CASE AUTH/3813/8/23

COMPLAINANT v ASTRAZENECA

Alleged off licence promotion of Tagrisso (osimertinib) to the public via LinkedIn

CASE SUMMARY

This case was in relation to a LinkedIn post, made by a third party, that was 'liked' by three UK-based AstraZeneca employees. The post, which was about the results of a pre-clinical study, referred to osimertinib in the context of certain EGFR-mutant lung tumours resistant to it.

The outcome under the 2021 Code was:

Breach of Clause 3.2	**Advertising a prescription only medicine to the public**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.2	**Failing to recognise the special nature of medicines**
Breach of Clause 26.1	**Advertising 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 not to promote a medicine prior to the grant of a marketing authorisation**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**

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 about AstraZeneca was received from an anonymous contactable complainant (who later became non-contactable) who described themselves as a current employee of AstraZeneca.

COMPLAINT

The complaint wording is reproduced below:

> "I write to make a complaint about a case of off licensed [sic] promotion to the public of AstraZeneca's lung cancer medicine osimertinib for Lung Cancer via LinkedIn by two named AZ employees ([named]) – please see attached LinkedIn profiles & likes.

Osimertinib (Tagrisso) is AZ's 8bn dollar blockbuster to treat EGFR mutated lung cancer. In a LinkedIn article about a piece of research conducted at the [named institution] the scientists write about how Osimertinib's potency can be enhanced in early stage pre clinical studies.

By 'liking' the article in which Osimertinib is mentioned by name in the actual post an off license indication has been promoted to the wider public.

This is the latest in a series of similar incidents where AZ senior UK based staff have promoted their medicines to the public online.

The frequency of such offences by AZ staff indicates a company culture of care free attitude towards the code, bringing the pharma industry into disrepute, and discredits AZ and the wider industry. Additionally, the repeated offences, lack of training on the code further discredit AZ's role in preserving the special nature of medicines and so AZ should consider a breach of Clause 2.

Additional clauses of relevance include:
- a failure to maintain high standards or any standards with such poor compliance and code oversight amongst AZ senior UK based employees
- promotion prior to the grant of a Marketing Authorisation is also applicable here as Osimertinib is not licensed for use beyond disease progression in combination with any experimental molecule or even as mono therapy
- sharing and liking on LinkedIn is a direct promotion to the wider public
- the special nature of medicines and in particular targeted therapies such as Osimertinib for a possible future indication has not be [*sic*] recognized here."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 3.2, 5.1, 5.2 and 26.1 of the 2021 Code.

ASTRAZENECEA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Further to your letter dated 24 August, AstraZeneca would like to respond to the allegations raised by the complainant in their email from 23 August. We are disappointed to receive another complaint from this individual who alleges to be employed by AstraZeneca.

LinkedIn Post

The LinkedIn post [provided by complainant] and the linked news article [provided] was written by a third party, [named institution], with no input from AstraZeneca.

The LinkedIn post and the linked news release (collectively referred to as 'Post') refers to Osimertinib in the context of lung cancers that are resistant to it.

The Post discusses emerging science, in the pre-clinical setting, exploring why lung cancers driven by mutations in Epidermal Growth Factor Receptor (EGFR) gene may become resistant to treatment with targeted therapies, as opposed to the use of

osimertinib in patients. It explores blocking mSWI/SNF complexes and clearly states that these are ‘a series of experiments’ in ‘cellular systems’ and ‘animal models.’ The linked news release in the LinkedIn post refers to the investigation of mSWI/SNF inhibitors in Phase I trials. The Post does not mention efficacy outcomes, specific indication, brand name or safety of osimertinib. Therefore, the reader is aware from the outset that this is experimental information. The Post is factual, does not make claims or reference any positive attributes of an AstraZeneca medicine. In addition, AstraZeneca does not have any mSWI/SNF disrupting drugs in clinical development at this time. Furthermore, the Post does not extrapolate the findings to draw conclusions in clinical use. Therefore, AZ contend that the post is non-promotional.

Based on the content and context of this Post, the mention of osimertinib is unlikely to result in an Healthcare Professional (HCP) to prescribe this medicine or a member of the general public to request this medicine from their HCP, therefore it is unlikely to lead to the administration, consumption, prescription, purchase, recommendation, sale, supply or use of osimertinib.

The AstraZeneca employees who liked the post were all from the AstraZeneca Research and Development organisation and have a genuine interest in these scientific advancements.

We do not believe that UK-based employees liking this post and disseminating the content of the post to their network constitutes promotion of a prescription only medicine or promotion of a medicine prior to grant of marketing authorisation. Therefore, AstraZeneca deny breaches of Clauses 5.1, 5.2, 3.1 and 3.2. It is unclear why PMCPA have requested AstraZeneca to consider the requirements of Clauses 3.2 and 26.1, as they are duplicate clauses. Nonetheless, AstraZeneca deny breaches of both clauses.

AstraZeneca employee engagement with the post

The complainant sent several screen shots of LinkedIn users that liked the post. From these screenshots, AstraZeneca identified three UK-based AstraZeneca employees who liked the post. On receipt of the complaint, all three employees were contacted and asked to withdraw their likes. This was actioned immediately. Employees were also asked to re-familiarise themselves with the Global Standard Employee Use of Personal Social Media channels for AZ and work-related content.

AstraZeneca confirms the employees mentioned above have read and signed the Global Standard Employee Use of Personal Social Media Channels for AZ and Work-Related Content before the LinkedIn post in question was published between June 2020 and November 2021. They had also 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. In addition, there were reminders about appropriate use of personal social media (in line with the Global Standard) via written and animated posts on global AstraZeneca Workplace groups (an internal social network) and July 2023. These posts have had approximately 22k views. These posts are often re-shared amongst other internal groups within the organisation.

With respect to the LinkedIn profiles of AstraZeneca employees, we acknowledge that their connections may include members of the public.

Comments made by the complainant

The complainant stated that 'this is the latest in a series of similar incidents where AZ senior UK based staff have promoted their medicines to the public online' however provides no complete case numbers and therefore we have provided no further comment to this statement.

Conclusion

AstraZeneca takes self-regulation seriously and our social media standard is robust and clear.

We do not believe that engaging with a post about advancements in science related to pre-clinical modelling data and mention of medicines used within these animal models constitutes promotion to the public. Furthermore, the engagement of this post by AstraZeneca employees does not bring the pharmaceutical industry into disrepute and thus refute a breach of Clause 2."

PANEL RULING

The Panel noted the complainant's allegations were regarding the alleged off-licence promotion to the public of AstraZeneca's lung cancer medicine, osimertinib, by senior UK-based employees. The complainant provided a screenshot of a LinkedIn post to support the allegation. The complainant alleged that the post, which included a linked news article, had been 'liked' by two UK-based employees; however AstraZeneca identified three UK-based employees who had 'liked' the post.

The Panel noted that the post at issue was made by the [named institution] and stated, "When lung cancers driven by mutations in the EGFR gene become resistant to osimertinib or other targeted therapies, epigenetic changes, rather than genetic changes are often to blame. In a new study in Cancer Cell, researchers at the [named institution] and [second named institution] show that the main source of these changes are mSWI/SNF chromatin remodeling complexes, which alter gene activity by changing DNA architecture. In a series of experiments in cellular systems and animal models, the researchers found that blocking mSWI/SNF complexes – either chemically or genetically – reversed resistance to osimertinib in a subset of EGFR-mutant lung tumours. The findings suggest that mSWI/SNF-disrupting drugs, particularly SMARCA4/2 ATPase inhibitors, may offer a way to restore the potency of osimertinib in these tumors".

The Panel noted that the post included a linked news article beneath the text, hosted on the [named institution's] website. The title of the article, which could be seen in full, was "Study Uncovers Epigenetic Source of Resistance to Targeted Therapy in EGFR-mutant Lung Cancer". The article, when viewed, was a news release which contained, among other things, the study title, names of the authors, the study summary and impact.

The Panel noted that the study summary in the news release contained identical text as that which appeared in the LinkedIn post at issue. The news release stated, under the bold heading "Impact", that "In certain *EGFR*-mutant lung tumors that are resistant to osimertinib, treatment

with mSWI/SNF inhibitors, now in the clinic in Phase I trials, may reinstate osimertinib sensitivity".

The Panel noted AstraZeneca's submission that the original LinkedIn post and the linked news release were written by a third party, the [named institution], with no input from AstraZeneca. The Panel considered that this post, made by a third party, independently of AstraZeneca, was not in scope of the Code.

However, three UK-based AstraZeneca employees had 'liked' the post. The Panel noted AstraZeneca's submission that the individual UK employees who had 'liked' the LinkedIn post were all from AstraZeneca's Research and Development organisation. In the Panel's view, the UK-based employees' 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 noted the complainant's allegation that the LinkedIn article at issue discussed how "osimertinib potency can be enhanced" and that by 'liking' the article in which osimertinib was mentioned by name, an off-licence indication had been promoted.

The Panel noted that osimertinib as monotherapy was indicated for:

- the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations.
- the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations.
- the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

The Panel noted AstraZeneca's submission that the post discussed emerging science in a pre-clinical setting, exploring why lung cancers driven by mutations in Epidermal Growth Factor Receptor (EGFR) gene may become resistant to treatment with targeted therapies, as opposed to the use of osimertinib in patients, and the linked news release referred to the investigation of mSWI/SNF inhibitors in Phase I trials.

The Panel noted AstraZeneca's submission that the post did not mention efficacy outcomes, specific indication, brand name or safety of osimertinib and that it was factual, did not make claims or reference any positive attributes of an AstraZeneca medicine, nor did it extrapolate the findings to draw conclusions.

The Panel noted that osimertinib was mentioned three times in the LinkedIn post at issue. The Panel noted that the first two mentions were in the context of a subset of EGFR-mutant lung cancers becoming resistant to osimertinib, and the **resistance being reversed** [emphasis added by the Panel] by blocking mSWI/SNF complexes. The third mention of osimertinib was in the context of mSWI/SNF-disrupting drugs potentially offering a way to **restore the potency** [emphasis added by the Panel] of osimertinib in such tumours. The Panel noted that the linked news release stated, beneath a bold heading "Impact", that "In certain EGFR-mutant lung tumors that are resistant to osimertinib, treatment with mSWI/SNF inhibitors, now in the clinic in Phase I trials, **may reinstate osimertinib sensitivity**" [emphasis added by the Panel].

The Panel considered the content of the LinkedIn post at issue and the linked news release in totality. Noting the reference to the use of osimertinib in lung cancers driven by mutations in the EGFR gene, and statements in the post and linked news release referring to resistance to osimertinib being reversed, the restoration of potency and reinstatement of osimertinib sensitivity, the Panel considered that the LinkedIn post and linked news release presented a favourable outcome for AstraZeneca and it was on this basis that the Panel made its rulings.

The Panel noted the complainant's allegation that "promotion prior to the grant of a marketing authorisation is also applicable here as osimertinib is not licensed for use beyond disease progression in combination with any experimental molecule or even as monotherapy".

Clause 3.1 stated 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 osimertinib was a prescription only medicine at the time of the post at issue, and ruled **no breach of Clause 3.1** accordingly.

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. The Panel noted AstraZeneca had not been asked to respond in relation to Clause 11.2; therefore, the Panel considered the allegation under Clause 5.1.

The Panel noted that the LinkedIn post at issue and the linked news release both referred to a series of experiments in cellular systems and animal models which had shown blocking mSWI/SNF complexes reversed resistance to osimertinib in a subset of EGFR-mutant lung tumours and the linked news release stated that "treatment with mSWI/SNF inhibitors, now in the clinic in Phase I trials, may reinstate osimertinib sensitivity." It was not clear to the Panel whether the statements in the post and linked news release implied that osimertinib should be used in combination with mSWI/SNF inhibitors to reverse osimertinib resistance and reinstate sensitivity. Noting that the complainant bore the burden of proof on the balance of probabilities, the Panel considered that they had not established that the LinkedIn post or news release at issue had promoted the use of osimertinib outside the terms of its marketing authorisation, and on balance, ruled **no breach of Clause 5.1** in this regard.

Clauses 3.2 and 26.1 stated that prescription only medicines must not be advertised to the public. The Panel noted that Clauses 3.2 and 26.1 were identical other than the supplementary information and treated the allegation on this point as one matter.

The Panel noted AstraZeneca's submission that the three UK-based employees' connections may include members of the public. The Panel, noting its view set out above that the LinkedIn post and the linked news release contained statements favourable to osimertinib, considered that, through the employees' 'likes', the post and news release had likely been proactively disseminated to members of the public and that this constituted promotion of osimertinib, a prescription only medicine, to the public. On balance, the Panel ruled **breaches of Clauses 3.2 and 26.1** in this regard.

The promotion of a prescription only medicine to members of the public was a serious matter and was such that AstraZeneca had failed to recognise the special nature of medicines and to

maintain high standards in this regard. The Panel ruled **breaches of Clauses 5.1 and 5.2** accordingly.

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

The Panel noted the complainant's allegation regarding "the frequency of such offences" by AstraZeneca staff indicating "a company culture of care-free attitude towards the Code, bringing the pharma industry into disrepute" and the "repeated offences" and "lack of training on the Code further discredit[ing] AstraZeneca's role in preserving the special nature of medicines".

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 these allegations; 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 noted that in its response AstraZeneca had detailed the training the company provided to raise awareness about social media and the actions taken on receipt of the complaint. It confirmed the three UK-based employees in question had withdrawn their 'likes' immediately on being contacted and were asked to re-familiarise themselves with the Global Standard Employee Use of Personal Social Media channels for AZ and work-related content policy. AstraZeneca submitted that the employees had read and signed the policy before the LinkedIn post in question was published and had also completed the AstraZeneca Code of Ethics Awareness training, which included a section on personal use of social media for work-related content. In addition, AstraZeneca issued reminders about appropriate use of personal social media (in line with the Global Standard) via written and animated posts on global AstraZeneca Workplace groups (an internal social network); these had been viewed widely.

Noting the above, the Panel considered that in the particular circumstances of this case, its breach rulings above adequately covered the matters at issue, and a breach of Clause 2 was not warranted. The Panel ruled **no breach of Clause 2** accordingly.

Complaint received **23 August 2023**

Case completed **20 September 2024**