

CASE AUTH/3554/8/21

COMPLAINANT v UCB

Alleged promotion of Bimzelx to the public on LinkedIn

An anonymous non-contactable complainant, who described him/herself as a member of the public/media, complained about a post on LinkedIn by a named organisation regarding Bimzelx (bimekizumab), which had been ‘liked’ by a UCB Pharma Ltd employee.

Bimzelx was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

The complainant alleged that UCB UK staff were promoting a prescription-only medicine to the public on LinkedIn.

The detailed response from UCB is given below.

The Panel noted UCB’s submission that the post in question was issued by the named organisation without UCB’s instruction, permission or prior knowledge; it had not been instigated, co-developed, commissioned or supported by UCB. The Panel had no evidence before it that this organisation was a ‘third-party’ to UCB as defined in the Code.

The Panel noted that the LinkedIn post at issue, ‘liked’ by the UCB UK based employee, referred to Bimzelx having been granted approval in the European Union representing the first marketing authorisation worldwide and claimed that Bimzelx was the first approved treatment for moderate to severe plaque psoriasis that was designed to selectively and directly inhibit both IL-17A and IL-17F.

The Panel noted UCB’s submission that the EMA had granted a marketing authorisation for Bimzelx in the European Union on 20 August 2021 and from that date Bimzelx had the legal classification prescription only medicine in Northern Ireland. The MHRA granted the PLGB licence on 25 August 2021.

It was not clear to the Panel, from the screenshot of the LinkedIn post provided by the complainant, what date the post in question was made by the named organisation and what date it was ‘liked’ by the UK based UCB employee. UCB inferred that the post and the ‘like’ most probably occurred on 24 August 2021, but this could not be definitively determined.

It appeared to the Panel, on the evidence before it, that the post in question was, on the balance of probabilities, ‘liked’ by the UK based employee on 24 August 2021, one day prior to the grant of the PLGB licence on 25 August. Nonetheless, the Panel noted UCB’s

submission that on 24 August, Bimzelx was a prescription only medicine in Northern Ireland, which was part of the United Kingdom. Clause 26.1 was thus relevant.

The Panel considered that the UCB employee's 'like' and, on the balance of probabilities, proactive dissemination of information about Bimzelx on LinkedIn, including the claim 'the first approved treatment for moderate to severe plaque psoriasis that is designed to selectively and directly inhibit both IL-17A and IL-17F' meant that Bimzelx had been promoted to the public and a breach of the Code was ruled. The Panel considered that high standards had not been maintained in this regard and a breach of the Code was ruled.

The Panel noted that it was not clear from the current UCB social media policy that 'liking' a LinkedIn post might proactively disseminate the information to one's LinkedIn connections and thus was a method of 'sharing' information which according to UCB was not permitted in relation to information on UCB products.

It appeared to the Panel that whilst the employee, who appeared to have a senior role within research at UCB, had acted contrary to the company's instructions regarding social media, he/she had not completed his/her mandatory social media policy training, which at the time of his/her actions was more than a month overdue, and it was not completed until after UCB's receipt of this complaint.

It appeared to the Panel that UCB had not adequately monitored employees' completion of mandatory social media policy training. The Panel considered, noting the absence of completed social media policy training by the employee in question, that the employee's 'like' and, on the balance of probabilities, proactive dissemination of information about Bimzelx on LinkedIn to members of the UK public, particularly noting that Bimzelx was not licensed in Great Britain at the time of the activity, meant that UCB had reduced confidence in the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

An anonymous complainant who described him/herself as a member of the public/media and who could not be contacted using the details provided complained about a post on LinkedIn by a named organisation regarding Bimzelx (bimekizumab) which had been 'liked' by a UCB Pharma Ltd employee.

Bimzelx was indicated for the treatment of moderate to severe plaque psoriasis in adults who were candidates for systemic therapy.

COMPLAINT

The complainant alleged that UCB UK staff were promoting a prescription-only medicine to the public on LinkedIn. The complainant provided a copy of the LinkedIn post, which was made by the named organisation, and above which was stated '[name] likes this'.

The LinkedIn post at issue stated:

'Congratulations to UCB on the first approval of bimekizumab!

UCB's BIMZELX® (bimekizumab) has been granted an approval in the European Union, representing the first marketing authorization worldwide. BIMZELX is the first approved treatment for moderate to severe plaque psoriasis that is designed to selectively and directly inhibit both IL-17A and IL-17F. [link]#mabs.'

When writing to UCB, the Authority asked it to consider the requirements of Clauses 26.1, 5.1 and 2 of the 2021 Code.

RESPONSE

UCB submitted that as a company it was committed to compliance with the Code. UCB expected its employees to maintain high standards at all times and respect the requirements of the Code in the spirit and the letter.

The post in question had been issued by a third party, independently, without knowledge or instruction by UCB. It was first brought to UCB's attention via the complaint letter.

UCB submitted that the post itself related to approval of Bimzelx (bimekizumab) by the European Marketing Agency (EMA) for use in the European Union. At the time of the post, the marketing authorisation in the United Kingdom (UK) for Bimzelx (bimekizumab) was pending the decision of the Medicines and Healthcare products Regulatory Agency (MHRA). UCB submitted that the product was therefore not legally classed as prescription only medicine in the UK.

UCB submitted that whilst it recognised that the endorsement of the post by the UK-based employee was not appropriate and might have, inadvertently, alerted the general public to the fact that Bimzelx had been granted a marketing authorization (MA) in Europe, it was important to note that the post did not relate to a product available in the UK at the time. Therefore, UCB considered that Clause 26.1 did not apply.

UCB submitted that the endorsement ('like') of the LinkedIn post by the individual UCB employee was against the company policy regarding personal use of social media. The employee acted without UCB's instruction, permission or prior knowledge.

UCB stated that over the past 18 months significant efforts had been invested in UCB to strengthen the governance framework and guidance with regard to the use of social media. Although UCB recognised that continuous efforts were needed on its side to ensure the principles and guidance in its policies were further embedded and consistently applied, it denied breaches of Clauses 5.1 and 2.

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

Clause 26.1

UCB submitted that the post was issued by a third party without UCB's instruction, permission or prior knowledge. It had not been instigated, co-developed, commissioned or supported by UCB as a company.

The third party was a United States based organisation which was an international association representing individuals and organizations involved in antibody-related research and development. The extent of the relationship between UCB and this organisation was limited to corporate membership, in return for which UCB received standard benefits available to all other corporate members, which included multiple other pharmaceutical companies.

UCB submitted that the post related to the approval of Bimzelx (bimekizumab) by the EMA. It did not refer to, nor apply to, availability of the medicine in the UK. The post was issued, and subsequently endorsed, by a UK-based UCB employee prior to grant of the marketing authorisation in the UK by the MHRA. For reference, the EMA had granted marketing authorisation for use of Bimzelx in European Union on 20 August 2021, the MHRA had confirmed their decision on 25 August 2021.

The subsequent endorsement by the UK-based company employee was done independently, without prior knowledge or instruction by the company. The employee's actions had contravened the company standards reflected in the UCB Social Media policy. After receiving the complaint, as a corrective action, the employee had removed the 'like' from the post.

Considering the post related to availability of the treatment in Europe and not the UK, UCB did not believe Clause 26.1 would apply in this instance and it denied a breach of the Code.

Clause 5.1 and 2

UCB submitted that as a company, it took compliance with the ABPI Code extremely seriously, it 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 it was operating in and over the past 18 months it had implemented initiatives intended to provide direction and appropriate guidance to all employees, with regard to the use of social media and the requirements of the Code. The policies and guidance explicitly prohibited interaction of any kind with posts relating to UCB products. UCB provided more details below:

- 1 **Social Media guidance** – issued in March 2020 pending revision of the Social Media policy communicated to all UK-based employees via email and endorsed by the Senior Leadership.
- 2 **Revised new starter induction** – the new starter induction programme had been revised to include a dedicated session, hosted by the Ethics & Compliance (E&C) team. The new programme commenced in March 2020 and was mandatory for all new joiners regardless of their role or function.
- 3 **Social Media policy** – UCB Social Media policy had been revised to reflect changes in the environment, a new version was released in June 2021. The training (with minimum annual refresher) on the policy was mandatory for all employees.

For these reasons, UCB strongly refuted breaches of Clauses 5.1 and 2.

Subsequent actions taken by UCB

UCB submitted that in light of the complaint and as part of its ongoing commitment to maintain high standards and compliance, it had taken the opportunity to re-emphasise its existing practices and it would take the following actions:

- A reminder communication to all employees to reinforce the Social Media policy standards completed with Senior leadership reinforcement messages.
- A refresher training on the Social Media policy for all UK-based employees to be hosted in Q1 2022; as previously the training would include case study examples illustrating application of the Code. Training completion would be monitored by the E&C team and a failure to complete within the required timeline would be escalated to the management, as appropriate.

Summary and conclusions

In conclusion, UCB submitted that the post was issued prior to grant of marketing authorisation in the UK, therefore UCB believed Clause 26.1 did not apply on these grounds.

Furthermore, UCB submitted that it had invested significant efforts to establish a governance framework and provide appropriate guidance to company employees regarding the use of social media. Although it recognised continuous efforts and awareness were needed to ensure good understanding and consistent application of the standards defined in UCB's policies, it did not believe it had failed to maintain high standards or brought discredit upon the industry in this instance. UCB strongly denied breaches of Clauses 5.1 or 2.

Request for further information from the Panel

Following a request for further information, UCB submitted that, in relation to dates and times, LinkedIn did not provide either a date or time stamp for posts or 'likes', therefore the exact time of the post or the employee 'liking' the post could not be established. The employee in question had since removed the 'like' as part of UCB's corrective action. The UCB press article announcing EU Commission approval of Bimzelx was published on 24 August 2021, at 06:00 British Summer Time. The named organisation published a related article on its own site on 24 August 2021. The time of publication was not indicated. UCB stated that it inferred that the post and the 'like' most probably occurred on 24 August 2021, but this could not be definitively determined.

UCB provided the job title of the employee in question at the time of the post. UCB submitted that social media guidance was issued to all employees in March 2020. Training for the revised social media policy was assigned to the employee who 'liked' the LinkedIn post at issue at the beginning of June 2021. This training was mandatory with an expected completion date at the beginning of July 2021. Upon identification of the issue in mid-November 2021, it was directly addressed with the employee for corrective and preventative actions. The employee completed the training at the beginning of December 2021. UCB submitted that to improve training monitoring, Ethics & Compliance would oversee regular monitoring on training completion of social media.

In relation to legal classification in Northern Ireland, UCB submitted that Bimzelx in Northern Ireland was a prescription only medicine from 20 August 2021, when the European Commission granted the authorisation. The 25 August 2021 approval referred to the grant of the PLGB licence, which was only applicable in the territory of Great Britain and did not include Northern Ireland.

PANEL RULING

The Panel was not an investigatory body as such; it made its rulings on the evidence provided by both parties noting that the complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel noted UCB's submission that the post in question was issued by the named organisation without UCB's instruction, permission or prior knowledge; it had not been instigated, co-developed, commissioned or supported by UCB. The Panel had no evidence before it that this organisation was a 'third-party' to UCB as defined in Clause 1.24 of the 2021 Code. It appeared to the Panel, on the evidence before it, that the extent of the relationship between UCB and the organisation in question was limited to corporate membership, in return for which UCB received standard benefits available to all other corporate members.

Nonetheless, the Panel noted UCB's submission that a UK based employee had 'liked' the post at issue.

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. 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 his/her 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. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. 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 that the LinkedIn post at issue, posted by the named organisation, and 'liked' by the UCB UK based employee, referred to Bimzelx having been granted approval in the European Union which represented the first marketing authorisation worldwide and claimed that Bimzelx was the first approved treatment for moderate to severe plaque psoriasis that was

designed to selectively and directly inhibit both IL-17A and IL-17F. The post included a link; the Panel did not have before it the content of what was accessible from that link and UCB made no submission in that regard.

The Panel noted UCB's submission that the EMA had granted a marketing authorisation for Bimzelx in the European Union on 20 August 2021 and the MHRA had confirmed its decision on 25 August 2021. The Panel further noted UCB's submission that in relation to legal classification in Northern Ireland, Bimzelx was a prescription only medicine from 20 August 2021, when the European Commission granted the authorisation. The 25 August 2021 approval referred to the grant of the PLGB licence, which was only applicable in the territory of Great Britain.

It was not clear to the Panel, from the screenshot of the LinkedIn post provided by the complainant, what date the post in question was made by the named organisation and what date it was 'liked' by the UK based UCB employee.

In this regard, the Panel noted UCB's submission that the UCB press article announcing EU Commission approval of Bimzelx was published on 24 August 2021, at 06:00 British Summer Time. The named organisation published a related article on its own site on 24 August 2021; the time of publication was not indicated. UCB inferred that the post and the 'like' most probably occurred on 24 August 2021, but this could not be definitively determined.

It appeared to the Panel, on the evidence before it, that the post in question was, on the balance of probabilities, 'liked' by the UK based employee on 24 August 2021, one day prior to the grant of the PLGB licence on 25 August. Nonetheless, the Panel noted UCB's submission that on 24 August, Bimzelx was a prescription only medicine in Northern Ireland, which was part of the United Kingdom.

The Panel noted that Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. Once the marketing authorisation had been granted, Clause 26.1 prohibited the promotion of a prescription only medicine to the public.

The Panel considered that as Bimzelx was a prescription only medicine in Northern Ireland on the day the post in question was 'liked' by the UK based employee, for the purposes of the Code which covered the UK including Northern Ireland, Clause 26.1 was relevant.

The Panel considered that in 'liking' the LinkedIn post at issue, the UK based employee had, on the balance of probabilities, proactively disseminated the information to his/her LinkedIn connections. The Panel did not know how many connections on LinkedIn the employee in question had and what their professional status was; UCB made no submission in that regard. On the balance of probabilities, not all of the employee's connections on LinkedIn would meet the Code's definition of a health professional or other relevant decision maker and therefore the information had likely been made available to members of the public.

The Panel considered that the UCB employee's 'like' and, on the balance of probabilities, proactive dissemination of information about Bimzelx on LinkedIn, including the claim 'the first approved treatment for moderate to severe plaque psoriasis that is designed to selectively and directly inhibit both IL-17A and IL-17F' meant that Bimzelx had been promoted to the public and a breach of Clause 26.1 was ruled. The Panel considered that high standards had not been maintained in this regard and a breach of Clause 5.1 was ruled.

The Panel noted that UCB's Social Media one page 'Do's and Don'ts' document, dated March 2020, entitled 'Think before you... CLICK' stated, *inter alia*, 'Do not interact with posts relating to UCB products (investigational or post-MA) even if those are issued by UCB' and 'Do not interact with posts initiated by third parties and relating to UCB' and defined 'interact' as being a comment, like, share or repost. Similar information was within the Ethics and Compliance Induction which had been mandatory for all new starters regardless of role or function since March 2020. Further, an email sent to staff on 30 March 2020 stated, 'You must not interact with (ie like, share, report, comment on) any posts that include reference to UCB products – whether issued by UCB or a third party' and the EU Social Media Guidance presentation, dated 20 March 2020, stated, 'You cannot do initial postings (including sharing and like) related to UCB, our products, or disease state (this includes press releases and third party content) on social media'.

The Panel noted, however, that at the time the employee had engaged with the post in question (August 2021), the effective social media policy, dated June 2021, stated, *inter alia*: 'We encourage employees to interact with UCB's social media content and share UCB news with their own networks at their discretion.' It further stated, *inter alia*:

'Do

- Amplify the UCB Patient Value story. Share, like, retweet, and comment on UCB posts (as long as comments follow the rules set forth in this social media policy).'

'Don't

- Mention, promote, discuss, or share information or commentary on UCB products, molecules (including those in development), treatment options and claims, or UCB's competitors in connection with any therapeutic or disease area.
- Mention or share UCB scientific data or give medical advice. This includes any information or news from UCB related to unapproved products, molecules, or unapproved uses of existing product and any information or news from third parties related to our pipeline.'

The Panel noted that it was not clear from this current policy that 'liking' a LinkedIn post might proactively disseminate the information to one's LinkedIn connections and thus was a method of 'sharing' information which was not permitted in relation to information on UCB products.

The Panel noted UCB's submission that the employee's actions had contravened the company standards reflected in the UCB Social Media policy.

The Panel noted UCB's submission that training for the social media policy (dated June 2021), which was effective at the time of the employee's actions (August 2021), was assigned to the employee on 2 June 2021. This training was mandatory with an expected completion date of 2 July 2021. The Panel noted UCB's submission that the employee completed the training on 3 December 2021, following UCB's receipt of this complaint. The Panel further noted UCB's submission that in light of this complaint, training completion would be monitored by the Ethics and Compliance team and failure to complete within the required timeline would be escalated as appropriate. It was not clear to the Panel how, or if, mandatory training on social media was

monitored, and non-compliance escalated, prior to UCB's receipt of this complaint; the company made no submission in that regard.

It appeared to the Panel that whilst the employee, who appeared to have a senior role within research at UCB, had acted contrary to the company's instructions regarding social media, he/she had not completed his/her mandatory social media policy training, which at the time of his/her actions was more than a month overdue, and it was not completed until after UCB's receipt of this complaint.

The Panel noted that company policies and the like were instrumental in providing a robust compliance framework. Such documents underpinned self-regulation and it was extremely important that employees were trained upon them and followed them. Regular training was particularly important for policies which covered activities that employees were likely to engage in on a daily basis, such as personal use of social media. It appeared to the Panel that UCB had not adequately monitored employees' completion of mandatory social media policy training. The Panel considered, noting the absence of completed social media policy training by the employee in question, that the employee's 'like' and, on the balance of probabilities, proactive dissemination of information about Bimzelx on LinkedIn to members of the UK public, particularly noting that Bimzelx was not licensed in Great Britain at the time of the activity, meant that UCB had reduced confidence in the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

Complaint received **27 August 2021**

Case completed **3 August 2022**