medicines and such posts should therefore be avoided unless you are an official Shionogi Europe spokesperson authorized for this purpose'. Readers were not, however, given any examples of what the 'certain information' might be. The Shionogi Europe IT Policy stated 'Use of WhatsApp, Twitter, Facebook and LinkedIn: Nominated staff, depending on their job description and job requirements, will be given permission to represent Shionogi Europe and use these applications and websites for business purposes' and advised readers, in section 6.3 about social media, that if they were unsure about the appropriateness of any social media content, they should refrain from posting it until they had discussed the matter with their line manager or a specified senior manager. Both policy documents stated that 'In general, we suggest you approach online worlds in the same way as the physical world – by using good judgement and common sense'. As both documents set out European policy, neither referred specifically to the ABPI Code but instead just referred generally to local requirements and so, in the Panel's view, UK staff did not have clear, comprehensive social media/IT guidance to aid compliance with the Code. Given the difficulties which could arise with regard to the use of social media, in the Panel's view, companies should give unambiguous guidance to help ensure that such forums were not used by employees in a way that was potentially within the scope of and inconsistent with the Code, particularly Clause 26.

The job description of the employee who had posted the LinkedIn material stated that the employee would be responsible for, *inter alia*, managing the company's presence on appropriate social media. The Panel noted Shionogi Europe's submission about the responsibilities, experience and competencies stated in the job description. There was, however, no requirement for that employee to have any knowledge about industry codes of practice. Although the employee who posted the LinkedIn material, and his/her line manager with whom he had/she had discussed it, had been trained on the social media and IT policies, the Panel had no information before it as to whether they had been trained on the UK Code.

The Panel considered that the Shionogi Europe LinkedIn posts would be read by a wide range of people including, on the balance of probabilities, members of the public. Both of the posts in question referred positively to Fetcroja. The Panel noted that Clause 26.1 prohibited the promotion of a prescription only medicine to the public and Clause 26.2 stated that statements must not be made to encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The Panel noted, however, that when the CHMP Update was posted, Fetcroja was not licensed and so it was not classified as a prescription only medicine. Clauses 26.1 and 26.2 only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code with regard to the first LinkedIn post. The Panel considered, however, that the marketing authorization update post with its announcement of 'Fantastic news!' did promote a prescription only medicine to members of the public and would encourage them to ask their health professional to prescribe it. Breaches of Clause 26.1 and 26.2 were ruled as acknowledged by Shionogi Europe.

The Panel noted that the CHMP Update, which referred to 'Great news for patients', was posted before Fetcroja had received a marketing authorization and so in that regard it promoted a

medicine prior to the grant of a marketing authorization; a breach of Clause 3.1 was ruled as acknowledged by Shionogi Europe.

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

With regard to Clause 2, the Panel noted Shionogi Europe's reference to Case AUTH/2455/11/11 but considered that the circumstances of that case were entirely different to this. In Case AUTH/2455/11/11 a company employee had sent a Tweet in error without the knowledge or authority of the company. Conversely, in this case, the social media posts were made with the knowledge and authority of Shionogi Europe; the company's social media policy appeared to allow public posting of certain information about Shionogi Europe's products by an employee who was an official Shionogi Europe spokesperson authorized for this purpose. The Panel noted that the person who ultimately posted the material on LinkedIn had, according to standard company process, permission to represent Shionogi Europe and use LinkedIn for business purposes and had discussed the matter with his/her line manager. The Panel was extremely concerned that, despite the use of a product name and language such as 'Great news' and 'Fantastic news!', Shionogi Europe had submitted that neither employee had considered the material in relation to the requirements of the Code; in the Panel's view this demonstrated either a complete lack of awareness of the Code or an extremely poor understanding of its application by both employees. The Panel noted that activities likely to be in breach of Clause 2 were promotion prior to the grant of a marketing authorization and conduct of employees which fell short of competent care. The Panel noted its comments and concerns above and considered that Shionogi Europe had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case, the Panel was concerned to note that, as part of its investigation, the company had discovered that a number of Shionogi Europe staff had liked/shared the posts, some of whom appeared to be based in the UK. The Panel noted that, according to the social media policy, employees could like/share/repost, without amendment, any social media post that has been publicly posted on social media by an official Shionogi Europe spokesperson who was authorised to post on behalf of the local Shionogi Europe entity. The Panel was mindful of the complex issues that had to be addressed by companies when advising staff about social media use. The increasing use of social media, both in the personal and business capacity, presented compliance challenges. In the Panel's view, employees might feel inclined to endorse posts which related to their company and, depending on the content, such activity might or might not fall within the scope of the Code and thus all employees should be mindful of the impression given about the acceptability of matters posted. It was therefore critical that companies provided clear and tailored guidance for employees which was regularly reviewed.

Complaint received **4 May 2020**

Case completed **24 July 2020**