

**CASE AUTH/3761/4/23**

## **COMPLAINANT v SAMSUNG BIOEPIS**

**Allegations about activity on LinkedIn**

### **CASE SUMMARY**

**This case was in relation to the alleged promotion of an unlicensed medicine on LinkedIn.**

**The Panel ruled a breach of the following Clauses of the 2021 Code:**

|                             |  |
|-----------------------------|--|
| <b>Breach of Clause 3.1</b> | <b>Promoting an unlicensed medicine</b>        |
| <b>Breach of Clause 5.1</b> | <b>Failing to maintain high standards</b>      |
| <b>Breach of Clause 8.1</b> | <b>Failing to certify promotional material</b> |

**The Panel ruled no breach of the following Clauses of the 2021 Code:**

|                                 |   |
|---------------------------------|---|
| <b>No Breach of Clause 16.1</b> | <b>Requirement that promotional material about prescription only medicines directed to a UK audience which is provided on the internet must comply with all relevant requirements of the Code</b> |
| <b>No Breach of Clause 26.1</b> | <b>Requirement not to advertise prescription only medicines to the public.</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 a complainant who described themselves as a concerned health professional about Samsung Bioepis.

### **COMPLAINT**

The complaint wording is reproduced below:

'The following was reposted and "liked" on LinkedIn by [named senior leader] of the company (included as an attachment).

This does not appear to have been approved for UK use.

It is also aimed at the general public as well as healthcare professionals.

This links to [website link provided].

This site has no barrier to ensure that the general public does not access inappropriate material, and therefore may be influenced as to upcoming medicines.

Please investigate.'

When writing to Samsung Bioepis, the Authority asked it to consider the requirements of Clauses 3.1, 5.1, 8.1, 16.1 and 26.1 of the 2021 Code.

## **RESPONSE**

The response from the parent company Samsung Bioepis is reproduced below:

'We received your complaint on 26 April regarding our [UK senior leader]'s LinkedIn post. This letter is in response to the registered complaint.

The case has been brought to our attention and we have reviewed our LinkedIn post as well as the landing page of our LinkedIn content posted on 31 March by Samsung Bioepis' headquarters.

At Samsung Bioepis, we strive to ensure that up-to-date, relevant and suitable information is delivered to our stakeholders so that they can stay informed about Samsung Bioepis' business updates. Our corporate LinkedIn account is managed by headquarters in South Korea as a global account. We post general business updates targeting our broad global audience, not specifically to any countries or professional groups, and the same applies to our corporate website.

The reason we manage our website and social media in such [a] manner is because we are a biopharmaceutical company focused on biosimilar development (from pre-clinical development up to regulatory approval), and when it comes to commercialization of our products, we have commercial partners that manage product specific content in different regions. Therefore, we have been operating our corporate website with having no barriers based on types of audience as well as not having a separate website/social media approval process by country as we haven't directly sold our products in UK.

Internally we have a rigorous review process in place, and we ensure that all the content uploaded on our website, social media or other digital platforms are compliant with our external communications policy.

In terms of our employees' social media usage, as we checked our [UK senior leader], [they had] 822 of LinkedIn connections, mainly consisted of recruitment agencies, and regrettably [the UK senior leader] had not yet received any training specific to social media.

We will ensure that all of our employees, working in South Korea or abroad, including [the UK senior leader] receive the necessary trainings in the future promptly upon joining the company and on a regular basis thereafter.

We have taken your suggestions on board and will review and reinforce our existing process, guidelines and trainings promptly to prevent any misunderstandings going forward.'

## **PANEL RULING**

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, current employment and interests; its application was not limited to the pharmaceutical industry or to healthcare.

Noting that material could be disseminated or highlighted by an individual on LinkedIn by posting, sharing, commenting or 'liking', 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; and depending on the settings potentially visible to others outside his/her network. 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.

The Panel noted the complaint concerned a senior UK employee's 'like' of a Samsung Bioepis corporate post on LinkedIn. Samsung Bioepis submitted that the original LinkedIn post at issue was made on its corporate LinkedIn account managed by headquarters in South Korea. This was a global account where general business updates were posted targeting the company's broad global audience and these were not specific to any countries or professional groups. The Panel considered that while the original post was outside the jurisdiction of the UK Code the action of the UK employee in engaging with it, on the balance of probabilities, would have proactively disseminated the material to their connections within the UK and this brought the post within the scope of the UK Code. The Panel noted the employee had 822 connections and while some may have been health professionals and other relevant decision makers, according to Samsung Bioepis many were recruitment agencies, and therefore likely to be members of the public.

The LinkedIn post announced the receipt of a positive CHMP (Committee for Medicinal Products for Human Use) opinion from the European Medicines Agency for the company's haematology biosimilar (which was not named in the post) and included a link inviting viewers to 'Check out the news here: [website link provided]'. The Panel noted it was a well-established principle that any material linked to in a social media post would be regarded as being part of that post and in this case the linked material was the News Releases page of the corporate website. This webpage included six tiles each with the title and date of a news release and linked to the relevant news release issued by the company. The Panel did not have copies of the press releases available from the webpage but noted that there was an important difference between the publication of a press release on a corporate media webpage and the proactive dissemination of that webpage to a broad audience.

The Panel noted the versions of the News Releases webpage submitted by the complainant and Samsung Bioepis differed due to webpage updates to include news releases made between the receipt of the complaint and the company's response. The Panel determined it would make its rulings in relation to the version submitted by the complainant. Of the six titles visible on the webpage three related to company business news and three to product milestones for Samsung Bioepis' biosimilars which included originator product names (generic and/or brand name) but no information about their therapeutic areas. One tile dated 31 March 2023 appeared to relate to the positive CHMP opinion referred to in the post. The Panel understood that the proactive dissemination of material, which directly or indirectly referred to a medicine on social media, was likely to be considered promotion of that medicine. In the Panel's view the LinkedIn post, which included the linked webpage, was therefore promotional.

The Panel noted that the positive CHMP opinion referred to in the post was announced on 31 March 2023 and the complaint was received on 5 April with the UK employee's engagement with the post occurring at some point in the intervening period. The Panel understood that, when the material was posted by Samsung Bioepis and liked by the UK employee, Samsung Bioepis did not hold UK marketing authorisations for its biosimilars named on the linked webpage. Noting that Clause 26.1 applied to prescription only medicines and that the Samsung Bioepis medicines were not licensed as such at the relevant time the Panel considered **Clause 26.1** was not relevant to the circumstances of the case and ruled **no breach**.

Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorisation. It considered that by 'liking' the post the UK employee had proactively disseminated the post and its linked webpage and thus had promoted unlicensed biosimilar medicines including to members of the public. **A breach of Clause 3.1** was ruled.

The Panel noted the allegation that the post did not appear to have been approved for UK use and that in this regard it had been asked to consider Clause 8.1. The Panel acknowledged that the original post on the corporate website would not have been certified but considered that prior to liking the post, the post (which was promotional material) should have been certified to ensure that it complied with the UK Code. The Panel noted that the LinkedIn post had not been certified and **a breach of Clause 8.1** was ruled.

The Panel was concerned to note the senior UK employee had not received any training specific to social media and that although Samsung Bioepis had a global external communications policy in place there did not appear to be a Code-related governance framework in place for the UK. In the Panel's view companies should assume that the Code would apply to all work-related, personal social media posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. 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 Samsung Bioepis' commitment to review and reinforce its existing process, guidelines and trainings but considered that the absence of a robust UK governance framework and specific social media training meant that high standards had not been maintained. The Panel ruled **a breach of Clause 5.1**.

The Panel noted the complainant had commented on access to the website being unrestricted stating, 'This site has no barrier to ensure that the general public does not access inappropriate material, and therefore may be influenced as to upcoming medicines.' and that Clause 16.1 had been raised by the Case Preparation Manager.

The Panel did not consider the complainant's statement amounted to an allegation regarding the absence of signposting on the post itself, rather the complaint appeared to be limited to the webpage and the absence of webpage 'barriers' in relation to the general public's accessibility. The Panel noted the relevant requirements set out in the supplementary information to Clause 16.1, Website Access.

The Panel noted that Clause 16.1 stated that promotional material about prescription only medicines directed at a UK audience provided on the internet must comply with all the relevant requirements of the Code. The Panel noted that Samsung Bioepis did not hold UK marketing authorisations for the biosimilars and as unlicensed medicines, at the time of the 'like' in question, they were not classified as prescription only medicines and thus Clause 16.1 and its supplementary information 'Website Access' did not apply to the proactive dissemination of the webpage. Similarly in relation to the references to the originator products, the Panel noted that Samsung Bioepis was not the holder of the relevant marketing authorisations and noting the definition of promotion at Clause 1.17, such medicines were not being promoted by Samsung Bioepis and thus Clause 16.1 which applied to promotional material was not applicable. Noting its comments above, and on this narrow technical point, the Panel ruled **no breach of Clause 16.1**.

**Complaint received**      **5 April 2023**

**Case completed**        **8 May 2024**