CASE AUTH/3707/11/22

COMPLAINANT v ASTRAZENECA

Allegations about a LinkedIn post for a new lung cancer treatment

CASE SUMMARY

This case was in relation to a LinkedIn post made by a senior AstraZeneca employee working for the US affiliate about a new lung cancer treatment combination, which was 'liked' by 14 UK-based employees. The complainant alleged, among other things, that the post promoted to the public.

There was an appeal by AstraZeneca of two of the Panel's rulings.

The outcome under the 2021 Code was:

No Breach Clause 2 [Panel's breach ruling overturned at appeal]	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
Breach of Clause 5.1 (x2) [Panel's breach ruling upheld at appeal]	**Failure to maintain high standards**
Breach of Clause 8.1	**Failure to certify promotional material**
Breach of Clause 8.6	**Failure to preserve a certificate**
Breach Clause 12.9	**Failing to include an adverse event reporting statement**
Breach Clause 26.1	**Advertising a prescription only medicine to the public**

This summary is not intended to be read in isolation.

For full details, please see the full case report below.

FULL CASE REPORT

A complainant who described themselves as a concerned health professional complained about a LinkedIn post made by an AstraZeneca employee in the United States (US) which they alleged had been commented on by an employee of AstraZeneca global based in the UK.

The LinkedIn post at issue stated:

> ‘I can’t believe that just a few weeks into my new role as [senior US role] at AstraZeneca, I get to share news of an FDA approval! Our new treatment combination has just been approved for people with Stage IV non-small cell lung cancer (#NSCLC).
>
> This disease is brutal for patients and their loved ones. It’s the most advanced form of lung cancer and the tumors do not respond to current standard therapies. Today’s announcement means that patients will have an option in their treatment arsenal that they didn’t have before. To offer new hope with the patient community during #LungCancerAwarenessMonth makes this moment even more special.
>
> This approval is the first of many that I hope to see in my new role. We’re working hard on behalf of patients who need us the most. – and we won’t stop until we’ve eliminated lung cancer as a cause of death.
>
> Learn more about the approval and what it means within this complex treatment setting here: [weblink].’

This was followed by an embedded video which was titled ‘ANNOUNCEMENT Now FDA Approved: Treatment combination for adults living with Stage IV (metastatic) NSCLC’ was displayed and consisted of this title slide and a second slide which stated ‘This approval provides a new option for patients with the most advanced from of lung cancer’.

If the link provided within the post was followed, the press release housed on the AstraZeneca US corporate website titled ‘IMFINZI and IMJUDO with chemotherapy approved in the US for patients with metastatic non-small cell lung cancer’ could be viewed and began by stating:

> ‘Approval based on POSEIDON Phase III trial results, which showed significant survival benefit with a limited course of IMJUDO added to IMFINZI and chemotherapy
>
> AstraZeneca’s IMFINZI® (durvalumab) in combination with IMJUDO® (tremelimumab) plus platinum-based chemotherapy has been approved in the US for the treatment of adult patients with Stage IV (metastatic) non-small cell lung cancer (NSCLC).’

COMPLAINT

The complainant provided a link to, and screenshot of, the LinkedIn post and noted that the first to comment on the post was employed by AstraZeneca Global based in the UK. The complainant provided a screenshot of a comment ‘Congrats [named employee of the original post]!!!’ made by a named person with a Global senior medical job title. The complainant alleged that, as could be seen in the comments, a screenshot of which was taken by the case preparation manager from the link provided by the complainant, there were several other members of AstraZeneca staff which worked for entities based in the UK that had also chosen to disseminate the news to all their links in the UK as well as elsewhere.

The complainant alleged that the post was promoting to the public, failed to maintain high standards, had not been certified before use, the certificate had not been kept for 2 years and the post lacked the unique identifier and adverse event statement.

When writing to AstraZeneca the Authority asked that it to consider the requirements of Clauses 2, 5.1, 8.1, 8.6, 12.9 and 26.1 of the 2021 Code.

ASTRAZENECA'S RESPONSE

AstraZeneca submitted that, firstly, it considered that the original LinkedIn post posted in November 2022 was outside the jurisdiction of the UK ABPI Code of Practice since:

- the employee responsible for the post was based in the US with responsibility for only US-based teams and activities. The individual was on international assignment from AstraZeneca UK Limited, the UK marketing company, with the AstraZeneca Pharmaceuticals, LP, the US marketing company.
- the post was intended for the employee's followers with information about a US-specific regulatory event and no UK-directed information.
- the employee had not targeted a UK audience; neither UK health professionals (HCPs) or the UK general public.

AstraZeneca submitted that, secondly, 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, and graphic. The LinkedIn post was further in line with the AstraZeneca US social media guidance, as written in the AstraZeneca 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 the PMCPA, the UK-based AstraZeneca employees, some employed by the UK marketing company and some employed by the global organization, were asked to withdraw their 'like' or 'comment'. All employees withdrew their 'like' or 'comment' immediately.

AstraZeneca submitted that it would like to assure the PMCPA that it regularly trained and reminded all UK-based (global and UKMC) employees about social media use in relation to work-related content covered by the standard operating procedure (SOP) on Employee use of personal social media channels for AstraZeneca and work-related content, version 3.0). 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.

Based in the UK, there were more than 8,000 AstraZeneca employees, which it 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 inadvertently engage with material that they should not engage with, or have a lapse in their assessment of what was permissible and what was not. On this occasion, despite its best efforts to train and educate, a limited number of UK-based employees liked and/or commented on a post that they should not have engaged with.

AstraZeneca stated that, as a global organization, it 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, it 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 brought the pharmaceutical industry into disrepute because a limited number of UK-based employees engaged with a single LinkedIn post intended for a US audience, which was immediately rectified with the 'likes/comments' being withdrawn once it was notified. Thus, AstraZeneca refuted being in breach of Clause 2.

In response to a request for further information, AstraZeneca submitted that, as mentioned in its initial response, the employee responsible for the original post was on international assignment from AstraZeneca UK Limited, therefore was employed by AstraZeneca UK.

The individual (as stated in the LinkedIn post) was a senior employee working for the US affiliate and currently resided in the US and their duties related solely to the US AstraZeneca business. Their responsibilities did not extend to the UK. As previously stated, the post was in line with US regulations and made reference to the availability of a medicine in US only.

It was common practice for global pharmaceutical companies to give opportunities to employees to work in different countries on international assignments. In this circumstance, where an employee was assigned to work in the US (solely for the US Marketing Company) and was based in the US, the Pharmaceutical Codes of Practice that the individual should apply to their day-to-day activities should be the US regulations, based on the employees' role and area of responsibility, and not the country that their contract was issued from. Otherwise, it could restrict the ability of that individual to do their job. This could have broad implications and make it challenging for any UK employee to take an international assignment in another country.

It was not possible to provide details of where all of the individual's connections on LinkedIn were based at the time of the post. It was not unusual for employees of a global organisation to have connections on LinkedIn across the world. For clarity, when AstraZeneca mentioned in its initial response that the post was not targeted to a UK audience, it meant that the individual had not taken any actions to specifically target a UK audience (e.g. through paid targeting, geo-targeting, etc).

Details of employees who engaged with the LinkedIn post

AstraZeneca submitted that the number of UK-based employees who liked or commented on the LinkedIn post in question was fourteen. The role titles of twelve of these employees were provided; two employees had left the organisation since the initial response and AstraZeneca submitted it could not provide their role titles. AstraZeneca submitted that, in addition, there was one person that had been specifically mentioned by the complainant, but upon receiving the complaint, the person did not work at AstraZeneca and therefore details of that person had not been included. AstraZeneca did not have a record of the comments made by the employees on the post in question.

Training for UK-based employees

AstraZeneca submitted that all employees identified in the initial response had read and understood the Global Standard - Employee use of personal social media channels for AstraZeneca and work-related content in the AstraZeneca e-learning platform between May 2020 and October 2022.

In addition, employees would have completed the AstraZeneca Code of Ethics awareness training, a mandatory online e-learning course, which included a section on personal use of social media for work-related content and signposted to the Global Standard on the Employee use of personal social media channels for AstraZeneca and work-related content.

There were also 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) to an audience of 'UK employees' in January 2022, November 2022 and July 2023. These posts have had approximately 22k views. These posts were often re-shared amongst other internal groups within the organisation.

SPC and indications for Imfinzi and Imjudo

Imfinzi indication at the time of the post was included in the summary of product characteristics (SPC) provided by AstraZeneca which was:

> 'IMFINZI as monotherapy is indicated for the treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on ≥ 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy (see section 5.1).
>
> IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ESSCLC).'

Imjudo (tremelimumab) was not indicated in the UK at the time of the post therefore no indication or SPC was provided.

Additional Information

AstraZeneca informed the PMCPA that in responding to the request for further information, it had identified another AstraZeneca employee who had liked the post. The post had 341 likes and this one was missed in error when responding to the initial complaint. This employee immediately unliked the post when requested to do so.

This employee had completed version 2.0 of the Global Standard – Employee use of external personal social media channels for work-related content, at the time of the post but had now also completed version 3.0. The guidance, with regard to engaging with product-related content in version 2.0 and 3.0, was similar.

PANEL RULING

The Panel noted AstraZeneca's submission that the original LinkedIn post was outside the jurisdiction of the UK as the employee responsible for the post was on international assignment to the AstraZeneca Pharmaceuticals, LP, the US marketing company from AstraZeneca UK Limited and was based in the US with responsibility for only US-based teams and activities and

the post had not targeted a UK audience and was intended for the employee's followers with information about a US-specific regulatory event and no UK-directed information.

The Panel considered, in general terms, that whether the activities of UK employees, who were on assignment to the US company whilst remaining contracted to the UK company, came within the scope of the UK Code, would be decided on a case-by-case basis bearing in mind, amongst other things, the UK nexus and, if relevant, the requirements of Clause 1.2. It was important that assignment arrangements were not used to circumvent the requirements of the Code.

The Panel noted AstraZeneca's submission that the duties of the individual in question related solely to the US business, their responsibilities did not extend to the UK. AstraZeneca also submitted that the individual in question should apply the US regulations to their daily activities based on the employee's role and area of responsibility, and not the country that their contract was issued from. The Panel noted its comment above that such matters should be decided on a case-by-case basis. The Panel considered that posting on a personal LinkedIn account a few weeks into the individual's new US assignment could be seen as different to that individual's other US activities. The post in question was not published on a US corporate social media account or similar, rather on a personal account apparently a few weeks after the individual had moved to the US and therefore it was likely that a number of the connections would be UK-based and, according to AstraZeneca, the post was intended for the employee's followers.

The Panel further noted that whilst the employee was based in the US at the time of the LinkedIn post, they were, according to AstraZeneca, still employed by AstraZeneca UK. In the Panel's view, noting the above, the LinkedIn post at issue therefore came within the scope of the ABPI Code.

The Panel noted that, separate to the actions of the employee that made the original post, fourteen UK-based AstraZeneca employees had engaged with the post which, on the balance of probabilities, would have been proactively disseminated to their connections within the UK, and therefore also brought the post within the scope of the UK Code.

The Panel noted that LinkedIn was different to some other social media platforms in that it was a business- and employment-orientated network and was primarily, although not exclusively, associated with an individual's professional heritage and current employment and interests; 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 on platforms, which included members of the public, would require that the post did not promote a prescription-only medicine 'POM'.

The Panel noted 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' or commented on a post, it increased the likelihood that the post would appear in his/her connection's LinkedIn feeds. 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. The Panel noted that the proactive dissemination of material, which directly or indirectly referred to a particular medicine on social media, was likely to be considered promotion of that medicine. 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. 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 considered that companies should assume that the Code would apply to all work-related, personal LinkedIn posts/activity by their employees unless, for very clear reasons, it could be shown otherwise. Any material associated with a social media post, for example, a link within a post, would be regarded as being part of that post. The Panel considered that 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.

The Panel considered, noting their content that the post and associated press release, which had been posted by the AstraZeneca UK employee on their personal LinkedIn profile, and, on the balance of probabilities, its proactive dissemination to that employee and the fourteen UK-based AstraZeneca employees' connections as a result of them engaging with it, constituted promotion of Imjudo and Imfinzi.

The Panel noted AstraZeneca's submission that 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. The Panel noted its comments above that the proactive dissemination of information regarding AstraZeneca's medicines to a UK audience brought the LinkedIn post within the scope of the UK Code and that, in the Panel's view, the LinkedIn post, which included the linked press release and embedded video, was promotional.

The Panel noted that the LinkedIn post had not been certified, as required, and a **breach of Clause 8.1** was ruled. As a consequence, there would be no certificate as required by Clause 8.6 and a **breach of Clause 8.6** was ruled. The LinkedIn post had no adverse event reporting statement and the Panel therefore ruled a **breach of Clause 12.9**.

The Panel noted that at the time of the LinkedIn post and the UK-based employees' engagement with it Imfinzi as monotherapy was indicated for the treatment of locally advanced, unresectable, non-small cell lung cancer (NSCLC) in adults whose tumours expressed PD-L1 on ≥ 1% of tumour cells, and whose disease had not progressed following platinum-based chemoradiation therapy, and in combination with etoposide and either carboplatin or cisplatin Imfinzi, was indicated for the first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

The Panel noted that, at the time of the LinkedIn post and the UK-based employees' engagement with it, Imfinzi was a prescription-only medicine, however, IMFINZI® (durvalumab) in combination with IMJUDO® (tremelimumab), plus platinum-based chemotherapy for the treatment of adult patients with Stage IV (metastatic), non-small cell lung cancer (NSCLC), was not a licensed indication. The Panel considered, on the balance of probabilities, that not all of the employees' 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 had likely been proactively disseminated to members of the public and constituted promotion of Imfinzi, a prescription-only medicine to the public, albeit for an unlicensed indication, and a **breach of Clause 26.1** was ruled. The Panel noted its comments and rulings above and considered that high standards had not been maintained and a **breach of Clause 5.1** was ruled.

The Panel noted that Imjudo was not indicated in the UK at the time of the post and the UK-based employees' engagement with it. The Panel noted that Clause 3.1, which had not been raised, prohibited the promotion of a medicine prior to the grant of its marketing authorisation and therefore the Panel considered the matter under Clause 5.1. The Panel considered, noting the content, that the post and associated press release posted by the AstraZeneca UK employee and, on the balance of probabilities, its proactive dissemination by that employee and the fourteen UK-based AstraZeneca employees' connections as a result of them engaging with it, constituted promotion of Imjudo, an unlicensed medicine including to members of the public and a **breach of Clause 5.1** was ruled.

The Panel noted that, according to AstraZeneca's initial response inside one business day of receipt of the complaint from the PMCPA the UK-based AstraZeneca employees were asked to withdraw their 'like' or 'comment', which was done immediately. The Panel further noted that in responding to the request for further information, AstraZeneca had identified another AstraZeneca employee who had liked the post which was missed in error when responding to the initial complaint. This employee immediately unliked the post when requested to do so. The Panel noted AstraZeneca's submission that all employees identified in the initial response had read and understood the Global Standard – Employee use of personal social media channels for AstraZeneca and work-related content. The Panel noted that that this document stated 'You are not permitted to share content that is product-related, even if it has been published on official AstraZeneca channels or websites'. In the Panel's view, however, it was not clear whether 'share' in this instance included any engagement with the post considering that elsewhere in the same document it stated 'You are not permitted to engage with (liking, sharing, commenting on) content that is product-related or is about disease education/awareness topics from 3rd party resources. There are no exceptions'. The Panel considered that the guidance could have been clearer in this regard.

The Panel noted that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity that was likely to be in breach of that clause. The Panel noted its comments and ruling above. The Panel noted that a senior AstraZeneca UK employee had proactively posted product-related material on their personal social media account. Furthermore, fourteen UK-based employees had engaged with the post resulting in its likely subsequent proactive dissemination to all of their LinkedIn connections which would, on the balance of probabilities, be a predominately UK audience. The Panel noted the titles of twelve of the UK-based employees and was concerned that they all appeared to be senior employees. The Panel was further concerned that engaging with the original LinkedIn post was clearly not an isolated occurrence. The Panel considered, noting the above, that in promoting the unlicensed medicine, including to members of the UK public, AstraZeneca had brought discredit upon, and reduced confidence in, the pharmaceutical industry and a **breach of Clause 2** was ruled.

APPEAL BY ASTRAZENECA

Background

AstraZeneca advised the Panel that the senior employee who was responsible for the Post was a UK employee on formal international assignment to AstraZeneca's US affiliate, based in the US, with responsibility solely for US-based teams and activities. Whilst combination treatment with Imfinzi and Imjudo was not authorised in the UK at the time of the Post, this related to a

US-specific regulatory event and did not target a UK audience. In these circumstances, it was AstraZeneca's firm view that the Post by the senior employee fell outside the scope of the Code.

However, AstraZeneca accepted that the engagement with the Post by UK-based employees disseminated the Post to their LinkedIn contacts and that this had breached the Code. AstraZeneca emphasised that, as soon as the issue was drawn to the attention of the relevant UK-based employees, they immediately withdrew their 'like' or 'comment' on the Post and advised the Panel that all UK based employees (those working for the UK marketing company and the global organisation) received regular training on use of social media. AstraZeneca strongly refuted any suggestion that the engagement by a relatively small number of UK based employees with the Post brought the industry into disrepute in breach of Clause 2 of the Code.

Imjudo was not licensed in the UK at the time of the Post. AstraZeneca had not been asked to consider Clause 3.1 in its response to the Complaint and the Panel therefore found a breach of Clause 5.1.

AstraZeneca's Appeal

AstraZeneca submitted that the Panel's conclusion that the Post, as made by the senior employee, was subject to the Code was incorrect and AstraZeneca therefore appealed the findings of a breach of Clauses 5.1(x1) and 2 of the Code, which relied upon this conclusion. Furthermore, the Panel's conclusion in relation to the Post, as made by the senior employee, was repeated in the Panel's analysis of each of the Code breaches considered and AstraZeneca respectfully suggested that the wording of the ruling should be revised in order to address this issue.

AstraZeneca accepted that the actions of the UK-based employees who engaged with the Post were in breach of the Code and AstraZeneca did not therefore appeal the findings of breaches of Clauses 5.1(x1), 8.1, 8.6, 12.9 and 26.1.

<u>The Post made by the senior employee</u>

AstraZeneca's submitted that the Post as made by the senior employee did not fall within the scope of the Code.

Clause 1.2 of the Code referred to information or promotional material about medicines which was placed on the internet outside the UK and stated that this 'will be regarded as coming within the scope of the Code, if it was placed there by:

- a UK company/with a UK company's authority, or
- an affiliate of a UK company, or with the authority of such a company, and it made specific reference to the availability or use of the medicine in the UK.

PMCPA's Social Media Guidance 2023 stated:

> 'Pharmaceutical companies may be held responsible for engagement with, or dissemination of, information by company employees who do so via their personal social media channels including, (a) if the employee can reasonably be perceived as representing the company, and/or (b) if the employee is instructed, approved, or facilitated by the company to do so.'

AstraZeneca submitted that the senior employee who originally made the Post at issue had a contract with AstraZeneca UK Ltd. However, since joining AstraZeneca many years ago they had worked in multiple countries .and currently the US. They were assigned from AstraZeneca UK Limited to AstraZeneca Pharmaceuticals, LP based in US from July 2022, initially in a global role. From November 2022, they were transferred from a global role to a US-facing role, working for AstraZeneca Pharmaceuticals LP and continuing to be based the US. The senior employee was responsible for the design, development and implementation of sales and marketing programmes for AstraZeneca's oncology medicines in the US. They had no responsibilities for global or UK functions.

AstraZeneca submitted that in circumstances where the senior employee had been formally assigned to AstraZeneca US, was located in the US and performed a US-facing function, there was no basis for concluding that the Post they made was placed on LinkedIn by or with the authority of an AstraZeneca entity based in the UK. In addition, the Post referred explicitly to the senior employee's US role and could not reasonably be perceived as representing an AstraZeneca entity based in the UK and the Post made no reference to use or availability of any medicine in the UK.

AstraZeneca responded to the reasons given by the Panel for concluding that the Post as made by the senior employee fell within the scope of the Code:

> *a) '…posting on a personal LinkedIn account a few weeks into the individual's new US assignment could be seen as different to that individual's other US activities'.*

AstraZeneca submitted that it was unclear why the Panel concluded that a post on LinkedIn 'a few weeks' into a US assignment could be viewed as different to the senior employee's other activities, particularly given the fact that they made their job status and US focus clear. They would continue to have UK-based contacts months or years after their assignment and therefore the fact that this commenced only a short time before the Post was made was irrelevant. The key criteria were those set out in Clause 1.2 and the PMCPA's Social Media Guidance; as explained above, there was no reason for concluding that the Post was placed by or with the authority of a UK-based entity and there was no reference to use of medicines in the UK:

> *b) '…it was likely that a number of the connections would be UK-based and, according to AstraZeneca, the post was intended for the employee's followers'.*

AstraZeneca submitted that the fact that a number of an individual's social media connections were UK-based was not a criterion determining whether a post fell within the scope of the Code either in the context of Clause 1.2 or the PMCPA's Social Media Guidance.

For completeness, in circumstances where the senior employee had worked in multiple locations since joining AstraZeneca in 2006, their social media connections were likely to be global rather than UK focussed:

> *c) 'whilst the employee was based in the US at the time of the LinkedIn post they were, according to AstraZeneca, still employed by AstraZeneca UK'.*

AstraZeneca submitted that the senior employee was employed by AstraZeneca UK Ltd but formally assigned to AstraZeneca LP in the US for a two-year period. During that period their employment with AstraZeneca UK Ltd remained in place for obvious reasons, but their

employment arrangements were varied. Their responsibilities focused exclusively on the US market.

In summary, AstraZeneca submitted that applying the provisions of Clause 1.2 and the PMCPA Social Media Guidance to the current situation resulted in a conclusion that the Post, as made by the senior employee, fell outside the scope of the Code. The converse view, that an employee of AstraZeneca in the UK who was assigned to AstraZeneca US and performed an exclusively US-facing role, nevertheless remained subject to the Code extended the geographical reach of the Code beyond its wording or intention and had far-reaching consequences for AstraZeneca's ability to manage its staff and its business globally. While an employee working for AstraZeneca US in a solely US-facing role must comply with US laws and codes, a requirement for such an employee to comply with the Code, which has no relevance in the US and does not reflect US rules, would effectively preclude temporary assignment of any UK employee to a US role. There was no logical reason to impose such a restriction and it was not required as a result of the Code or PMCPA Guidance.

Two findings of breach of Clause 5.1

AstraZeneca stated that the Panel found two breaches of Clause 5.1 arising from dissemination of the Post and its references to a combination treatment which was not, at that time, licensed in the UK: (a) the finding of breach of Clause 26.1 and (b) the promotion of an unlicensed medicinal product in circumstances where a potential breach of Clause 3.1 had not been raised. While AstraZeneca accepted one finding of breach of Clause 5.1, the company believed that two findings were unexplained (and therefore unfair) and duplicative.

The Panel concluded that the Post had likely been disseminated to members of the public and, as Imfinzi, one element in the treatment combination was a prescription only medicine, found a breach of Clause 26.1 of the Code, albeit that the Post related to an unlicensed indication. As a result of the finding of breach of Clause 26.1, the Panel also ruled a breach of Clause 5.1. However, no explanation was provided for this finding in the circumstances of this case and previous decisions by the PMCPA demonstrated that a finding of breach of Clause 26.1 did not, without more, establish a breach of Clause 5.1 (e.g. Case AUTH/3473/2/21).

AstraZeneca stated that the second finding of a breach of Clause 5.1 arose from the fact that AstraZeneca had not been asked to respond to Clause 3.1, which prohibited the promotion of a medicinal product prior to the grant of a marketing authorisation, in circumstances where at the time of the Post, Imjudo had not been licensed in the UK.

Overall, therefore, AstraZeneca submitted that while no specific explanation had been given for the ruling of breach of Clause 5.1 as a result of the finding of breach of Clause 26.1 it seemed that this was due to the fact that this arose from promotion of Imfinzi outside the terms of its marketing authorisation. This duplicated the ruling of breach of Clause 5.1 in relation to promotion of Imjudo prior to the grant of a marketing authorisation as both findings relate to promotion of an unlicensed treatment combination. In other words, the Panel had seemingly ruled a separate breach of Clause 5.1 for each element in the unlicenced treatment combination. Two findings of breach of Clause 5.1 were unjustified and inappropriate in this situation.

The ruling of breach of Clause 2

AstraZeneca submitted that the Panel's finding of breach of Clause 2 of the Code was seemingly based on the fact that a senior employee had proactively posted promotional material on their personal LinkedIn account and 14 UK- based employees (12 of whom appeared to the Panel to be senior) had engaged with that post. However, in circumstances where, as explained above, the original post by the senior employee did not fall within the scope of the Code, a central part of the Panel's reasoning fell away, and on this point AstraZeneca questioned whether the finding of a breach of Clause 2 was warranted.

AstraZeneca submitted that it accepted that the actions of the 14 UK-based employees who engaged with the Post were in breach of the Code. However, AstraZeneca was committed to self-regulation and continued to review and update its training programme in relation to employee use of personal social media channels and engagement with AstraZeneca and work-related content.

Finally, the Panel referred to previous cases arising from engagement of AstraZeneca UK-based employees with posts on LinkedIn. AstraZeneca submitted that it took all PMCPA decisions very seriously, however every case involved different issues. In the context of the very large number of AstraZeneca employees subject to the Code, it was not surprising that there were more decisions relating to AstraZeneca than some other companies.

RESPONSE TO THE APPEAL BY THE COMPLAINANT

There was no response to the appeal by the complainant.

APPEAL BOARD RULING

The Appeal Board took account of AstraZeneca's submission that the post at issue by the senior employee was made on their personal LinkedIn account, had referred to recent FDA approval of combination treatment with Imfinzi (durvalumab) and Imjudo (tremelimumab) for lung cancer and included an embedded video and link to a press release on AstraZeneca US's corporate website. The Appeal Board observed from AstraZeneca's submission that the senior employee has a contract with AstraZeneca UK Ltd but was on international assignment with the US affiliate. The representatives from AstraZeneca at the appeal confirmed that the senior employee had a US line manager, and that the post at issue had been made on instruction by AstraZeneca US and had been approved by it. AstraZeneca submitted that the combination treatment detailed in the post, intended for a US audience, was not licensed in the UK at the time the post was made.

The Appeal Board took account of AstraZeneca's submission that the LinkedIn post was in line with the AstraZeneca US social media guidance, which included that members of the North American Leadership team were permitted to post product-related content.

The Appeal Board did not have details of the geographical breakdown of the senior employee's LinkedIn contacts; however, it observed AstraZeneca's submission that while most recently employed in the UK, this individual had also worked in multiple countries and was currently residing in the US.

On the evidence before it, the Appeal Board considered that the Code did not apply to the original post made by the senior employee, which was placed by a US company and made no specific reference to the availability or use of the medicine in the UK. The Appeal Board

considered that it was the interaction with the post by 14 UK-based employees that brought it within the scope of the Code.

The Appeal Board observed that AstraZeneca had appealed one of the two rulings of a breach of Clause 5.1 of the Code as it considered that these were duplicative for one post and questioned why each medicine from the unlicensed combination had been ruled upon separately. When asked at the appeal hearing which of the two Clause 5.1 rulings it would want to see overturned, AstraZeneca said that the Clause 5.1 ruling in relation to the promotion of a prescription only medicine to the public was the ruling it wished to see overturned.

AstraZeneca had accepted that the engagement with the post by UK-based employees had disseminated the post to their LinkedIn contacts, thus it had accepted the Panel's ruling of a breach of Clause 26.1 for promotion of Imfinzi, a prescription-only medicine, to the public, albeit for an unlicensed indication. The Appeal Board considered that the promotion of a prescription only medicine to the public was a serious matter in itself and was such that AstraZeneca had failed to maintain high standards. The Appeal Board further considered that Imjudo, an unlicensed medicine, had also been promoted, and that this was a separate matter in breach of Clause 5.1. The Appeal Board considered that **both breaches of Clause 5.1 should be upheld**. **The appeal on this point was not successful**.

The Appeal Board observed that 14 UK based employees had liked the post at issue despite AstraZeneca training its employees and the potential for disciplinary action for non-compliance with the social media policy. The Appeal Board accepted that prompt action was taken by AstraZeneca in instructing the 14 employees to remove their engagement with the post in question.

The Appeal Board observed that the supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity that was likely to be in breach of that clause. Furthermore, promotion to the public was a serious matter that would often lead to a breach of Clause 2, however, this was considered on a case by case basis. While the Appeal Board considered that the original post was not in scope of the Code, its interaction by 14 UK-based employees had brought the material in scope of the Code. Nonetheless, the Appeal Board considered that Clause 2 was a sign of particular censure and should be reserved for such use; in the particular circumstances of this case, the Appeal Board considered that a Clause 2 was not warranted. The Appeal Board ruled **no breach of Clause 2**. The appeal on this point was successful.

Complaint received **16 November 2022**

Case completed **5 March 2024**