**CASE AUTH/3810/8/23**

# COMPLAINANT v GSK

## Alleged promotion of Jemperli (dostarlimab) on LinkedIn

### CASE SUMMARY

**This case was in relation to a LinkedIn post by GSK, shared and 'liked' by UK GSK employees, about the status of Jemperli's (dostarlimab) licence expansion in the US.**

**The outcome under the 2021 Code was:**

| | |
|---|---|
| **Breach of Clause 5.1** | **Failing to maintain high standards** |
| **Breach of Clause 26.1** | **Promoting a prescription only medicine to the public** |

| | |
|---|---|
| **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 marketing authorisation** |
| **No Breach of Clause 26.2** | **Requirement that information about prescription only medicines which is made available to the public must be factual, balanced, must not raise unfounded hopes of successful treatment or encourage the public to ask their health professional to prescribe a specific prescription only medicine.** |

**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 who described themselves as an ex-employee, about GlaxoSmithKline UK Limited.

### COMPLAINT

The complaint wording is reproduced in below:

> "A GSK employee has shared status of Jemperli's licence expansion in the US on their LinkedIn profile – with a link to GSK media press release. This is currently not licensed in the EU nor in the UK. Multiple UK colleagues have liked this and therefore spread to their own networks – further communicating this unlicensed medicine to the UK public. Photos included [link provided]."

When writing to GlaxoSmithKline, the Authority asked it to consider the requirements of Clauses 2, 3.1, 5.1, 26.1 and 26.2 of the Code.

**GSK'S RESPONSE**

The response from GSK is reproduced below:

> "GSK was extremely disappointed to receive your letter dated 16th August 2023, in which the PMCPA informed us of a complaint from an ex-employee of GSK regarding the above. [copies of post, 'likes' and press release provided]. The PMCPA has asked us to consider clauses 2, 3.1, 5.1, 26.1 and 26.2 of the ABPI code of practice (the code).
>
> As referred to above, the complaint relates to the liking by UK-based staff of a LinkedIn post about the FDA approval for a licence extension for Dostarlimab in the USA.
>
> 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. GSK acknowledges a breach of clause 26.1 but not clauses 2, 3.1, 5.1 and 26.2. The rationale for this is set out below.
>
> **Background**
>
> Endometrial cancer (EC) is a disease in which malignant cells form in the lining of the uterus. It is a heterogenous disease, with significant morbidity and mortality. In the UK, there are approximately 9,700 cases of EC diagnosed annually, making it the fourth most common cancer amongst women. Of these, almost 2,900 patients are diagnosed with primary advanced or recurrent EC each year. Primary advanced or recurrent endometrial cancer is associated with a range of debilitating symptoms, affecting physical functioning and health related quality of life and only 15% to 20% of patients survive longer than five years. No systemic anticancer therapy is licensed for use in the treatment of primary advanced or recurrent EC, however platinum-based chemotherapy is recommended in guidelines and considered a standard of care.
>
> Dostarlimab is licensed in the UK as follows:
>
> *"JEMPERLI (Dostarlimab) 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."* [SPC provided]
>
> In the USA, the FDA has recently approved an extension to the licence for earlier use of Dostarlimab in the treatment algorithm for EC. The USA team released a press release aimed at trade and investment media about this approval by the FDA.
>
> The original LinkedIn post in question was posted by one of GSK's Italy based staff on the 8th August 2023. The post was about and linked to the press release from the GSK USA affiliate about the approval of Dostarlimab for an extension to its licence for the treatment of endometrial cancer. The post clearly makes a reference to the FDA as well as the fact

that the approval for dostarlimab was in the USA. GSK contends that the US press release is out of scope of the code, and we have therefore not focused on it in our response. As the employee who originally posted on LinkedIn is based in Italy, GSK also contends that the involvement of this employee also falls outside of the scope of the code and hence have not made any further reference to or comments about this in our response.

The complainant alleges that the post was liked by several UK based employees of GSK. GSK can confirm that the post was liked by several non-UK based employees, but only two UK-based GSK staff members who both have Global roles and are not within the UK affiliate team. GSK acknowledges that the actions of the two UK based employees brings the LinkedIn post within the scope of the code. Please see below for further information about the two UK based employees as requested by the PMCPA:

**UK based GSK employee 1**.

- Employee 1 is a Global Clinical Development [job title], working in clinical trial research and development and does not have a role in the communication and/or promotion of our medicines. Neither are they in a customer facing role. Their role is focused on global GSK clinical trial operations in immuno-oncology.
- The individual completed the GSK social media training on 16th June 2020. [copy provided]
- They have 423 LinkedIn connections, approximately a third of whom are health professionals and a further third GSK employees. The remaining third are a mixture of individuals, potentially including members of the public.

**UK based GSK employee 2**

- Employee 2 is a Global Value, Evidence & Outcomes (VEO) [job title]. They are also not in a communication, promotional or customer facing role.
- The individual completed the GSK social media training on 16th July 2020. [copy provided]
- They currently have over 1700 LinkedIn connections of which just under 50% of connections (approximately) are UK based. These include 505 current GSK employees and 543 past GSK employees.

GSK have also reviewed the press release to which the post linked and are comfortable that the contents are fair, balanced, and accurate. Its aim was to provide information to trade and investment media only.

**GSK response to potential breach of clause 3.1**

The PMCPA has asked us to consider several clauses in our response including clause 3.1 of the code. As mentioned above, Dostarlimab is licensed in the UK. The approval by the FDA was for an extension to that license for Dostarlimab to be used earlier in the treatment pathway in the USA. On this point, GSK therefore denies a breach of clause 3.1 in line with the previous ruling in case AUTH/3690/8/22 as Dostarlimab has not been promoted prior to the grant of the MA [marketing authorisation] which permits its sale or supply.

**GSK response to potential breach of clauses 26.1, 26.2 and 5.1**

As acknowledged above, by engaging with the post, the 2 UK-based GSK employees brought the post within the scope of the code. On the same day as GSK received the PMCPA's letter, the 2 staff members were contacted to remove their "likes" of the post which they confirmed was done immediately on 16th August (i.e., the same day as GSK received the PMCPA's letter). GSK accepts a breach of clause 26.1 as the two employees should not have liked a post the content of which may be deemed as advertising to the UK public. Given that the post was potentially seen by the LinkedIn network of the 2 UK-based employees, GSK considered seriously whether it may in any way raise unfounded hope in any members of the public within those networks. It is our strong belief that it would not have done so because the post referred to the US press release which we are confident is accurate, fair and balanced, and while it was not meant for the public, both the post and the press release in question are very clearly directed at a USA market which we contend would also be obvious to UK members of the public. We therefore deny a breach of clause 26.2.

GSK does acknowledge however, that because we accept a breach of clause 26.1, high standards have not been maintained and therefore accept that a breach of clause 5.1 has also occurred.

**GSK response to potential breach of clause 2**

The PMCPA has also asked GSK to consider clause 2. GSK strongly believes that this case does not bring discredit upon or reduce confidence in the pharmaceutical industry. We strongly believe that clause 2 is and should be reserved for special sanction when fundamental flaws in the internal workings of a company have been identified, including deliberately deceptive behaviour or where there is a significant risk to patient safety.

As mentioned above, GSK undertook an urgent review of our internal policies and procedures around social media. We are confident that we have robust processes in place which are of a high standard, and which are followed by all UK staff. GSK would like to highlight that the social media training undertaken by the two individuals in question [copy provided], makes it abundantly clear in point number 1 of the guidance that employees must not like or engage in social media posts mentioning a GSK product. It states the following: *'If the content mentions or refers to GSK prescription products, R&D assets or competitor products you must not like, comment, share or post.'*

We also strongly believe that the actions of the 2 UK-based GSK staff members occurred because of human error due to misplaced enthusiasm rather than any active or deliberate attempt at any form of promotion. We also strongly believe that there is no potential for the safety of patients to have been compromised in this instance. For these reasons we deny that GSK has breached clause 2.

**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 two of our employees rather than any deliberate attempt to promote to the UK public. We therefore acknowledge breaches of clause 26.1 and 5.1

with the respective explanations for this position. We do however deny breaches of clauses 3.1, 26.2 and 2 for the reasons also explained above."

**Further information from GSK**

"GSK wanted to write immediately to correct an error in reference to our social media policies with regards to the details stated in our reply to you on 6th September regarding the above case.

GSK would like to correct the term 'SOP' in the list of enclosures– GSK SOP on social media'. The social media training referred to in our complaint response is not in fact a standard operating procedure (SOP). The training itself is a guidance training document that all GSK employees need to complete.

GSK would like to reiterate and highlight that the social media training undertaken by the two individuals in question, makes it abundantly clear in point number 1 of the guidance that employees MUST not like or engage in social media posts mentioning a GSK product. It states the following: *'If the content mentions or refers to GSK prescription products, R&D assets or competitor products you must not like, comment, share or post.'*

GSK apologises unreservedly for referring to a 'GSK SOP' in the enclosure list at the end of our response when in fact it is training as a guidance document, as referred to throughout the body of our response and the attachment name itself 'GSK_SocialMedia_guidelines_final.pdf'.

Notwithstanding this error of reference to an SOP when it is in fact mandatory training as a guidance document, GSK maintains that we have robust training in place to ensure GSK employees have a clear understanding of how to engage safely with social media."

**PANEL RULING**

The Panel noted the complainant's allegations were regarding a LinkedIn post, with a link to a GSK media press release, which was shared by a GSK employee and 'liked' by UK GSK employees, communicating the status of Jemperli's (dostarlimab) license expansion in the US. The complainant alleged this amounted to "communicating [an] unlicensed medicine to the UK public".

The complainant submitted a screenshot of the LinkedIn post at issue and a second screenshot showing two GSK employees who had 'liked' the post, to support the allegation.

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 and current employment and interests; its application was not limited to the pharmaceutical industry or to healthcare. 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 that the post at issue mentioned Jemperli, a GSK prescription only medicine. The Panel noted that at the time of the post, Jemperli was 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 had progressed on or following prior treatment with a platinum-containing regimen.

The Panel noted that the LinkedIn post at issue, made by a GSK employee, stated: "Today's [FDA] expanded approval of Jemperli redefines the treatment landscape for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer.'' This was followed by the hashtags #endometrial cancer and #oncology. Beneath the text, appeared a large GSK logo and a link to the associated press release on gsk.com; the partially visible title of the press release stated "Jemperli (dostarlimab) plus chemotherapy approved in the US as t…".

The Panel noted GSK's submission that the LinkedIn post was published by one of GSK's Italy-based staff. The post was about and linked to the press release from the GSK USA affiliate about the approval of dostarlimab for an extension to its licence for the treatment of endometrial cancer. GSK also submitted that the post was 'liked' by several non-UK based employees, but only by two UK-based GSK staff members who both had Global roles and were not within the UK affiliate team.

The Panel considered the content of the LinkedIn post at issue and the linked press release in totality. In the Panel's view, the post, which included the indication for Jemperli, and the linked press release, which included the prominent title 'Jemperli (dostarlimab) plus chemotherapy approved in the US as the first new frontline treatment option in decades for dMMR/MSI-H primary advanced or recurrent endometrial cancer', the bold statement 'Jemperli is the only immuno-oncology treatment approved in the frontline setting for this patient population in combination with chemotherapy', statements such as 'With this approval, Jemperli is now indicated earlier in treatment in combination with chemotherapy for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer' and a quote by [a senior global employee] "Today's expanded approval of Jemperli redefines the treatment landscape for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer. Until now, chemotherapy alone has been the standard of care with many patients experiencing disease progression. In the RUBY trial, Jemperli plus chemotherapy demonstrated a 71% reduction in the risk of disease progression or death versus chemotherapy in this patient population, providing statistically significant and clinically meaningful benefit. These results and today's approval underscore our belief in the potential for Jemperli to transform cancer treatment as a backbone immune-oncology therapy." could not be seen as anything other than promotional, and it was on this basis that the Panel made its rulings.

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 noted the text at the top of the linked press release stated 'Issued: London, UK. For media and investors only'. The Panel noted that the press release included the US indication and a link to US prescribing information for Jemperli towards the end of the press release and noted GSK's submission in this regard that the USA team released a press release aimed at trade and investment media about this approval by the FDA. The Panel noted that the press release stated that an application for this new indication remains under review in other countries, including the UK. The Panel noted that although the post included the web address gsk.com there was no direct reference to its intended audience. Similarly, the linked press release made no mention that it was intended for a US audience. In the Panel's view, it was not sufficiently clear to readers that the press release was intended for a US-only audience.

Nonetheless, noting that the complainant bore the burden of proof, and noting the above, the Panel considered that the complainant had not established, on the balance of probabilities, whether GSK UK was responsible for the LinkedIn post at issue and the linked press release. The content of the post as provided by the complainant did not appear to have a UK nexus. The Panel considered that the LinkedIn post at issue, made by a GSK employee based in Italy, was not in scope of the Code.

The Panel noted GSK's submission that two UK-based employees, both of whom had Global roles and were not within the UK affiliate team, had 'liked' the LinkedIn post at issue. The Panel considered that it was the interaction with the post by the two UK-based employees that brought it within the scope of the Code, and 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.

Clause 3.1 states that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply. The Panel noted that Jemperli was licensed in the UK at the time of the post at issue, and on that basis ruled **no breach of Clause 3.1**.

The Panel noted that GSK held the marketing authorisation for Jemperli and at the time of the LinkedIn post and the UK-based employees' engagement with it, Jemperli was a prescription-only medicine, however, Jemperli in combination with chemotherapy, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H), was not a licensed indication. The Panel noted GSK's submission that each of the employees who had 'liked' the post had 423 and 1700 LinkedIn connections, respectively, potentially including members of the public, and considered, on the balance of probabilities, that not all of the employees' connections on LinkedIn would meet the Code's definition of a health professional or other relevant decision maker. It therefore followed that the promotional LinkedIn post had likely been proactively disseminated to members of the public and constituted promotion of Jemperli, a prescription only medicine, to the public, albeit for an unlicensed indication, and **a breach of Clause 26.1** was ruled, as accepted by GSK.

The Panel noted that Clause 11.2 of the Code 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. The Panel noted that GSK had not been asked to respond to Clause 11.2. The Panel noted its comment above, that use of Jemperli in combination with chemotherapy was not a licensed indication.

The Panel noted that the UK-based employees 'liking' the post would, on the balance of probabilities, have disseminated the post to the employees' followers, which included health professionals and members of the public, as submitted by GSK. The Panel considered that this dissemination had, on the balance of probabilities, meant that Jemperli had not been promoted in accordance with the terms of its marketing authorisation; the Panel considered that high standards had not been maintained in this regard, and **a breach of Clause 5.1** was ruled, as accepted by GSK.

Whilst GSK had been asked to respond to Clause 26.2, the Panel considered that the complainant had not made an allegation about this clause, and ruled **no breach of Clause 26.2** accordingly.

Clause 2 of the Code was a sign of particular censure and reserved for such use. The Panel noted that the UK-based employees who had 'liked' the LinkedIn post at issue were not senior employees and that, on receipt of the complaint, GSK had acted promptly in instructing the UK-based employees to remove their 'likes' on the post, which they had done immediately.

The Panel noted its comments and rulings above and considered that its concerns were adequately covered by the breach rulings. It did not consider that the particular circumstances of this case warranted a breach of Clause 2, and **no breach of Clause 2** was ruled.

**Complaint received** **10 August 2023**

**Case completed** **11 October 2024**