CASE AUTH/3687/8/22

COMPLAINANT v ASTRAZENECA

Alleged pre-licence promotion/promotion of an unlicensed indication

CASE SUMMARY

This case was in relation to UK employees' engagement with a LinkedIn post by an AstraZeneca US employee and associated press release about Enhertu (trastuzumab deruxtecan) and an alleged breach of undertaking.

The Panel ruled a breach of the following Clauses of the 2021 Code on the basis that eight UK-based employees had acted contrary to AstraZeneca's training and policies by liking the post which disseminated positive information about an Enhertu clinical trial and promoted the medicine for an unlicensed indication to the employees' connections which would likely have included members of the public.

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**

The Panel ruled no breach of the following Clauses of the 2021 Code on the basis that:

- **Enhertu had a marketing authorisation and was classified as a prescription only medicine at the time of the complaint**
- **it was clear that the post was authored by an AstraZeneca US employee and that the content was promotional, and thus the post was not disguised**
- **AstraZeneca had acted promptly on being made aware of the complaint and it was not established that it had breached its undertaking to take all reasonable steps to avoid similar breaches.**

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 a marketing authorisation**
No Breach of Clause 3.3	**Requirement to comply with an undertaking**
No Breach of Clause 3.6	**Requirement that materials and activities must not be disguised promotion**
No Breach of Clause 5.1	**Requirement to maintain high standards**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of a marketing authorisation**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

DETAILS OF THE CASE

A contactable ex-employee of AstraZeneca complained about UK employees' engagement with a LinkedIn post and associated press release about Enhertu (trastuzumab deruxtecan).

The LinkedIn post read:

> 'So many of us know first hand the devastating impact of lung cancer and the urgent need for innovative treatment options especially for the later stages when there are fewer effective medicines. But today is an important day for patients, their families and those of us in the oncology community: the FDA has approved our therapy for certain patients with metastatic non-small cell lung cancer.
>
> Today's news shows that we're changing what it means to be diagnosed with lung cancer. And we're shifting the conversation from a one-size-fits-all treatment approach to treating a person's specific disease. Most critically, with every new approval, we're potentially giving someone more time with their loved ones.
>
> While today's approval is a big accomplishment, we're not slowing down. We know there is still much more work to be done to improve outcomes at every stage of disease – and the need to do so urgently because patients are waiting. https://bit.ly/3SWPCsG
>
> #Oncology #CancerResearch #LungCancer.'

The post included an image of a lung with 'FDA approval offers new treatment option for people living with metastatic non-small cell lung cancer'.

The linked press release titled 'ENHERTU (fam-trastuzumab deruxtecan-nxhi) approved in the US as the first HER2-directed therapy for patients with previously treated HER2-mutant metastatic non-small cell lung cancer' was housed on AstraZeneca's US corporate website.

THE COMPLAINT

The complainant had raised concern about the poor culture within the company, especially surrounding pre-license activities, many times to their line manager.

Their specific concern related to UK employees (including senior UK-based global employees as well as UK marketing company employees – in this case a total of 8 employees) 'liking' a LinkedIn post which related to disguised promotion for a currently unlicensed indication and could also be considered pre-license promotion. As the content had been 'liked' by UK personnel, it could be seen by UK clinicians and patients in their network. There had been numerous trainings on this matter so the only reason that UK-based employees had liked this was to share the data far and wide with UK clinicians to prime the market on a product which was already launched in the metastatic breast space to raise awareness and 'noise' for upcoming HER2low and lung cancer indications. In effect, the liking of the post had further disseminated the material within the UK on a platform such as LinkedIn which was a general public platform and not specifically for clinicians.

The link in the post went into detail about the medication, the data and the recently approved FDA indication, and as it was directly linked the information within could reasonably be assumed to be a part of the LinkedIn post. The complainant thought it was evident that the link was

poised for a global (including the UK) audience and by UK employees 'liking' the post, the link and its contents were fully available to be seen by UK clinicians in their networks, and having checked many of their connections were clinicians. This was undoubtedly pre-license promotion as well as disguised promotion of a product which was likely to be launched in the near future in the UK. The link itself contained a prominent quotation by a senior AstraZeneca global employee as well as safety information.

The complainant stated that it was worrying that this continued to be a common trend for AstraZeneca having had breaches ruled for similar issues in the following Code cases: Cases AUTH/3411/10/20, AUTH/3412/10/20, AUTH/3430/11/20, AUTH/3011/1/18 and AUTH/3248/9/19.

The complainant wanted this to be raised with AstraZeneca and addressed for a compliant working environment within the UK marketing company where the culture was encouraged to be a non-compliant one.

Following a request for further information from the case preparation manager, the complainant the person who posted the original LinkedIn post was confirmed to be an employee in the US marketing company and the names and job titles of the 8 UK-based employees who engaged with the post were provided.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.3, 3.6, 5.1, 11.1, 11.2 and 26.1 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca submitted that the original LinkedIn post was outside the jurisdiction of the UK ABPI Code of Practice since:

- the individual was a US-based AstraZeneca US marketing company employee
- the employee was not employed by the AstraZeneca PLC global organization headquartered in the UK, nor were they employed by AstraZeneca UK Limited – the UK marketing company
- the employee had not targeted a UK audience; neither UK health professionals or the UK general public
- the post was intended for the US-based employee's followers, for which given their principal locality, the majority were US-based.

The post was in line with US external regulations and AstraZeneca US social media policy. In the US, it was permissible to make this type of post on social media, which included a link to an AstraZeneca press release housed on the AstraZeneca US corporate website. The LinkedIn post was also in line with the AstraZeneca US social media guidance, as written in its US Policy Handbook, in that members of the North American Leadership team were permitted to post product-related content. There was no requirement for examination or certification of social media posts by a Global Nominated Signatory in line with ABPI Code requirements because the US-based employee was operating in accordance with the US internal AstraZeneca social media policy and US external regulation.

There was never any purposeful intent by the Global AstraZeneca organization to promote a medicine, disguised or otherwise, to a UK audience. It was not posted on any global-owned social media corporate channels nor were UK-based employees encouraged to engage with the

post. Additionally, the LinkedIn post was not amplified through any internal global communication framework.

Inside one business day of receipt of the complaint from PMCPA, the UK-based employees, some employed by the UK marketing company and some employed by the global organization, were asked to withdraw their 'like'. All except one, withdrew their 'like' immediately. One employee, who was on annual leave, withdrew their 'like' inside 5 business days.

AstraZeneca assured the PMCPA that it regularly trained all UK-based (global and UKMC) employees on social media, including the standard operating procedure (SOP) covering personal use of social media for work-related content. In addition, prior to key congresses, where it anticipated social media activity might peak, it briefed all relevant employees again on the 'dos' and 'don'ts' of social media engagement.

Based in the UK, there were more than 8,000 employees, which AstraZeneca estimated could equate to tens of thousands, if not hundreds of thousands of social media interactions on a weekly basis, and thus it expected that sometimes individuals might accidently engage with material that they should not engage with, or have a lapse in judgment of what was permissible and what was not. On this occasion, despite its best efforts to train and educate, a limited number of UK employees liked a post that they should not have engaged with.

As a global organization, AstraZeneca strove to do the right thing, to regularly engage with its employees, and to educate and train them on all aspects of external communication, including social media. What it communicated through all UK global social media channels and all UK-based senior employee social media accounts was cognisant of, and sought to uphold, the UK Code of Practice, with the appropriate level of review and approval. Additionally, through education and training, AstraZeneca strove to mitigate the risk of material that was appropriate to be posted in one country coming into the view of another country. AstraZeneca did not believe it had brought the pharmaceutical industry into disrepute because a limited number of UK-based employees had 'liked' a single LinkedIn post intended for a US audience, which was immediately rectified with the 'likes' being withdrawn once AstraZeneca was notified. Thus, AstraZeneca refuted being in breach of Clause 2.

THE PANEL RULING

The Panel noted that the LinkedIn post in question stated, among other things:

> 'But today is an important day for patients, their families and those of us in the oncology community: the FDA has approved our therapy for the treatment of certain patients with metastatic non-small cell lung cancer.'
>
> and
>
> 'we're shifting the conversation from a one-size fits all approach to treating a person's specific disease. Most critically, with every new approval, we're potentially giving someone more time with their loved ones.'

The Panel noted that the LinkedIn post included an illustration of a lung with what appeared to be a tumour and a statement in large type, superimposed over the image, highlighting that the FDA approval offers a new treatment option for people living with metastatic non-small cell lung cancer (NSCLC); the post itself did not appear to name a specific AstraZeneca medicine.

The LinkedIn post was followed by a number of hashtags, #Oncology, #CancerResearch and #LungCancer, and linked to a press release housed on the AstraZeneca US corporate website.

This press release concerned the US approval of Enhertu (fam-trastuzumab deruxtecan-nxki) for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumours have activating HER2 (ERBB2) mutations as detected by an FDA approved test, and who have received a prior systemic therapy.

The Panel noted AstraZeneca's submission that the original LinkedIn post was outside the jurisdiction of the UK Code on the basis that the post was made by a US-based employee who was not employed by a UK-based company, it was intended for a US audience and was not targeted at a UK health professional or lay audience; according to AstraZeneca, the post was in line with the US social media guidance, as written in the US Policy Handbook which permitted certain very senior employees to post original content that was product-related with the guidance and approval of Corporate Affairs.

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. 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 that eight UK-based AstraZeneca employees had engaged with ('liked') the LinkedIn post in question. In that regard, the Panel considered that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, by posting, sharing, commenting or liking.

The Panel understood that if an individual 'liked' a post, it increased the likelihood that the post would appear in their 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 their LinkedIn profile page which was visible to their connections; an individual's profile page was also potentially visible to others outside their network depending on the individual's security settings. Company employees should assume that such activity would potentially be visible to health professionals or other relevant decision makers and members of the public.

The Panel considered that the eight UK employees' act of liking the post would have, on the balance of probabilities, proactively disseminated the LinkedIn post to their connections within the UK. It followed that the liking of the post by AstraZeneca UK employees brought the post within the scope of the UK Code.

The Panel noted that whilst the LinkedIn post at issue did not name a specific medicine, it had drawn attention to the US approval of a new treatment for certain patients with non-small cell lung cancer; readers were able to click the link within the post to be directed to the linked press release which formed part of the LinkedIn post and mentioned the medicine by name and provided information about the medical research underpinning the approval, the Enhertu development program, existing licensed indications globally which included the UK licensed indication for the treatment of certain patients with unresectable or metastatic HER2-positive breast cancer as referred to by the complainant. The press release included efficacy and safety data about the medicine and contained quotes from a medical oncologist and senior employees

within AstraZeneca and Daiichi Sankyo welcoming the approval as a new treatment option in metastatic NSCLC.

The Panel noted that it was an accepted principle that any material associated with a social media post, for example a link within a post, would be regarded as being part of that post and it was possible, given the broad definition of promotion, for material to be promotional without mentioning a product by name. In the Panel's view, there was a difference between making a press release available within the media section of a company's website or only to the press, to be published or not, and linking to it on a social media platform with the expectation that a wider audience would read it.

In the Panel's view, the LinkedIn post, which stated 'FDA approval offers new treatment option for people living with metastatic non-small cell lung cancer' and the linked press release about Enhertu, could not be anything other than promotional.

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 Enhertu was licensed and classified as a prescription only medicine in the UK at the time that the eight UK-based employees had 'liked' the LinkedIn post, made by the US employee. The Panel noted that Clauses 3.1 and 11.1 had been raised but only applied to medicines which did not yet have a marketing authorisation. On the very narrow technical point, that Enhertu did have a marketing authorisation at the time, the Panel ruled **no breach of Clauses 3.1 and 11.1**.

However, the Panel noted that the LinkedIn post related to the approval of Enhertu in the US for patients with previously treated HER2-mutant metastatic NSCLC, which did not appear to be the licence for Enhertu in the UK at the time the eight UK-based employees had 'liked' the LinkedIn post. The Panel therefore considered that the liking of the LinkedIn post by the eight UK-based employees resulted in its proactive dissemination to the UK employees' connections, and Enhertu being promoted for an unlicensed indication and a **breach of Clause 11.2** was ruled.

The Panel further considered, on the balance of probabilities, that not all of the employee's 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, which included the press release on Enhertu, had likely been proactively disseminated to members of the public. The Panel thus considered that Enhertu, a prescription only medicine at the time of the activity, had been promoted to the public, albeit for an indication it was not licensed for in the UK, and **a breach of Clause 26.1** was ruled.

The Panel noted that Clause 3.6 of the Code stated that materials and activities must not be disguised promotion. In this regard, the Panel considered that the proactive dissemination of a promotional LinkedIn post, authored by an AstraZeneca US employee, by UK-based AstraZeneca employees, was clearly promotional and thus, in the Panel's view, did not constitute disguised promotion as alleged. **No breach of Clause 3.6** was ruled.

The Panel noted that AstraZeneca had been asked to consider the requirements of Clause 3.3 in relation to the complainant's allegation that this case followed a common trend for AstraZeneca which had been ruled in breach for similar issues in the following cases: Cases AUTH/3411/10/20, AUTH/3412/10/20, AUTH/3430/11/20, AUTH/3011/1/18 and AUTH/3248/9/19. Clause 3.3 stated that when an undertaking had been given in relation to a ruling under the Code, the company concerned must ensure that it complied with that undertaking.

The Panel noted that in Case AUTH/3011/1/18, a complaint was submitted about various misleading or unsubstantiated statements contained within an AstraZeneca PLC press release but did not involve the promotion of a medicine that was not in accordance with the particulars listed in its SPC or distribution of the press release via social media.

Case AUTH/3411/10/20 and Case AUTH/3412/10/20 concerned a LinkedIn post and associated press release about an unlicensed medicine posted by Daiichi Sankyo's US marketing company on a US LinkedIn channel that was liked by an AstraZeneca UK-based employee and a breach was ruled as a medicine was promoted prior to the grant of its marketing authorisation.

Case AUTH/3430/11/20 concerned a number of AstraZeneca UK employees liking a LinkedIn post and associated press release about an unlicensed medicine which appeared on the personal LinkedIn account of an AstraZeneca global employee.

The Panel noted that Case AUTH/3248/9/19 involved promotion of a licensed medicine for an unlicensed indication and promotion of a prescription only medicine to the public by a UK-based employee who had used his/her personal Twitter account to retweet data from a clinical trial originally posted by health professionals following a presentation at an international congress.

The Panel noted its comments and rulings above in relation to the current case (Case AUTH/3687/8/22) where, in its view, a licensed medicine had been promoted to the public and had been promoted for an unlicenced indication and considered that it was thus different to Cases AUTH/3011/1/18, AUTH/3411/10/20, AUTH/3412/10/20 and AUTH/3430/11/20 as cited by the complainant. Whilst the Panel considered that there were some similarities in relation to Case AUTH/3248/9/19, it noted that companies had to give an undertaking that the material/activity in question and any similar material/activity, if not already discontinued or no longer in use, would cease forthwith and give an **assurance that all possible steps** would be taken to avoid similar breaches of the Code in the future (emphasis added by Panel). In considering whether AstraZeneca had complied with its previous undertaking in this regard and had taken all possible steps to avoid similar breaches, the Panel noted the company's submission that it regularly trained employees as was confirmed by the complainant who referred to numerous trainings on social media in his/her complaint. According to AstraZeneca, it regularly trained all UK-based employees on social media and, in addition, prior to key congresses, where it anticipated social media activity might peak, it briefed all relevant employees again on the 'do's' and 'don'ts' of social media engagement.

The Panel noted that AstraZeneca did not provide any UK specific social media guidance. Instead, it provided a global standard social media document, on employee use of personal social media channels and work-related content, which appeared to apply to all countries including the US. The Panel considered, nonetheless, the document overall appeared to discourage employees from engaging with product-related posts and referred readers to country specific rules. Whilst the Panel was concerned that, in spite of all the training and reminders provided, eight UK-based AstraZeneca employees had 'liked' the LinkedIn post at issue, it did

not consider that it had been established that AstraZeneca had breached the undertaking given in any of the cases cited by the complainant as alleged and **no breach of Clause 3.3** was ruled. The Panel consequently ruled **no breach of Clauses 5.1 and 2** in this regard.

The Panel was concerned that the liking of the LinkedIn post was clearly not an isolated incident; eight UK-based employees appeared to have acted contrary to AstraZeneca's training and policies, and promoted a prescription only medicine to their connections in the UK, which would likely have included members of the public, for an indication that Enhertu was not yet licensed for in the UK. In this regard, the Panel considered that high standards had not been maintained and 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 Enhertu had a marketing authorisation, albeit for a different indication than was promoted in the disseminated LinkedIn post at issue.

The Panel was concerned that the 'liking' of the LinkedIn post was not an isolated incident despite AstraZeneca's submission that it had regular training and guidance in place and in this regard, it was not clear to the Panel whether non-compliance was escalated or if there were any ramifications for employees failing to comply with the company's instructions. The Panel was further concerned to note that the job titles of the individuals who liked the post appeared to include a number of senior roles which was not disputed by AstraZeneca.

The Panel noted AstraZeneca's submission that there was never any purposeful intent by the Global AstraZeneca organisation to promote a medicine, disguised or otherwise, to a UK audience, that the post was not posted on any global-owned social media corporate channels and UK employees had not been encouraged to engage with the post. The Panel further noted AstraZeneca's submission that on this occasion, despite its best efforts to train and educate, a limited number of UK employees liked a post that they should not have engaged with and, once alerted to UK-based employees having liked the post, AstraZeneca took prompt action to ensure the 'likes' were withdrawn.

The Panel noted that Clause 2 was used as a sign of particular censure and was reserved for such use. In the Panel's view, AstraZeneca had been let down by a number of employees who had promoted an AstraZeneca medicine outside the terms of its marketing authorisation, contrary to the company's procedures and training. Whilst the Panel had a number of concerns as set out above, it considered that, in the particular circumstances of this case, its rulings of breaches above adequately covered the matters raised and, on balance, ruled **no breach of Clause 2**.

Complaint received **18 August 2022**

Case completed **18 August 2023**