CASE AUTH/3690/8/22

COMPLAINANT v GLAXOSMITHKLINE

Promotion of dostarlimab (Jemperli) on LinkedIn

CASE SUMMARY

This case was in relation to a LinkedIn post independently created by a renowned cancer institution which was 'loved' by a UK-based senior medical GlaxoSmithKline (GSK) employee.

The Panel ruled a breach of the following Clauses of the 2021 Code because the senior employee's engagement with the post had, on the balance of probabilities, proactively disseminated the material to their connections which included members of the public and promoted Jemperli for an indication that was outside of the terms of its marketing authorisation:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.2	**Promotion inconsistent with the summary of product characteristics**

The Panel ruled no breach of the following Clauses of the 2021 Code because Jemperli already had a marketing authorisation, albeit for a different indication than mentioned in the article, and because the Panel noted GSK appeared to have the requisite policies and training in place:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**

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 non-contactable complainant who described him/herself as a concerned health professional about the promotion of dostarlimab on LinkedIn.

COMPLAINT

The complainant highlighted social media activity of a senior medical GSK employee who allegedly endorsed a LinkedIn post with the reaction 'loves this' from a cancer centre regarding data that was highlighted at the annual ASCO 2022 meeting and published concurrently in the

New England Journal of Medicine. By clicking on the post, the article highlighted the data from the meeting for the GSK investigational immunotherapy product dostarlimab.

The complainant stated dostarlimab did not have a marketing authorisation for the treatment of rectal cancer in the United Kingdom and as the employee was a UK based employee, the engagement with the post allegedly fell under the scope of the Code and on the balance of probabilities, proactively disseminated the material/notification of this post to his/her LinkedIn connections which would likely predominantly be within the UK.

The complainant was concerned that a UK based medical employee who had UK based connections had overwhelmingly endorsed the post within a public forum, which represented an act of solicitation and promotion to the public.

The complainant stated he/she believed this represented a breach of Clause 3.1 (promotion of a medicine prior to its marketing authorisation) and a breach of Clause 5.1 (failure to maintain high standards) under the PMCPA 2021 Code.

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.1, 5.1, 11.2.

RESPONSE

GSK submitted it was committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations and took this complaint very seriously.

GSK provided information requested by the PMCPA:

- **How many followers/connections did the senior medical employee have?**
    - Approximately 2,100 connections

- **If possible, please comment on their status (members of the public or health professionals)?**
    - Many connections (approximately > 95%) were health professionals involved in healthcare, pharmaceutical, hospital, or industries related to the pharmaceutical and life sciences sector, 308 work for GSK. 1,200 were based in the UK, 900 outside of the UK (USA, Switzerland, Asia). Key word searches were applied to the connections held within the account and the numbers with the following key words in their titles included:
        - Consultant 193
        - Clinical 146
        - Medical in their School/University title 117
        - NHS 101
        - Hospital 32
        - Doctor 18
        - Registrar or SpR 7

- **Details as to when the post was interacted with by the senior medical employee:**
    - The post was engaged with by clicking ‘love’ on the post once by the medical employee in June 2022, whilst attending the American Society of Clinical

Oncology (ASCO) conference in the United States. The post was engaged with once and no comments were made to the post. The post was not forwarded, saved or shared on LinkedIn or any other platform. The recollection of the medical employee concerned is that at the time the post was interacted with, it contained only a link to the patient video (copy provided) and did not link to the article which has been highlighted by the complainant – within which a specific medicine is mentioned.

- **A copy of the certificate approving the post in question for dissemination if any (please state the qualifications of your signatories):**
    - The post and all associated content referred to in this complaint was made independently by an internationally renowned cancer treatment and research institution based in New York, USA. GSK was not involved in the creation or distribution of this post and linked content. Therefore, it was not reviewed or approved in advance by a GSK signatory.

Clauses 3.1, 5.1, 11.2

GSK accepted that it had breached Clauses 3.1, 5.1 and 11.2 of the 2021 Code. GSK understood that it was a well-established principle that interaction by a company employee with an independent, external LinkedIn post brought it within scope of the ABPI Code of Practice. Despite the post itself, or the linked patient video, not mentioning GSK, or a GSK medicine specifically, GSK recognised that the nature of the content can be reasonably deemed to be indirect promotion of an unauthorised indication, as the study discussed in the post involved only a GSK medicine. Furthermore, GSK was unable to conclusively demonstrate that the original post interacted with, by a UK employee, did not contain a link to the additional article highlighted by the complainant. Therefore, GSK also accepted that despite the predominant use of the general term “immunotherapy” (24 times), the linked article did also specifically mention “dostarlimab (Jemperli)” once, as highlighted by the complainant.

Defence of Clause 2

GSK did however deny a breach of Clause 2. GSK had no involvement in the creation or distribution of the post in question. It was made independently by an internationally renowned cancer treatment and research institution based in New York, USA. GSK submitted it had clear and robust social media policies, with specific guidance and training for all employees on how to appropriately engage with content about GSK on their personal social media channels. This training made it clear that if the content mentioned or referred to GSK prescription products, R&D assets or competitor products, employees must not like, comment, share or post. GSK also included evidence that the GSK employee in this case completed this training prior to interacting with the post. Therefore, GSK submitted it had clear and robust social media policies and training in place for all its employees.

Before interacting with the post and in line with their training, the GSK UK employee checked to ensure that neither GSK nor its products and assets were mentioned in the post or linked content. As discussed above, their recollection was that the original post they “loved” did not, at that stage, link to the article which mentioned a specific product as highlighted by the complainant, just the patient video. GSK submitted the employee confirmed that had they seen any product mention, they would not have interacted with the post. Notwithstanding the above, on reflection, this individual now recognised that even the posted contents which they did see

can be reasonably deemed to be referring to a GSK medicine and unlicensed indication, albeit indirectly, and thus this was an individual error of judgement on their part.

Therefore, in this circumstance, failure to maintain high standards was due to an error of judgement of one individual employee, and not due to systematic, organisational failures. GSK noted that there had been several similar cases where companies had been found in breach of Clause 3.1, but not Clause 2, because the failing was deemed to be by an individual employee, despite robust company policies and training being in place – AUTH/3422/11/20; AUTH/3411/10/20 and AUTH/3412/10/20; AUTH/3390/9/20; AUTH/3483/3/21. GSK believed the same conditions applied in this case too.

GSK took its obligations on this matter very seriously. It had already taken the following corrective actions:

- The GSK employee had "unloved" the post
- The GSK employee had repeated the relevant social media training and discussed the case with both GSK and independent, experienced ABPI signatories
- Although GSK's current social media policies and training made it clear to not interact with content which both mentions **"or refers"** to GSK prescription products, R&D assets or competitor products, GSK committed to update its social media policies and training such that it is even clearer that content could still indirectly promote a medicine even if there iwas no specific mention of a product or asset.

Conclusion

In closing, GSK accepted that interaction by an individual UK employee with an independent, external organisation's LinkedIn post was a breach of Clauses 3.1, 5.1 and 11.2 of the 2021 Code.

However, GSK did believe that it had in place clear and robust policies and training on how employees should engage with content on their social media channels. On this occasion the above breaches were due to an individual error of judgement of a single UK employee. Therefore, GSK refuted that clause 2 was breached.

PANEL RULING

The Panel noted that the complaint was in relation to a LinkedIn post by a renowned cancer institution which had been engaged with a 'love' reaction by an individual who appeared to be a senior medical GlaxoSmithKline (GSK) employee and who, according to GSK, had 2,100 connections on LinkedIn with approximately greater than 95% being health professionals and 1,200 being based in the UK.

The Panel noted GSK's submission that the post and all associated content referred to in this complaint was made independently by an internationally renowned cancer treatment and research institution based in New York, USA; therefore, it was not reviewed or approved in advance by a GSK signatory.

The post started with the paragraph 'Breaking #ASCO22 News: A small but groundbreaking new study published today in NEJM Group and being presented at the American Society of

Clinical Oncology (ASCO) annual meeting by MSK experts [name of HCP1] and [name of HCP2] demonstrates remarkable results when leveraging #immunotherapy alone to beat back rectal cancer that had not spread to other tissues' and was followed by a thumbnail of a patient video and appeared to link to an article titled 'Rectal Cancer Disappears After Experimental Use of Immunotherapy'.

The Panel noted that the complainant drew particular attention to a paragraph in the linked article which stated 'All patients in the trial must have stage 2 or 3 rectal tumors that are MMRd – which makes their cancer particularly sensitive to immunotherapy. The patients were given the checkpoint inhibitor dostalimab (Jemperli) intravenously every three weeks, for six months. The Panel noted a snippet of the next section of the article was visible under the heading 'No More Symptoms of Rectal Cancer' and stated 'The results surprised even [name of HCP1] and [name of HCP2]…'.

The Panel noted GSK's submission that despite the post and the linked patient video not mentioning GSK or a GSK medicine specifically, it recognised that the nature of the content could be reasonably deemed to be indirect promotion of an unauthorised indication, as the study discussed in the post involved only a GSK medicine. Furthermore, GSK also accepted that despite the predominant use of the general term "immunotherapy" (24 times), the linked article did also specifically mention "dostarlimab (Jemperli)" once, as highlighted by the complainant.

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.

The Panel considered that on the balance of probabilities, by engaging with the post, the UK employee had proactively disseminated the material to their connections on LinkedIn and had thus brought the post within the scope of the UK Code.

The Panel noted that Clauses 3.1 and 11.1 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 prescription only medicines to the public while Clause 11.2 required that the promotion of a medicine must be in accordance with the terms of its marketing authorisation and must not be inconsistent with the particulars listed in its Summary of Product Characteristics (SPC).

The Panel noted that Section 4.1, Therapeutic indications, of the Jemperli SPC stated 'JEMPERLI is indicated as monotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen'. In this regard, the Panel noted the article and post at issue referred to the use of Jemperli in rectal cancer. The Panel considered that the proactive dissemination of the post at issue by the UK medical employee to his/her connections meant that Jemperli had been promoted for an indication that was outside of the terms of its marketing authorisation and **a breach of Clause 11.2** was ruled, as acknowledged by GSK.

The Panel noted the complainant had cited Clause 3.1 which stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply. In this regard, the Panel noted that Jemperli already had a marketing authorisation, albeit for a different indication than mentioned in the article, and on this very technical point, the Panel ruled **no breach of Clause 3.1** of the Code.

The Panel, noting on the balance of probabilities that the senior medical employee had proactively disseminated the post to their connections on LinkedIn which included members of the public, and noting its rulings of a breach of Clause 11.2 above along with the nature of the position of the senior medical employee, considered that high standards had not been maintained. A **breach of Clause 5.1** was ruled.

The Panel noted promotion prior to the grant of a medicine's marketing authorisation was, amongst other things, an example of an activity that was likely to be in breach of Clause 2. In this regard, the Panel noted the medicine had a marketing authorisation, albeit for a different indication than promoted in the article.

In the Panel's view, GSK had been let down by a senior employee who had promoted a GSK medicine outside the terms of its marketing authorisation, contrary to GSK's social media policies and training which made clear to not interact with content which mentioned or referred to GSK prescription products.

Nonetheless, the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use. GSK appeared to have the requisite policies in place and the employee had been trained. The Panel noted the incident appeared to be isolated and considered that in the particular circumstances of this case, its rulings of breaches above adequately covered the matters raised; on balance, **no breach of Clause 2** was ruled.

* * * * *

Complaint received **6 September 2022**

Case completed **17 August 2023**