CASE AUTH/3823/9/23 ***NO BREACH OF THE CODE***

COMPLAINANT v GSK

Alleged promotion to the public and missing obligatory information from promotional posts on LinkedIn

CASE SUMMARY

This case was in relation to GSK employees' interaction with LinkedIn posts that referred to momelotinib being approved for treatment of myelofibrosis in the USA. The complaint was that these online interactions amounted to promotion of a prescription only medicine to the public in the UK, and that they did not include the required prescribing information nor black triangle.

The outcome under the 2021 Code was:

No Breach of Clause 12.1	**Requirement to include up-to-date prescribing information**
No Breach of Clause 12.10	**Requirement to include the black triangle in promotional material**
No Breach of Clause 26.1	**Requirement not to advertise prescription only medicines to the public**

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 about GSK.

COMPLAINT

The complaint wording is reproduced below:

> "Promotion of product to public. Missing of obligatory information for a promotional post No PI or black triangle."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 12.1, 12.10 and 26.1 of the Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

> "GSK was extremely disappointed to receive your letter dated 19th September 2023, in which the PMCPA informed us of a complaint from a pharmaceutical company employee regarding the allegation of promotional posts on LinkedIn by GSK staff and therefore promotion to the public and missing obligatory information related to the post [enclosures provided]. The PMCPA has only asked us to consider clauses 12.1, 12.10 and 26.1 of the ABPI code of practice (the code).
>
> GSK takes its responsibility of abiding by the letter and the spirit of the code and all other relevant UK rules and regulations very seriously and following the complaint, we have conducted an internal review of the circumstances related to the post. However, GSK denies breaches of clauses 12.1, 12.10 and 26.1 for the reasons set out below.
>
> **Background**
>
> Myelofibrosis is a rare blood cancer that results from dysregulated JAK-signal transducer and activator of transcription protein signalling and is characterised by constitutional symptoms, splenomegaly, and cytopenia's. There are an estimated 380 new diagnoses of myelofibrosis each year in the UK, with an estimated 5-year survival of 56.7% [enclosures provided]**.** It is estimated 2,060 people living with myelofibrosis in the UK will have been diagnosed during the last 10 years [enclosures provided]. JAK inhibitors, ruxolitinib and fedratinib, are licensed for use in the treatment of myelofibrosis. In the UK, Myelofibrosis is usually treated by specialist Haematologists.
>
> Momelotinib does not have marketing authorisation in the UK currently.
>
> In the USA, the FDA has recently approved momelotinib for the treatment of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF (post-polycythaemia vera and post-essential thrombocythemia), in adults with anaemia. The approved post [enclosures provided] was placed on the GSK corporate channel on LinkedIn signposting and linking to the approved press release [enclosures provided] which was available on the hosting page. The hosting page was on the clearly labelled media and investor page on GSK.com.
>
> The signposting on LinkedIn made clear the intended audience using *#media #investors* and it was posted by members of the GSK global team, some of whom are based in the UK. We have reviewed the content of the original press release which was intended to provide information to trade and investment media only and had been approved for use, and are comfortable that it is accurate, factual, fair, and balanced. We also note the additional guidance provided by the PMCPA for the 2021 code which states that press releases do not require a PI. Additionally, we have reviewed the first post signposting to the press release which was also signed off for use and are confident that it is also appropriate and cannot be considered promotional as there is no mention of any product name.
>
> One of GSK's Switzerland-based staff then posted about the approval and linked it to the original press release, on Fri 15 September 2023 [enclosures provided]. GSK contends

that the post clearly makes a reference to the approval being granted by the FDA as well as the fact that it was for the USA. As the employee who subsequently posted about the FDA approval on LinkedIn is based in Switzerland, GSK contends that the involvement of this employee falls outside of the scope of the code and hence have not made any further reference to or comment about this in our response.

The complainant alleges that the posts were 'liked' by several UK based employees of GSK. GSK can confirm that the posts were indeed liked by several non-UK based employees, but only three UK-based GSK staff members: one within the UK affiliate team (Employee 1) and two who both have Global roles but are not UK affiliate team staff members (Employees 1 and 2). GSK acknowledges that the actions of the three UK-based employees brings the LinkedIn posts within the scope of the code. The PMCPA has requested details of the individuals including about their LinkedIn networks. Please see below the requested information:

UK based GSK employee 1.

- [GSK provided details and enclosure relating to this person's role, the fact they had completed their social media training, and the number and nature of their LinkedIn connections].

UK based GSK employee 2.

- [GSK provided details and enclosure relating to this person's role, the fact they had completed their social media training, and the number and nature of their LinkedIn connections]

UK based GSK employee 3.

- [GSK provided details and enclosure relating to this person's role, the fact they had completed their social media training, and the number and nature of their LinkedIn connections]

GSK actions following complaint

As acknowledged by GSK above, by engaging with the post the 3 UK-based GSK employees brought the post within the scope of the code. Prior to receiving the letter from the PMCPA on Tues 19 September, GSK had already identified that two UK based staff members (employee 1 and 2) had 'liked' the LinkedIn post in question about the FDA approval for momelotinib in the USA. These staff members were contacted immediately and confirmed they had 'unliked' the LinkedIn posts on Mon 18 September.

An internal GSK briefing document regarding the FDA decision on momelotinib plus a reminder on appropriate social media engagement as stated in the GSK UK Social Media Guideline, was sent to GSK staff within the UK affiliate Oncology team (97 members) on the 18 September 2023. This included all staff members of the UK momelotinib team [enclosures provided].

On the same day as GSK received the PMCPA's letter on 19 September, the third GSK employee was contacted to remove their 'like' of the post which they confirmed as having been done immediately on the same day. Given that the post was potentially seen by the LinkedIn network of the 3 UK-based employees, GSK carried out a detailed internal investigation around the circumstances and content of the posts in question. We are

confident that the original press release to which the post referred is accurate, fair and balanced. Both the post and the press release in question are very clearly about the FDA's decision about momelotinib in the USA which we contend would also be obvious to the wider LinkedIn network of the three GSK staff involved,

GSK response to potential breach of clause 26.1

As mentioned above, momelotinib does not currently have marketing authorisation for use in the UK. It is therefore not a prescription medicine available to patients. GSK therefore contends that clause 26.1 does not apply to this case on this technical point. GSK notes that there is previous precedence of rulings of a similar nature by the PMCPA in Case AUTH/3597/1/22. We therefore deny a breach of clause 26.1.

GSK response to potential breach of clause 12.1 and 12.10

GSK acknowledges that by 'liking' the post, the three UK-based GSK staff members have brought it within the scope of the code. As previously mentioned however, momelotinib does not have marketing authorisation in the UK and therefore does not have Prescribing Information (PI) or summary of product characteristics (SPC) available for use. GSK also notes that the PMCPA has not asked us to consider clause 11.1 in this case. In the context of the fact that the PMCPA has not asked us to consider promotion of a product prior to the granting of its marketing authorisation, GSK contends that there is no rationale for the requirement for a PI or black triangle. We therefore deny a breach of clauses 12.1 and 12.10.

Summary

In summary, GSK would like to reiterate that we take our responsibility of respecting and abiding within the ABPI code of practice extremely seriously. We are disappointed to have received this complaint and as set out above, believe this to have been because of human error and a lack of judgement by three of our employees rather than any deliberate attempt to promote to the UK public.

We have responded to the complaint on the basis of the allegations made and clauses cited, and with the narrow scope of the complaint received, believe we are not in breach of clauses as alleged. However, GSK recognise that we were not asked to consider clause 11.1. As the product in question does not have a UK marketing authorisation, had we been asked to respond to this clause as part of the complaint, our response would have been different. Regardless, given the immediate response by GSK, even before a complaint was received, we firmly believe that self-regulation has been achieved. However, with respect to the specific clauses the PMCPA asked us to consider, GSK denies breaches of clauses 12.1, 12.10 and 26.1.

We would be grateful if the PMCPA does not share our internal training policy and personalised information about the three UK based employees with the complainant or elsewhere due to company and personal confidentiality."

PANEL RULING

The Panel noted that LinkedIn was a global business and employment-oriented network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment interests. In the Panel's view it was, in principle, acceptable for pharmaceutical companies to use corporate LinkedIn accounts for corporate news and updates although they needed to be mindful of the compliance issues that might arise. The Panel considered that companies should assume that the Code would apply to all corporate LinkedIn posts and all work-related, personal LinkedIn posts by their employees 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 including, among other things, content and who had posted the material.

The Panel noted that the complainant made allegations about promotion to the public and missing obligatory information for a promotional post that had no prescribing information or black triangle. The complainant provided screenshots of a post made on the GSK corporate LinkedIn account, and its associated 'reactions' and a screenshots of a second post made by a GSK employee, and its associated 'reactions', to support their allegation.

The approved LinkedIn post and linked press release

The Panel noted that it was an established principle under the Code that UK-based global or other such companies were subject to the Code. In the Panel's view, the approved LinkedIn post at issue came within the scope of the ABPI Code because it was posted by members of the GSK global team, some of whom were based in the UK at the time, and the post had been 'liked' by two UK-based GSK employees (Employee 1 and Employee 3), as noted in the screenshot of 'reactions' to the post provided by the complainant. The Panel noted GSK's submission in this regard that Employee 1 worked in a non-customer facing commercial management role in UK vaccines and Employee 3 worked in a senior non-customer facing role within clinical trials.

The Panel considered the approved LinkedIn post including the linked press release at issue in totality. The LinkedIn post stated:

> "#News for #investors and #media: Today we announced that the FDA has approved our new treatment for #myelofibrosis that may address key manifestations of the disease, namely anaemia, constitutional symptoms and splenomegaly.
>
> Myelofibrosis is a blood cancer that can lead to severe low blood counts, including anaemia and thrombocytopenia; constitutional symptoms such as undesired weight loss and fatigue; and splenomegaly or an enlarged spleen. People living with myelofibrosis face unique challenges, such as anaemia. Blood transfusions are often required to manage it and can impact overall survival and quality of life.
>
> Learn more: [weblink]."

The linked press release was headed: "Stock-exchange announcement, For media and investors only, Issued: 15 September 2023, London UK. Ojjaara (momelotinib) approved in the US as the first and only treatment indicated for myelofibrosis patients with anaemia".

The body of the press release, which included the brand and generic names of the medicine and its indication, provided information on the MOMENTUM study and SIMPLIFY-1 phase III

trial, the disease state, and several quotes, including one from a senior GSK Oncology employee, stating, among other things: “Given this high unmet need, we are proud to add Ojjaara to our oncology portfolio and address a significant medical need in the community. We look forward to helping improve outcomes in this difficult-to-treat blood cancer”. The Panel noted that the second page of the press release contained a link to US prescribing information.

The Panel noted GSK’s submission that the approved post was placed on the GSK corporate channel on LinkedIn, signposting and linking to the approved press release which was available on the hosting page. The hosting page was on the clearly labelled media and investor page on GSK.com and “The signposting on LinkedIn made clear the intended audience using *#media #investors*”.

The Panel considered that care should be taken when using hashtags and signposting an intended audience on social media platforms. The PMCPA Social Media guidance, in that regard, states, among other things, that ‘pharmaceutical companies should note there is a difference between making a press release/ information available only to investors or to the relevant press, to be published or not, and linking to it on a social media platform open to the wider public where it may be read by a broader than intended audience’; that ‘business press releases should identify the business importance of the information and should only be aimed at the intended financial and investment audience’ and that ‘using social media channels to communicate this information is complex as by their nature social media channels are open to a broad audience, beyond the intended audience for the post itself’. The Panel therefore did not necessarily agree that the use of a hashtag was a satisfactory way to highlight the intended audience; especially as a hashtag was generally used to search for and identify information on a certain topic. The Panel further noted that the word ‘media’ was not restricted to a financial or investment audience and could include medical or consumer media.

The Panel noted GSK’s submission that the approved LinkedIn post, signposting to the press release could not be considered promotional as there was no mention of product name. The Panel considered that it was established in case precedent that the content of a social media post and linked material were considered in totality, and in general, the combination of product name and indication was likely to be seen as promotional.

However, the Panel noted the complainant’s allegation was very narrow and was specifically that the post was “Promotion of product to public” and was “Missing of obligatory information for a promotional post. No PI or black triangle”.

The Panel noted that the approved LinkedIn post referred to the FDA approval of GSK’s new treatment for myelofibrosis, and the linked press release was hosted on the media and investor page on GSK.com, both of which made the intended audience clear from the outset. The title of the press release clearly stated the approval was in the US. The Panel noted that Clause 26.1 only applied to prescription only medicines; momelotinib did not have a marketing authorisation in the UK at the time when the approved LinkedIn post was made, as submitted by GSK, and on that narrow technical point, the Panel ruled **no breach of Clause 26.1** of the Code. It therefore followed that there was no requirement for the post or press release to include prescribing information or include a black triangle symbol; the Panel ruled **no breach of Clauses 12.1 and 12.10** of the Code.

The second LinkedIn post made by a GSK employee

The Panel noted the content of a second post, made by a GSK employee, which stated: “What a journey over last 2 years! Diligence… acquisition… integration… and now launching #impossibleisnothing #gskproud #myelofibrosis #patientaccess #teameffort #aheadtogether #oncology”. Beneath this text appeared a large, prominent GSK logo and the partially visible title of a press release hosted on gsk.com, which stated: “Ojjaara (momelotinib) approved in the US as the first and only treatment indicated for myelofib…”.

The Panel noted GSK’s submission that a Switzerland-based GSK employee posted about the approval [of momelotinib] and linked it to the original press release (the same press release that was linked in the approved LinkedIn post above). The Panel noted GSK’s submission that the post at issue made reference to approval in the US, and as the employee who subsequently posted about the FDA approval on LinkedIn was based in Switzerland, the involvement of this employee fell outside of the scope of the Code.

The Panel considered, in general terms, that whether the activities of global or regional employees came within the scope of the UK Code, would be decided on a case-by-case basis bearing in mind, amongst other things, the UK nexus and, if relevant, the requirements of Clause 1.2. The Panel, noting that the complainant bore the burden of proof, and noting the above, considered that the complainant had not established, on the balance of probabilities, that GSK UK was responsible for the post made by a Switzerland-based employee. The content of the post as provided by the complainant did not appear to have a UK nexus.

However, the Panel noted that the post at issue was ‘liked’ by Employee 2, [job title redacted] based in the UK, as noted in the screenshot of ‘reactions’ to the post provided by the complainant. The Panel noted that GSK’s response to the PMCPA did not comment on this post.

The Panel considered that the interaction with the post by a UK-based employee brought it within the scope of the Code. It was well established that if an employee’s personal use of social media was found to be in scope of the Code, the company would be held responsible.

However, given the Panel’s ruling above that Clause 26.1 only applied to prescription only medicines (and momelotinib was not licensed in the UK at the time when the second LinkedIn post was made by the Switzerland-based employee), the Panel ruled **no breach of Clause 26.1** of the Code in relation to Employee 2 ‘liking’ that post. It therefore followed that there was no requirement for the post or press release to include prescribing information or include a black triangle symbol; the Panel ruled **no breach of Clauses 12.1 and 12.10** of the Code.

Complaint received **18 September 2023**

Case completed **20 November 2024**