CASE AUTH/3796/7/23

COMPLAINANT v ASTRAZENECA

Alleged off-licence promotion of datopotamab deruxtecan to the public on LinkedIn

CASE SUMMARY

This case was in relation to a LinkedIn post, made by a third party, about the results of a phase 3 clinical study evaluating the use of datopotamab deruxtecan in certain lung cancer patients, that was 'liked' by an AstraZeneca employee.

The outcome under the 2021 Code was:

Breach of Clause 3.1	**Promoting a medicine prior to the grant of a marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**

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 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 26.1	**Requirement to not advertise prescription only medicines to the public**
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, contactable complainant, who described themself as an employee, about AstraZeneca. The complainant later became non-contactable.

COMPLAINT

The complaint wording is reproduced below:

> "Attached is a further example of AZ promoting an off license indication of its product Datopotamab to the public on LinkedIn.
>
> As can be seen an AZ employee has liked the post about Tropion Lung 01 and so the following clauses have been breached. Unfortunately despite bringing this to the attention of the individual to simply unlike the post, the concerned individual refuses to comply with the code.
>
> Clauses to consider are:
>
> Clause 2 as this is now one of many offenses of promotion to the public
> 26.1 and 26.2
>
> 3.1 – as the HCP community on LinkedIn (Lung Oncologists) are being promoted to prior to a Marketing Authorisation
>
> 5.1 – a failure to repeatedly maintain high standards & a refusal to take a simple corrective action, such as unliking a post."

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

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

> "The allegation raised by the complainant in their email from 7 July is that an AstraZeneca employee has liked a LinkedIn post about the TROPION-Lung01 study.
>
> The complainant insinuates from their email sign off "Kind Regards Concerned AZ" that they are an AstraZeneca employee, however, the complainant is anonymous to AstraZeneca and we have received no information that confirms that they are an AstraZeneca employee.
>
> **Our Investigation**
>
> The AstraZeneca employee who liked the post is based in the UK and works in the research and development function at AstraZeneca as a [job title].
>
> On receipt of the complaint, the AstraZeneca employee was contacted to request that they withdraw their "like" of the post. The individual immediately took the requested action.
>
> The individual confirmed that they had never been contacted previously for any issue with respect to social media engagement nor in relation to this post. The individual had not discussed the liking of the post with anyone at AstraZeneca. Our findings are at odds with the complainant who makes the allegation that "*despite bringing this to the*

attention of the individual to simply unlike the post, the concerned individual refuses to comply with the code" but provides no evidence to support their allegation.

Training

The employee has read and signed the Global Standard - Employee use of personal social media channels for AZ and work-related content, v3.0 in November 2020, and completed the AstraZeneca Code of Ethics awareness training, a mandatory online e-learning course which is delivered on an annual basis and includes a section on personal use of social media for work-related content. The individual was asked to refamiliarise themselves with the Global Standard. Thus, with respect to training, high standards have been maintained by AstraZeneca and so we deny a breach of Clauses 5.1 and 2.

Content of LinkedIn Posts

The original LinkedIn post was made by a third party. The third party is a director [initials] of a [named] company[, and this links to an article released by [named publication].

Since the post is a third-party post for which AstraZeneca had no involvement, there is no requirement for examination or certification. Therefore, there are no certificates.

We cannot fulfil the PMCPA request to supply the Summary of Product Characteristics for datopotamab deruxtecan because it is not a licensed medicine anywhere in the world.

At the time of the third-party post, datopotamab deruxtecan was in clinical development, it was not available to prescribe in any market and no regulatory submission for any indication had been made anywhere in the world. We plan to share the TROPION-Lung01 trial data with regulatory authorities to discuss next steps. We do not consider the liking of this post to be in breach of Clause 3.1.

LinkedIn Profile

We acknowledge that LinkedIn is a professional networking site, and that the PMCPA has previously determined that unless closed groups are used, or the individual can guarantee that their connections are HCPs, then any content being disseminated on LinkedIn is likely to include members of the public. From the individual's LinkedIn profile they have 500+ connections, and thus we accept that some of their connections may include members of the public. In this case, the medicine being discussed in the LinkedIn post is not licensed anywhere in the world, so we refute an allegation of promoting a prescription only medicine to the UK public (Clause 26.1) and we refute an allegation of raising unfounded hopes of a successful treatment or misleading with respect to the safety of the product (Clause 26.2).

Conclusion

AstraZeneca is concerned that unsubstantiated allegations are being raised by an alleged AstraZeneca employee about another individual employee not willing "*to*

comply with the code". Such allegations can be distressing and damaging reputationally for the individual concerned.

We do not believe that the post in question constitutes promotion of a prescription only medicine to the public or promotion prior to grant of Marketing Authorisation. At the time of the third-party post, the medicine was not available to prescribe in any market and no regulatory submission for any indication had been made anywhere in the world. Therefore, we deny any breaches of the Code.

Furthermore, we believe that a single UK-based employee liking a LinkedIn post does not result in the individual or the AstraZeneca organization as a whole failing to maintain high standards or bringing disrepute upon the pharmaceutical industry. Thus, we refute being in breach of lack of high standards (Clause 5.1) or bringing the pharmaceutical industry into disrepute (Clause 2).''

PANEL RULING

The Panel noted that the complaint related to a LinkedIn post made by a third party, which reported positive results from the phase 3 TROPION-Lung01 trial evaluating the use of datopotamab deruxtecan versus docetaxel in certain lung cancer patients. The post included a link to an article on [named publication] titled "AstraZeneca and Daiichi Sankyo share positive results from phase 3 lung cancer study", which shared the same trial data. The Panel noted the wording of the post was the same as that in the linked article, although the linked article contained an additional three paragraphs towards the end.

The Panel noted that the final part of the linked article made reference to positive phase 3 trial data for Tagrisso (osimertinib), an AstraZeneca medicine, as an additional treatment for patients with early-stage epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) who had undergone surgery to remove their primary tumour, stating that the drug was associated with a 51% reduction in risk of death compared to placebo in both the primary analysis population (patients with stages 2 to 3a EGFRm NSCLC) and in the overall trial population (stages 1b to 3a). The Panel noted that the allegations made by the complainant were limited to datopotamab deruxtecan; as there were no allegations made regarding Tagrisso, the Panel made no ruling in relation to this product.

The Panel noted that the LinkedIn post at issue and the linked article both contained the same prominent image of the AstraZeneca name and logo on what appeared to be the exterior of the company's offices.

The Panel noted AstraZeneca's submission that the original LinkedIn post was made by a third party, a senior employee of another named company, in which AstraZeneca had no involvement. The Panel considered that this post, made by an employee of another company, independently of AstraZeneca, was not in scope of the Code.

However, a single UK-based employee had 'liked' the post. The Panel noted AstraZeneca's submission that the individual UK employee who 'liked' the LinkedIn post had 500+ connections. In the Panel's view, the UK-based employee's engagement with the post would have proactively disseminated it to their LinkedIn connections in the UK, which likely included members of the public. The Panel determined that this brought the LinkedIn post 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.

The Panel considered the content of, and the impression created by, the LinkedIn post at issue and the linked article. It noted the inclusion of positive statements, including that datopotamab deruxtecan had demonstrated "statistically significant improvement in progression-free survival compared with standard chemotherapy", and that, while the data for overall survival were immature at the time of analysis, "an 'early trend' was observed in favour of datopotamab deruxtecan". Similarly, positive comments from a senior AstraZeneca employee were quoted, for example, that the study results challenged "the entrenched standard of care in a previously treated and unselected patient population that has long deserved an alternative to chemotherapy" and "These first phase 3 trial results from the datopotamab deruxtecan clinical programme provide compelling evidence for the potential role this TROP2-directed antibody drug conjugate can play in treating patients with lung cancer."

The Panel considered that the immediate and overall impression created by the post at issue and linked article as a whole and, in particular, the positive statements regarding datopotamab deruxtecan, meant that the original LinkedIn post and linked article could not be seen as anything other than promotional, and it was on this basis that the Panel made its rulings.

The Panel considered the status of datopotamab deruxtecan in light of Clause 3.1, which prohibited the promotion of a medicine prior to the grant of its marketing authorisation. The Panel noted AstraZeneca's submission that datopotamab deruxtecan was in clinical development and that the company planned to share the TROPION-Lung01 trial data with regulatory authorities to discuss next steps. The Panel further noted that the LinkedIn post and linked article described the TROPION-Lung01 trial as a late-stage study, and that the positive results of the phase 3 clinical trial appeared to be the key message. Noting the above, in the Panel's view, datopotamab deruxtecan was not so early in its development such that it could not be considered a medicine.

Noting the content of the LinkedIn post at issue, and the linked article, including the name of the product and positive outcomes in relation to treatment in patients with locally advanced or metastatic NSCLC, the reference to 'statistically significant improvement in progression-free survival' and 'compelling evidence for the potential role this TROP2-directed antibody drug conjugate' could play in treating patients with lung cancer, the Panel considered that by 'liking' the post, the UK employee had proactively disseminated the post and linked article, thus promoting datopotamab deruxtecan prior to the grant of its marketing authorisation. A **breach of Clause 3.1** was ruled.

The Panel considered that 'liking' the post would, on the balance of probabilities, have disseminated the post to the employee's followers, which might have included health professionals and members of the public. The promotion of a medicine prior to the grant of a marketing authorisation was a serious matter and was such that AstraZeneca had failed to maintain high standards. The Panel ruled a **breach of Clause 5.1** in this regard.

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines once a marketing authorisation had been granted, and Clause 26.2 stated, among other things, that information about prescription only medicines which is made available to the public must not raise unfounded hopes of successful treatment. On the narrow technical point that datopotamab deruxtecan did not have a UK marketing authorisation and therefore was not a prescription only

medicine at the time of the post at issue, the Panel ruled **no breach of Clause 26.1.** Noting that Clause 26.2 applied only to prescription only medicines, the Panel ruled **no breach of Clause 26.2**.

The Panel noted the complainant made two allegations regarding AstraZeneca's failure to maintain high standards. Firstly, that there had been a "failure to repeatedly maintain high standards" and secondly, that the UK employee in question had refused "to take a simple corrective action, such as unliking a post".

With regard to the first allegation, the Panel noted that the complainant bore the burden of proving their complaint, on the balance of probabilities. The Panel considered that the complainant had not provided sufficient information with regard to a repeated failure to maintain high standards, and had not discharged their burden of proving the allegations to show that a breach of the Code had occurred. Therefore, the Panel ruled **no breach of Clause 5.1** accordingly.

With regard to the second allegation, AstraZeneca submitted the employee had immediately withdrawn their 'like' when asked to do so. The Panel noted AstraZeneca's submission that the individual confirmed that they had never been contacted previously for any issue with respect to social media engagement nor in relation to this post and that the individual had not discussed the 'liking' of the post with anyone at AstraZeneca. The Panel noted that the complainant bore the burden of proof on the balance of probabilities and that the complainant had not established that the UK-based employee in question had refused to take a simple corrective action such as 'unliking' a post. The Panel ruled **no breach of Clause 5.1** in this regard.

Clause 2 of the Code was a sign of particular censure and reserved for such use.

The Panel noted the complainant's allegation that 'this is now one of many offences of promotion to the public'. The Panel noted that the complainant bore the burden of proving their complaint, on the balance of probabilities. It was not clear to the Panel what information the complainant had provided with regard to this allegation; it was not for the Panel to infer reasons to support the complainant's allegations; it was for the complainant to make out their complaint on the balance of probabilities.

Nonetheless, the Panel considered that promotion prior to the grant of the marketing authorisation was an example of an activity likely to be in breach of Clause 2; whether it amounted to a breach of that clause, however, was considered on a case-by-case basis. The Panel noted that the UK-based employee was not a senior employee and that, on becoming aware of the complaint, AstraZeneca had acted promptly in instructing the UK-based employee to remove their 'like' on the post, which they had done immediately. The Panel noted AstraZeneca's submission that the individual was asked to refamiliarise themselves with the Global Standard.

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 7 July 2023

Case completed **14 August 2024**