CASE AUTH/3775/6/23

COMPLAINANT v ASTRAZENECA

Alleged promotion of Breztri (formoterol fumarate/ budesonide/ glycopyrronium) to the public

CASE SUMMARY

This case related to a LinkedIn post made by a US-based employee, which had been 'liked' by a UK-based employee, and promoted Breztri (formoterol fumarate/ budesonide/ glycopyrronium) to the public.

The outcome under the 2021 Code was:

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	**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 9.1	**Requirement that all relevant personnel concerned with the preparation or approval of material or activities covered by the Code must be fully conversant with the Code and the relevant laws and regulations**

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 had later become non-contactable, about AstraZeneca.

COMPLAINT

The complaint wording is reproduced below:

> 'I have been entrusted by an AZ colleague to report another example of a UK based Global Senior colleague, 'liking' a post about an AZ medicine (Breztri), thereby promoting it to the public on LinkedIn.

> Unfortunately this particular colleague [named employee] has previously worked in a code/compliance setting and despite our efforts asking for such colleagues to 'unlike' the post, many are refusing to back down and don't see it as a matter of grave concern ie promotion to the public.
>
> Moreover as can be seen in the attached evidence the LinkedIn post mentions Breztri by name and with a medical claim. This is also linked to an AZ press release about this data, presented at ATS, recently as 23rd May 2023.
>
> I consider the lack of code training for UK based Global AZ teams in Cambridge & London as a matter of grace [sic] concern. The "we will just get a slap on the wrist" from the PMCPA attitude condones such non-compliant behaviour warranting a Clause 2 and audit of compliance.
>
> Additional to the direction [sic] promotion to the public as per 26.1, a failure to maintain high standards (5.1), and not recognizing the special nature of medicines (26.2) have been breached here.
>
> However, I want to re-emphasise the non-compliant culture, the lack of care by senior medical colleagues in UK based Global, is something that requires firm action to safeguard patient safety.''

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 5.1, 5.2, 9.1, 26.1 and 26.2 of the Code.

ASTRAZENECA RESPONSE

The response from AstraZeneca is reproduced below:

> ''Further to your letter, AstraZeneca would like to respond to the allegation raised by the complainant in their email. The complainant has provide [sic] a screenshot showing that three AstraZeneca employees liked a LinkedIn post. We identified two employees [initials of first employee and second employee] based in the US, and one employee based in the UK with a Global job role [initials of third employee]. One of the two US-based employees [initials of second employee] has a Global job role.
>
> **Our Investigation**
>
> On receipt of the complaint, the two employees with Global roles were contacted and asked to withdraw their "like". This was actioned immediately by both employees.
>
> With respect to the complainant's allegation that "despite our efforts asking for such colleagues to unlike the post, many are refusing to back down and don't see it as a matter of [grave] concern", we would dispute this in the strongest possible terms – in any incidence in which an employee has been contacted, they willingly comply with the request to withdraw their 'like'. Contrary to the complainant's allegation, they are always apologetic for their error and are eager to rectify the situation. It is typically the responsibility of either the UK Compliance Director or the Global Compliance Business

Partner for the Therapy Area, to contact individuals who have 'liked' posts – these individuals have confirmed to the investigation team that there has never been a refusal to comply with any such request.

Furthermore, in this particular instance, neither of the two Global employees have been contacted previously to withdraw a 'like', reaction or, comment from any social media platform – it is a first time error of judgement in both cases, for which they have both apologised.

With respect to the PMCPA's request to understand the residency of the employees, we can confirm that one employee [initials of second employee] is a resident in the US, has a Global job role and is employed by the US marketing company. The original LinkedIn post in question was made by a US-based individual [initials of fourth employee], who is employed by the AstraZeneca US Marketing Company. The post was intended for a US audience, with content not relevant to a UK audience nor targeted to a UK audience. The post did not contain or make specific reference to the availability or use of a medicine in the UK and therefore we believe the liking of this post by the US individual, to be out of scope of the UK ABPI Code of Practice.

Training

With regard to the UK-based employee [initials of third employee], we can confirm that they are a resident in the UK, with a Global job role and are employed by the Global organization based in the UK. [Initials of third employee] read and signed the Global SOP Employee use of personal social media channels for AstraZeneca and work-related content, v3.0 in August 2021, 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. Moreover, as soon as AstraZeneca received the complaint from PMCPA, the individual was contacted to remove the 'like', which they did so immediately and without fuss. Thus, with respect to training, high standards have been maintained by AstraZeneca and so we deny a breach of Clauses 5.1, 9.1, and 2.

The complainant said that "[they] consider the lack of code training for UK-based Global AZ teams in Cambridge & London as a matter of [grave] concern." We contend that this is a non-specific allegation without merit or evidence. Every employee at AstraZeneca is required to complete their training and sign that they understand the regulations.

Content of LinkedIn Posts

The original LinkedIn post was made by a US-based AstraZeneca employee [initials of fourth employee] on [their] personal LinkedIn account, and this links to a press release posted on the AstraZeneca US corporate site. There is 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 is operating in accordance with the US internal AstraZeneca social media policy and US external regulation. Therefore, there are no certificates.

The LinkedIn post is about [initials of fourth employee]'s attendance at a congress in America alongside referencing two studies which had been reported at the congress.

The URL link to the press release automatically includes the title of the article which only includes the US brand name (Breztri) alongside the name of US website (astrazeneca-us.com) where the press released is housed. The press release was intended and written for a US audience, housed on a US website, and does not make reference to the availability or use of the medicine in the UK. The brand name for the product in the UK is Trixeo.

We believe that it is highly unlikely that a member of the UK public would make a direct connection between the post and a prescription only medicine available in the UK, based solely on an immediate read of the LinkedIn post and be encouraged to ask their doctor about this medicine.

We cannot fulfil the PMCPA request to supply the Summary of Product Characteristics for Breztri because Breztri is not a medicine licensed under this brand name in the UK. However, please find attached a copy of the Trixeo Summary of Product Characteristics. Please note that the brand name Trixeo is not mentioned in the post, the URL descriptor, or the linked content (the press release) itself.

LinkedIn Profiles

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 [initials of third employee]'s public profile [they] have 500+ connections, and thus we accept that some of [their] connections may include members of the public. However, as stated above, given the original post was clearly intended for a US audience and that the product is commercialised under a completely different brand name in the UK, without wishing to diminish the importance of the issue, when taken together, we believe that the risk associated with this error is negligible.

Conclusion

At AstraZeneca we understand that given the nature of social media, some people may inadvertently 'like' posts in error. Our investigations have revealed that 'liking' of posts is never done with blatant disregard to internal policy, but individuals have admitted making genuine mistakes, which they have always been quick to rectify.

We believe that a single UK-based employee 'liking' a LinkedIn post which was intended for a US audience, and does not make reference to the availability or use of the medicine in the UK, does not result in the individual or the AstraZeneca organization as a whole, misunderstanding the special nature of medicines, failing to maintain high standards or bringing disrepute upon the pharmaceutical industry. Thus, we refute being in breach of respecting the special nature of medicines (Clause 5.2), lack of training (Clause 9.1), lack of high standards (Clause 5.1) or bringing the pharmaceutical industry into disrepute (Clause 2). AstraZeneca takes self-regulation seriously and we are disappointed to have received this complaint. Although our social media standard instructs employees not to engage with any product-related content and we take steps to immediately address complaints regarding our employees' engagements with social media posts, it is difficult to give reassurances that individual employees will not make

similar mistakes in future. To this end, we would welcome the PMCPA's assistance to revise its procedure on how complaints of this nature are handled.

I trust that the enclosed information provides sufficient information for the Panel to rule on all matters in question. Please do not hesitate to contact me should you consider any further information necessary.''

PANEL RULING

The Panel noted that the original LinkedIn post at issue stated:

'Had a fantastic week at the American Thoracic Society Congress 2023. Two very important studies highlighted below from our team.

Increased risk of CV events post COPD exacerbation even in newly diagnosed patients.

Prompt COPD treatment reduced the risk of future exacerbations.'

The post, made by a US-based AstraZeneca employee, included the link - astrazeneca-us.com, which took a reader to a press release on a US website. The title of the press release, which was partially visible, stated 'New AstraZeneca data presented at ATS 2023 strengthen the body of evidence supporting e…'. Beneath this appeared a partial preview of the content of the press release, which stated 'EROS real-world outcomes data show prompt initiation of BREZTRI is associated with a reduced risk of future exa…'.

The Panel noted the press release, accessed via the link, discussed AstraZeneca data presented at the American Thoracic Society (ATS) conference, including results from the EROS trial, a real-world evidence analysis of Breztri in patients with Chronic Obstructive Pulmonary Disease (COPD) and contained the generic name of Breztri, budesonide/ glycopyrronium/ formoterol, its indication, important safety information and a link to the full Breztri prescribing information and patient information. The Panel further noted that the press release stated that Breztri Aerosphere was approved to treat COPD in more than 50 countries worldwide, including the US. The press release made no specific mention of the availability of Breztri in the UK. The Panel noted that the name of the generic compound, budesonide/ glycopyrronium/ formoterol fumarate, was included in the first paragraph of the press release and mentioned throughout the material.

The Panel noted that LinkedIn was a social media platform which was a business and employment-orientated network; its application was not limited to the pharmaceutical industry or to healthcare. In the Panel's view, it was, of course, not unacceptable for company employees to use personal LinkedIn accounts; the Code would not automatically apply to all activity on a personal account. The Panel noted that compliance challenges often arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company.

The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways which included 'liking'. The Panel understood that if an individual 'liked' a post, it increased the likelihood that the post would appear in his/her 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 his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would therefore potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn.

The Panel noted that UK employees were likely to follow the social media accounts of overseas affiliates which might have codes, laws and regulations that differed to the UK. AstraZeneca had submitted its Global social media policy that provided guidance on what was, and what was not, acceptable.

The Panel noted AstraZeneca's submission that the original LinkedIn post in question was made by a US-based individual, who was employed by the AstraZeneca US Marketing Company and that the post was intended for a US audience, with content not relevant to or targeted at a UK audience. The Panel noted AstraZeneca stated that the original post was 'liked' by two employees based in the US, and one employee based in the UK with a global job role.

The Panel considered, in general terms, that whether the activities of global employees came within the scope of the UK Code, would be decided on a case-by-case basis bearing in mind, among other things, the UK nexus and, where relevant, the requirements of Clause 1.2. The Panel, noting that the complainant bore the burden of proof, and noting the above, considered that the complainant had not established that the original post at issue came within the scope of the Code.

However, the Panel considered the interaction with the post by a UK-based employee had 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.

The Panel noted AstraZeneca's submission that the individual UK employee who 'liked' the LinkedIn post, had 500+ connections. The Panel considered that the employee would, on the balance of probabilities, have members of the public, health professionals and other relevant decision makers among others, as connections with their account on LinkedIn and as such the message would have been disseminated to these individuals in the UK.

The Panel noted AstraZeneca had submitted their global social media policy which stated, among other things, 'You are **not** (emphasis added) permitted to share content on your personal channels that is product-related, even if it has been published on official AstraZeneca channels or websites (like product-related press releases on AstraZeneca.com or a country website)'.

The Panel noted that the complainant had alleged direct promotion to the public and that AstraZeneca had failed to maintain high standards. They additionally alleged a failure to recognise the special nature of medicines and had cited Clause 26.2. The Panel noted that the

allegation made by the complainant was not applicable to Clause 26.2 and made its ruling under Clause 5.2, which had been raised by the case preparation manager.

The Panel considered the content of the post at issue and the linked press release in totality.

The Panel noted that budesonide/ glycopyrronium/ formoterol was marketed in the UK under the brand name Trixeo; Breztri was the brand name for the compound in the US and the brand name mentioned in the post at issue; both the brand name in the US and the generic name for both the US and UK were mentioned in the press release. The Panel further noted that the indication for Trixeo, in the UK, was the maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. The linked press release contained the indication for Breztri, in the US, which stated 'BREZTRI AEROSPHERE is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD)'.

The Panel noted that the generic compound budesonide/ glycopyrronium/ formoterol fumarate, under the brand name Trixeo, was a licensed prescription only medicine in the UK at the time of the post at issue; the brand name Breztri was not licensed in the UK.

The Panel considered that the statement in the post 'Prompt COPD treatment reduced the risk of future exacerbations', would, on the balance of probabilities, provoke interest, prompting a reader to click on the linked press release.

The Panel noted AstraZeneca's submission that the post at issue was intended for a US audience but considered that the American Thoracic Society and its conference was recognised globally as a source of information on the latest research and thus the subject matter of the post was such that it was likely to elicit interest beyond the US. In this regard the Panel noted that although the post included the web address astrazeneca-us.com there was no direct reference that it was intended for a US audience. Similarly, the linked press release made no mention that it was intended for a US audience. Links to AstraZeneca's US website and its US Twitter handle were provided in the press release together with US contact information (two US telephone numbers and a US Media Mailbox email address) on page 8 of the 9-page press release however in the Panel's view, it was not sufficiently clear to readers that the material was intended for a US-only audience.

The Panel noted its comments above that the name of the generic compound, budesonide/ glycopyrronium/ formoterol fumarate, was mentioned throughout the material, including at the start of the press release.

The Panel considered that the post at issue, including the claim 'EROS real-world outcomes data show prompt initiation of BREZTRI is associated with a reduced risk of future exa…', coupled with the statement 'Prompt COPD treatment reduced the risk of future exacerbations', and the linked press release containing real-world data analysis on the use of Breztri (budesonide/ glycopyrronium/ formoterol fumarate), could not be seen as anything other than promotional material. In the Panel's view, on the narrow point, that budesonide/ glycopyrronium/ formoterol fumarate, which was a prescription only medicine in the UK at the time of the post, albeit under the brand name Trixeo, a prescription only medicine had been advertised to the public and **a breach of Clause 26.1** was ruled.

The Panel considered that the statement 'BREZTRI is associated with a reduced risk of future exacerbations in people living with COPD' near the top of the press release, followed by the statement 'Results from the EROS real-world retrospective study showed that initiating fixed-dose triple-combination therapy BREZTRI AEROSPHERE® (budesonide/ glycopyrronium/ formoterol fumarate) within 30 days of a qualifying moderate or severe exacerbation in patients with COPD (chronic obstructive pulmonary disease) is associated with a decreased risk of future exacerbations by 24% vs. delaying treatment by one to six months, and by 34% vs delaying treatment six months to one year.' could, on the balance of probabilities, prompt further interest from the reader, such that they might be encouraged to ask their health professional to prescribe a specific prescription only medicine. In this regard, the Panel considered that AstraZeneca had failed to recognise the special nature of medicines and ruled **a breach of Clause 5.2.**

The Panel considered that AstraZeneca had been badly let down by the UK employee who had 'liked' the post despite the company training on its social media policy and the AstraZeneca Code of Ethics awareness training. The Panel further considered the difference in the licensed indications of budesonide/ glycopyrronium/ formoterol fumarate in the US and the UK above. The indication in the linked press release was broader than the indication for budesonide/ glycopyrronium/ formoterol fumarate licensed as Trixeo in the UK, which was limited to use in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist or combination of a long-acting beta2-agonist and a long-acting muscarinic antagonist. The Panel considered that, in 'liking' the post at issue, and the subsequent proactive dissemination of information about a prescription only medicine, including the broader indication to the UK employee's LinkedIn connections, which would mislead a reader that budesonide/ glycopyrronium/ formoterol fumarate was indicated for use in the UK outside of the UK licensed indication, which was a serious matter, AstraZeneca had failed to maintain high standards, and **a breach of Clause 5.1** was ruled.

The Panel noted the complainant's allegation that the lack of Code training for UK based Global AstraZeneca teams in Cambridge & London was a matter of grace [sic] concern.

The Panel noted AstraZeneca's submission that the UK-based employee who had 'liked' the post at issue, was a resident in the UK, with a global job role and was employed by the global organisation based in the UK. The employee had read and signed the global SOP 'Employee use of personal social media channels for AstraZeneca and work-related content', in August 2021, and completed the AstraZeneca Code of Ethics awareness training, a mandatory online e-learning course which was delivered on an annual basis and included a section on personal use of social media for work-related content.

Noting the above, the Panel considered that the complainant had not established that there was a lack of Code training for UK based Global teams, and it ruled **no breach of Clause 9.1** in this regard.

Clause 2 of the Code was a sign of particular censure and reserved for such use. The Panel noted that prompt action was taken by AstraZeneca in instructing the UK-based employee to remove the 'like' from LinkedIn, which was 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 **7 June 2023**

Case completed **14 August 2024**