

**CASE AUTH/3726/1/23**

**COMPLAINANT v UCB**

**Alleged promotion of Fintepla (fenfluramine) on LinkedIn**

**CASE SUMMARY**

This case was in relation to a LinkedIn post shared by a UCB employee based in Germany and liked by a senior UK employee. The post stated ‘Hope for patients with Lennox-Gastaut Syndrome!’ and included a linked article on a third party website titled ‘Epilepsia Publishes Interim Results of Open-Label Extension Study of FINTEPLA (fenfluramine) Oral Solution in Patients with Lennox-Gastaut Syndrome (LGS)’.

The outcome under the 2021 Code was:

<b>Breach of Clause 3.2</b>	<b>Advertising a prescription only medicine to the public</b>
<b>Breach of Clause 3.6</b>	<b>Disguised promotion</b>
<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>Breach of Clause 11.2</b>	<b>Promotion of a medicine outside the terms of its marketing authorisation</b>

**This summary is not intended to be read in isolation.  
For full details, please see the full case report below.**

**FULL CASE REPORT**

A complaint was received from an anonymous, non-contactable complainant that described themselves as a UK doctor about a LinkedIn post from UCB Pharma Ltd.

**COMPLAINT**

The complainant stated that they were a UK doctor in general medicine. They had gone onto their LinkedIn account and were scrolling and saw the post from a named UCB employee. The post was for a treatment Fintepla for Lennox-Gastaut Syndrome (LGS). LGS was not licenced in the UK so this was allegedly inappropriate promotion of the medication. The complainant stated they were also shown this by a medical student and a patient and felt this type of underhand promotion should not be allowed. The complainant provided a copy of screenshots for the LinkedIn article and the link to the article. The complainant stated that the post had been liked by many non-medical people and was viewed on 6 December 2022.

When writing to UCB, the Authority asked it to consider the requirements of Clauses 3.2, 3.6, 5.1 and 11.2 of the Code.

**RESPONSE**

UCB stated that the company were committed to compliance with the Code. UCB expected its employees to maintain high standards at all times and respected the requirements of the Code in the spirit and the letter.

### **Response to the complaint**

UCB stated that the LinkedIn post in question originated in Germany by a UCB employee in a global role based in Germany. The post linked an article from a UCB press release for the US market, which was distributed over the US PR Newswire to media in that market. The article was reviewed and approved in the US in line with UCB's internal approval processes and US regulations and submitted to The Office of Prescription Drug Promotion (OPDP), the US governing body for branded promotional materials.

The LinkedIn post itself was not an official authorised UCB post. The LinkedIn post was assessed as out of scope of the Code as the employee was not a resident in the UK and not employed by any UCB UK affiliate. The linked article was not published in the UK nor created for a UK audience.

UCB stated that in its commitment to the Code principles, the complaint was shared with the European and German compliance teams for corrective and preventative actions as per local German requirements and guidelines. The Germany-based employee had since confirmed that the post had now been deleted.

As the LinkedIn post originated outside of the UK and referenced an article for the US market, it was UCB's understanding that Clauses 3.2, 3.6, 5.1 and 11.2 did not apply in this instance. UCB therefore denied all breaches of the Code in relation to the complaint.

Over the past 12 months, significant efforts had been invested in UCB to further strengthen the governance framework and guidance with regard to use of social media, including, but not limited to, a UK-specific social media policy, mandatory training in the UK on the local policy, regular monitoring of training completion, live training for all new starters and repeated communications on the topic. UCB therefore denied a breach of Clause 5.1.

### **Voluntary admission**

UCB stated that whilst it believed that the post itself was out of scope of the Code, the company did discover, during the investigation of the complaint, that one UCB UK employee 'liked' the post from their personal LinkedIn account. The endorsement ('like') of the LinkedIn post by the individual UCB employee was against the UK and Ireland social media Policy regarding personal use of social media. The employee acted without UCB's instruction, permission or prior knowledge, but of their own accord.

The complaint was dated 6 December 2022, with the attached LinkedIn post showing the post was made one week before. Based on UCB's understanding of LinkedIn timelines, the post was most likely made between 23 and 29 November 2022. The UK-based employee would have 'liked' the post subsequently. Training records showed that the UK employee had successfully completed the local social media training at this time and that the company could reasonably expect that they would have had an understanding at the time of the 'like' that this was in violation of company policy. UCB took rapid action to have the post removed by the

Germany-based employee, thereby also removing the 'like', and addressing the policy non-compliance with the UK-based employee, who would also have additional training and the action filed on their employee record.

The employee was senior and had a global development role with no direct reports. The employee was not a representative, as defined by the ABPI Code, of UCB and, as such, their role did not include or permit them to promote UCB products, nor were they an official spokesperson of UCB. The employee had approximately 600 followers, the majority of which were based outside of the UK. Approximately 65% of followers were health professionals and 35% members of the public.

UCB stated that it recognized that the endorsement of the post by the UK-based employee was not appropriate and might have, inadvertently, alerted the UK general public to research being conducted into the use of FINTEPLA (fenfluramine) as a possible treatment for LGS. As of the time of the LinkedIn post, FINTEPLA (fenfluramine) was not approved for the treatment of LGS in the UK but was an approved prescription-only medicine for the treatment of Dravet syndrome.

UCB therefore voluntarily admitted that the action by the UK-based employee was not in line with Clauses 3.2 and 11.2 of the Code.

#### **Further details relating to specific clauses**

UCB stated that it had included further details below and addressed the allegations made by the complainant, considering each clause in turn.

#### **Clauses 3.2 and 11.2**

In relation to the complaint, the UCB press release for the US market predominately related to the study of FINTEPLA (fenfluramine) in relation to LGS. It was not created for, or by, the UK market. The article was clearly intended for a US audience; it noted several times that the product was approved for LGS in the US and, apart from investor relation contact details, all reporting and contact information was for the US. UCB believed that it was clear to readers that the article did not relate to the use of FINTEPLA in the UK. Towards the end of the main body of the article there was explicit mention that the product was approved in Europe for Dravet syndrome, which was in line with the GB marketing authorisation.

UCB stated that it considered Clauses 3.2 and 11.2 did not apply as this was not a UK company-endorsed post, UK press release or authorised action by a UK company spokesperson or representative.

As noted above, UCB voluntarily admitted that the requirements of Clauses 3.2 and 11.2 had not been met by the UK-based employee 'liking' the post.

#### **Clause 3.6**

The US press release and the German employee LinkedIn post were not intended, or created, for the UK market. Through the unauthorised actions by the UK-based employee liking the post, UCB acknowledged that UK health professionals and members of the public might have inadvertently been made aware of the study. It was clear to readers viewing the press release that the article related to a UCB medicine and included details of the approved European

indication. In this regard, UCB did not believe that the content was disguised and therefore denied a breach of Clause 3.6.

### **Clause 5.1**

As a company, UCB took compliance with the Code extremely seriously and expected its employees to maintain high standards at all times and respect the requirements of the Code in the letter and the spirit. UCB recognised the need to act compliantly in the evolving digital environment in which UCB were operating. Over the past 12 months, in line with the company's undertaking, UCB had taken all possible steps to avoid instances of non-compliance and to provide comprehensive guidance to all employees with regard to the use of social media and the requirements of the Code. The policies, guidance and training explicitly prohibited interaction of any kind with posts relating to UCB products. Details were below:

- 1 **UCB's UK and Ireland Social Media Policy** – issued in September 2022 and communicated October 2022.
- 2 **Mandatory training for UK employees** – issued October 2022 and training completion monitored on a weekly basis for three months after due date. Overdue training was followed up by senior employees for anyone who had not completed training by the due date. At the close of monitoring, training completion was at 99%.
- 3 **New starter induction** – the new starter induction programme includes a dedicated session, hosted by the Ethics & Compliance team. The programme was mandatory for all new joiners regardless of their role or function.
- 4 **Communication** – multiple communications had been shared with UK staff about the importance of compliance with social media guidelines and requirements, both through written communication and at live events.

For these reasons, UCB strongly refuted a breach of Clause 5.1.

### **Subsequent actions taken by UCB**

In UCB's continuous improvement efforts and as part of the company's ongoing commitment to maintain high standards and compliance, UCB had established consequence management for anyone breaching the UK and Ireland Social Media Policy. Regular communications and training would continue and be adapted based on new guidance and as the environment evolved.

### **Summary and conclusions**

In conclusion, the LinkedIn post and press release provided were, in UCB's view, not in scope of the Code and therefore Clauses 3.2, 3.6, 5.1 and 11.2 did not apply to the materials cited in the complaint.

UCB stated that it acknowledged that the subsequent 'liking' of the post was not in line with the requirements of Clauses 3.2 and 11.2 and had taken corrective action accordingly, in line with the company's established processes.

Furthermore, UCB had invested significant efforts to establish a robust governance framework and provide appropriate guidance to company employees regarding the use of social media. UCB would continue to adapt its governance framework in line with the latest PMCPA guidance

and PMCPA cases to ensure high standards were maintained. For this reason, and those stated above, UCB strongly denied breaches of Clause 5.1.

## **PANEL RULING**

The Panel noted the LinkedIn post at issue stated 'Hope for patients with Lennox-Gastaut Syndrome!' and included a linked article on a third party website titled 'Epilepsia Publishes Interim Results of Open-Label Extension Study of FINTEPLA (fenfluramine) Oral Solution in Patients with Lennox-Gastaut Syndrome (LGS)'. The Panel noted that UCB submitted that the LinkedIn post had been shared by a UCB employee in a global role based in Germany; the post linked an article from a UCB press release for the US market, which was distributed over the US PR Newswire to media in that market. The article was reviewed and approved in the US in line with UCB's internal approval processes and US regulations and submitted to the US governing body for branded promotional materials. The LinkedIn post itself was not an official, authorised UCB post.

The Panel noted UCB's submission that, in their view, the post was not in scope of the ABPI Code as the employee was not a resident in the UK and not employed by any UCB UK affiliate. The linked article was not published in the UK nor created for a UK audience. The Panel, however, noted UCB acknowledged one senior UCB employee had 'liked' the post from their personal LinkedIn account.

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; its application was not limited to the pharmaceutical industry or to healthcare. In the Panel's view, it was, of course, not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. 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. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking. The Panel understood that if an individual 'liked' a post, it increased the likelihood that the post would appear in their connections' LinkedIn feeds, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. Company employees should assume that such activity would, therefore, potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. Whether the Code applied would be determined on a case-by-case basis, taking into account all of the circumstances including, among other things, content and distribution of the material. If an employee's personal use of social media was found to be in scope of the Code, the company would be held responsible. The Panel considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example, a link within a post, would be regarded as being part of that post.

Companies must have comprehensive and up-to-date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them. The Panel noted UCB's submission that the endorsement ('like') of the LinkedIn post by the individual UCB employee was against the UK and Ireland social media policy regarding personal use of social media. The employee acted without UCB's instruction, permission or prior knowledge, but of their own accord. The employee was not a representative, as defined by the ABPI Code, of UCB and, as such, their role did not include or permit them to promote UCB products, nor were they an official spokesperson. The Panel noted that the employee had approximately 600 followers, the majority of which were based outside of the UK, of which approximately 65% of the employee's followers were health professionals and 35% were members of the public.

The Panel considered the senior UK employee's engagement with the post would have proactively disseminated the material to the individual's LinkedIn connections in the UK, which included health professionals and members of the public, and therefore brought the LinkedIn post and associated material within the scope of the UK Code.

The Panel noted Fintepla (fenfluramine) was classified as a prescription only medicine in Great Britain (GB) and was indicated for the treatment of seizures associated with Dravet syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older when the LinkedIn post in question was posted and 'liked' by the UK employee. The Panel noted the article heading within the LinkedIn post, and the linked article, concentrated on use of Fintepla in patients with Lennox-Gastaut Syndrome; Fintepla was not licensed for use in Lennox-Gastaut Syndrome in GB at the time of the complaint and therefore Fintepla had been promoted outside of the terms of its marketing authorisation. The Panel therefore **ruled a breach of Clause 11.2 as acknowledged by UCB**. Noting the employee's connections included members of the public, to whom the content would, on balance, have been distributed to, **the Panel also ruled a breach of Clause 3.2 as acknowledged by UCB**.

The Panel noted UCB's submission that it was clear to readers viewing the press release that the article related to a UCB medicine; in this regard, the Panel based its ruling on the LinkedIn post visible. The Panel noted neither the contents of the original post by the UCB employee in Germany nor said employee's visible headline job title made any reference to UCB. Individuals for whom the post would have appeared would have had to click on the linked article to know it was a UCB medicine or click on the Germany based employee's profile to see they worked at UCB.

Clause 3.6 stated materials and activities must not be disguised promotion. The supplementary information to Clause 15.6 'Disguised Promotional Material', the wording of which closely aligned to Clause 3.6, stated, amongst other things, that promotional material must not give the impression that it is non-promotional and the identity of the responsible pharmaceutical company must be obvious.

Whilst the Panel noted that the post mentioned Fintepla, the Panel considered that it was not clear that the medicine was that of UCB. Noting its comments above, the Panel considered, on balance, the way in which Fintepla had been promoted, including being outside the terms of its marketing authorisation, without making clear there was company involvement in the post, was such that promotion had been disguised on a public platform and **a breach of Clause 3.6 was ruled**.

The Panel noted that companies were responsible for the acts and omissions of their employees; training records showed that the senior UK employee had successfully completed the local social media training at or around the time of liking the post and that the company could reasonably expect that they would have had an understanding at the time of the 'like' that this was in violation of company policy. Whilst the Panel considered UCB had been badly let down by its employee who had been trained on social media and acted contrary to UCB's instructions, the Panel, nonetheless, noted that the employee was senior and had advertised a prescription only medicine to their connections, including members of the public, in a manner which was not in accordance with the terms of its marketing authorisation. In that regard, the Panel considered high standards had not been maintained and **a breach of Clause 5.1 was ruled.**

**Complaint received**      **10 January 2023**

**Case completed**        **4 January 2024**