CASE AUTH/3803/07/23

COMPLAINANT v GSK

Promotion of dostarlimab in a press release

CASE SUMMARY

This case was in relation to a press release issued by GSK that allegedly promoted the use of an unlicensed medicine, Jemperli (dostarlimab), to the public.

The complainant had provided evidence of news stories in three pharmaceutical industry publications about the fact that the Medicines and Healthcare products Regulatory Agency (MHRA) had issued a positive scientific opinion about dostarlimab. This opinion was issued under MHRA's Early Access to Medicines Scheme (EAMS) and related to the use of dostarlimab for treating patients with endometrial cancer.

The complainant alleged that GSK was promoting Jemperli (when it did not have a marketing authorisation for this oncology indication), and promoting it to the public to encourage people to ask their doctor to prescribe it.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.2	**Promoting a medicine for an unlicensed indication**
Breach of Clause 26.1	**Promoting a prescription only medicine to the public**
Breach of Clause 26.2	**Providing unbalanced information and encouraging members of the public to ask for a specific prescription only medicine**

No Breach of Clause 3.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 11.1	**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 an anonymous, non-contactable complainant about GSK.

COMPLAINT

The complaint wording is reproduced below, with some minor typographical errors corrected:

> "I am writing to complain about the recent press GSK has done in relation to their new oncology indication for dostarlimab and a new scheme they are promoting. It appears to me that GSK is promoting the use of an unlicensed medicine to the public, in what I can only assume is to get more patients aware of their new scheme for the medicine before it is available on the NHS in order to get them to ask their physicians for it. Given this medicine does not currently hold a license, nor has it been appraised by NICE, the examples below appear to be prelicensed promotion, and to the public no less, not upholding the high standards the company usually does in relation to this. Additionally, one of the people quoted in the article (photo attached) is the [senior commercial role] who on LinkedIn says [extract from the person's 'About' section, which mentioned "strong commercial background", "sales" and "marketing"]. Given this, it seems like the point of the article is to push the sales of this new medicine to patients, before it has even reached the NHS. [Senior medical employee] also quotes 'patients don't have time to wait' sounding like they are trying to bypass the usual systems and get the public to access dostarlimab through this article, as soon as possible before it's licensed. Physicians are made aware of EAMS schemes through the usual routes, so the press releases don't feel like education to physicians but instead geared to public knowledge. The complainant provided two web links."

When writing to GSK, the PMCPA asked it to consider the requirements of Clauses 3.1, 5.1, 11.1, 11.2, 26.1 and 26.2 of the Code.

GSK'S RESPONSE

The response from GSK is reproduced below:

> "The complainant has made allegations regarding a dostarlimab press release.
>
> GSK is committed to following both the letter and the spirit of the ABPI Code of Practice and all other relevant regulations and takes this complaint very seriously.
>
> You have asked us to respond with regards to clauses 3.1, 5.1, 11.1, 11.2, 26.1 and 26.2 of the 2021 Code.
>
> GSK maintains that there are circumstances under which it is appropriate to issue a press release regarding an EAMS but acknowledges that the execution of the dostarlimab press release was suboptimal and as a result GSK acknowledges breaches of clauses 5.1, 11.1, 11.2, 26.1 and 26.2. GSK denies a breach of clause 3.1 and will set out the background and arguments below.
>
> **Background information on Endometrial cancer and Dostarlimab**
>
> 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 surviving 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 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.'

Dostarlimab has received a positive scientific opinion for use in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy.

Background on the MHRA's Early Access to Medicines Scheme (EAMS)

Under the scheme, the MHRA will provide a scientific opinion on the benefit/risk balance of the medicine, based on the data available at the time of the EAMS submission. For a medicine to then be included in an EAMS they must meet the following criteria:

- Criteria 1: Life threatening or seriously debilitating condition and high unmet need (i.e., there is no methods available or existing methods have serious limitations)
- Criteria 2: The medicinal product is likely to offer significant advantage over methods currently used in the UK.
- Criteria 3: The potential adverse effects of the medicinal product are considered to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit/risk balance.
- Criteria 4: The applicant is able to supply the product and to manufacture it to a consistent quality standard (Good Manufacturing Process (GMP).

Rationale for releasing a Press release for the advanced endometrial cancer EAMS

GSK maintains that there are circumstances under which it is appropriate to issue a press release regarding an EAMS and believed the announcement of this EAMS to be newsworthy as:

- It represents the joint commitment from government and industry, in this case a large UK-headquartered bio-pharmaceutical company, to pharmaceutical innovation; and
- The positive scientific opinion and inclusion in an EAMS of a medicine intended to treat, diagnose, or prevent seriously debilitating or life-threatening conditions where there are no adequate treatment options.

However, GSK concedes that mistakes were made in the preparation and execution of the press release in this instance. The press release was developed by GSK in partnership with an external [named medical communications agency]. It was examined through our UK approval system by a registered pharmacist [details of registered signatory provided]. In addition, once approved and before its release, the press release was shared with the MHRA.

The press release was issued as an email with an attachment (in pdf format) to medical and trade media; and health correspondents at national media by [named medical communications agency] and GSK Corporate team.

On receipt of the complaint, GSK conducted a detailed review of the press release and how it was managed in our approvals process.

GSK concedes that the inclusion of the words, '*patients don't have time to wait'* in the UK [senior medical employee's] quotation, could be perceived as emotive and may have created the perception of urgency for members of the public to ask their health care practitioners to prescribe dostarlimab in this indication.

GSK also concedes that the audience of UK National, medical and trade media is too broad for an EAMS related press release. The inclusion of UK National media outlets, may, with hindsight, be considered as disseminating to a public audience.

GSK accepts therefore a breach of clause 26.1 (promotion of prescription only medicines to the public) and clause 26.2 (statements must not be made for the purpose of encouraging members of the public to ask their healthcare professional to prescribe a specific prescription only medicine).

Following acceptance of the above breaches, Dostarlimab does not have a licence for use in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR) / microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer (EC) and who are candidates for systemic therapy. As this indication is subject to the EAMS, GSK acknowledges that the press release in question may be seen to be promoting prior to the grant of the marketing authorisation (MA) and not in accordance with its MA and inconsistent with the SPC. We therefore acknowledge a breach of clauses 11.1 and 11.2.

In our response you have asked us to consider clause 3.1, which states that '*A medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply'*. With reference to Case AUTH/3690/8/22, as recently ruled by the PMCPA, GSK respectfully challenges a breach of clause 3.1 as the prescription only medicine, dostarlimab, already has a marketing authorisation for use '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'. Therefore, Dostarlimab has not been promoted prior to the grant of the MA which permits its sale or supply.

GSK acknowledges that in view of the reasons for the breaches of clauses 11.1, 11.2, 26.1 and 26.2 of the Code, it has failed to maintain high standards and therefore also acknowledges a breach of clause 5.1.

Conclusion

GSK takes its responsibility under the ABPI Code very seriously and deeply regrets these breaches. GSK has carried out an initial internal investigation related to the press release in question. Whilst we can confirm that all current GSK steps for the review and approval of press releases were followed, considering this case, GSK is in the process of further evaluating our systems and processes for reviewing and approving press releases and quotations in all external communications to prevent similar situations in the future."

PANEL RULING

This complaint related to a press release issued by GSK that allegedly promoted the use of an unlicensed medicine, Jemperli (dostarlimab), to the public.

The complainant had provided evidence of news stories in three pharmaceutical industry publications about the fact that the Medicines and Healthcare products Regulatory Agency (MHRA) had issued a positive scientific opinion about dostarlimab. This opinion was issued under MHRA's Early Access to Medicines Scheme (EAMS) and related to the use of dostarlimab for treating patients with endometrial cancer.

The complainant alleged that GSK was promoting Jemperli (when it did not have a marketing authorisation for this oncology indication), and promoting it to the public to encourage people to ask their doctor to prescribe it. The Panel considered this complaint in relation to Clauses 3.1, 5.1, 11.1, 11.2, 26.1 and 26.2 of the 2021 Code.

In its response to the complaint, GSK provided the PMCPA with the underlying press release on which these three news stories were based. The press release, labelled "For media and investors only", was distributed to more than 25 medical and trade media outlets, alongside the following mainstream national media outlets: Press Association, Daily Mail, Mail on Sunday, Express, Mirror, Times, Telegraph, The Sun and Evening Standard.

The press release included the opening bullet point "Dostarlimab represents the first treatment breakthrough in this setting of endometrial cancer since 1990" and a quote from a senior medical employee, the opening line of which was "There is a significant unmet need in endometrial cancer and patients don't have time to wait." The press release also included a quote by a senior commercial employee stating "dostarlimab plus chemotherapy could represent the first meaningful frontline treatment advancement in decades".

The Panel took account of the language used and the audience of the media outlets the press release had been sent to. In the Panel's view, the press release could not be seen as anything other than promotional.

GSK accepted in its response to the PMCPA that issuing the press release to national, medical and trade media was too broad for disseminating EAMS-related information. The Panel agreed that the press release had been provided to a very wide range of media outlets, including most

of the mainstream news publications in the UK. The Panel, taking into account the content of the press release, concluded that its provision to consumer press amounted to the promotion of a prescription only medicine to the public. The Panel ruled **a breach of Clause 26.1**.

The Panel also considered that the content of the press release was inconsistent with several requirements of Clause 26.2. The first quote, from GSK's senior medical employee, was that "patients don't have time to wait". The Panel concluded that this was information about a prescription only medicine that was not being presented in a balanced way. Noting the emotive and positive language, the Panel considered the content of the press release raised unfounded hopes of successful treatment and was likely to encourage members of the public to ask their health professional to prescribe dostarlimab. The Panel therefore ruled **a breach of Clause 26.2.**

The Panel considered section 4.1, Therapeutic indications, of the Jemperli summary of product characteristics (SPC). This stated that 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 has progressed on or following prior treatment with a platinum-containing regimen".

The Panel noted GSK's submission that it did not have a licence for use in combination with platinum-containing chemotherapy for the treatment of adult patients with dMMR/MSI-H primary advanced or recurrent EC and who are candidates for systemic therapy. In this regard, the Panel considered the press release constituted promotion of an EAMS indication for dostarlimab that was outside the terms of its marketing authorisation. The Panel ruled **a breach of Clause 11.2**, as acknowledged by GSK.

Clause 3.1 of the Code stated that a medicine must not be promoted prior to the grant of the marketing authorisation which permits its sale or supply. Jemperli already had a marketing authorisation, albeit for a different indication than referred to in the press release and, on this technical point, the Panel ruled **no breach of Clause 3.1**.

The Panel noted GSK had also been asked to respond to a similar clause; Clause 11.1. The supplementary information to that clause stated that "medicines or indications that are approved for EAMS must not be promoted". However, the Panel considered the matter had been adequately covered by its rulings in relation to Clauses 3.1 and 11.2 above, and therefore ruled **no breach of Clause 11.1**.

While the Panel noted the press release was developed in partnership with an external agency, examined by an experienced medical signatory, and shared with the MHRA before being issued, the Panel queried how GSK had considered it appropriate to issue information about an unlicensed EAMS indication to consumer press.

Overall, the Panel was very concerned about the distribution of the press release to mainstream news publications in the UK, bearing in mind that it advertised a prescription only medicine to the public for an indication that was not licensed. The Panel considered it was apparent that GSK had failed to maintain high standards and the Panel ruled **a breach of Clause 5.1**, as acknowledged by GSK.

Complaint received 26 July 2023

Case completed **06 December 2024**