CASE AUTH/3051/6/18

COMPLAINANT v ALEXION

Promotional material posted on LinkedIn

A contactable complainant who described themselves as a concerned UK health professional complained about material received on his/her LinkedIn feed from Alexion Pharmaceuticals. The posted message informed readers that, *inter alia*, Alexion had submitted an EU application for approval of ALXN1210 as a treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH).

The complainant submitted that it seemed that the posting appeared in his/her feed since Alexion employees in the UK had liked it which then presented it to their connections which included a variety of people including many people in the UK who were not health professionals. The post detailed the company, the medicine and what it was used for.

The detailed response from Alexion is given below.

The Panel noted the complainant's allegation that the LinkedIn post, which led to a press release about Alexion and ALXN1210, appeared in his/her LinkedIn feed because Alexion UK employees had liked it which then presented it to their connections. The Panel noted that the complainant had not named or otherwise referred to a specific Alexion UK employee that was in his/her network on LinkedIn. The Panel further noted Alexion's submission that when it was advised of the complaint, the post had received over 300 'likes' on LinkedIn including a 'small handful' of likes from Alexion UK employees.

The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, including 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 his/her connections LinkedIn feeds thereby disseminating the post. 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 security settings. The Panel considered it was likely that Alexion UK employees' connections would include UK members of the public and might include UK health professionals. The Panel noted that the LinkedIn post and associated press release was 'liked' by a number of Alexion UK employees. In the Panel's view the act of liking the material amounted to proactive dissemination of the material within the UK and brought it within the scope of the Code.

The Panel noted Alexion's submission that the post and press release in question were factual, non-promotional, corporate announcements relevant, in their entirety, to the investor community and that they originated from a LinkedIn account operated by Alexion Pharmaceuticals Inc. based in the US with no involvement of the UK affiliate. The Panel noted Alexion's submission that the post did not target UK users or directly mention the UK. The Panel noted, however, that in liking the post, Alexion UK employees had, on the balance of probabilities, proactively disseminated it within the UK to an audience far wider than the intended financial community.

The Panel noted that the LinkedIn posting informed readers that Alexion had submitted an application for approval of ALXN1210 as a treatment for patients with paroxysmal nocturnal haemoglobinuria (PNH) in the European Union (EU). The US filing and Japanese submission were also referred to. The linked press release provided more detail. It described the results of two large Phase 3 studies and included statements such as 'We are excited about this next important step towards our goal of establishing ALXN1210 as the new standard of care for patients with PNH…' and 'Building on 10 years of proven efficacy and safety with Soliris and 25 years of leadership in complement biology...'. Soliris (eculizumab) was an Alexion prescription only medicine, available in the UK, indicated in adults and children for the treatment of PNH. Soliris was described in the press release as 'a first-in-class complement inhibitor ...' and ALXN1210 was described as an 'innovative, long acting C5 inhibitor discovered and developed by Alexion ...'. The press release also stated that Alexion and Soliris had received some of the pharmaceutical industry's highest honours for medical innovation in complement inhibition.

The Panel noted its comments above and considered that on the balance of probabilities not all the Alexion UK employees' connections to whom the post might have been disseminated to by virtue of their 'like' would have been health professionals. Thus, in the Panel's view and on the balance of probabilities the LinkedIn post and associated press release had been disseminated to members of the public.

The Code prohibited the promotion of prescription only medicines to the public. The Panel noted that the product, ALXN1210, was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue were liked by the UK employee and on this very narrow technical point the Panel ruled no breach of the Code.

However, the Panel considered that the Alexion UK employees' like of the LinkedIn post and associated press release regarding an unlicensed medicine and the potential subsequent dissemination to all of their connections meant that Alexion had failed to maintain high standards and a breach of the Code was ruled.

The Panel considered that the Code required companies that wished to rely on prior permission to be able to demonstrate that recipients had agreed to receive promotional material by such means. Nonetheless, the Panel noted that the complainant bore the burden of proof and considered that he/she had not provided evidence to show that there had been a breach of the Code in this regard and no breach was ruled.

The Panel noted Alexion's submission that the Alexion Global Social Media Policy stated, *inter alia*, that employees were permitted to 'like' Alexion's social media posts but might not provide further comment. The Panel noted that Alexion was, however, reviewing the social media policy to see whether changes were necessary for the UK and might guide UK employees not to 'like' certain posts on social media in future. The Panel was concerned that there appeared to be no UK specific guidance at the time of the complaint. The Panel considered that the lack of adequate UK specific social media guidance at the time of the complaint meant that Alexion had failed to maintain high standards and a breach of the Code was ruled.

The Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

A contactable complainant who described themselves as a concerned UK health professional complained about material received on his/her LinkedIn feed from Alexion Pharmaceuticals. The posted message informed readers that, *inter alia*, Alexion had submitted an EU application for approval of ALXN1210 as a treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH).

COMPLAINT

The complainant noted that the LinkedIn posting linked through to a long press statement about Alexion and its new compound ALXN1210.

The complainant submitted that it seemed that the posting appeared in his/her feed since Alexion employees in the UK had liked it. This had, in turn, been presented to all of their links which included a variety of people.

The complainant imagined that there was a very small number of people that needed updates about a compound before it was approved, but this posting had gone well beyond that.

The complainant alleged that the link would include many people in the UK who were not health professionals. The post detailed the company, the medicine and what it was used for.

When writing to Alexion, the Authority asked it to consider the requirements of Clauses 2, 9.1, 9.9, 26.1 and 26.2 of the Code.

RESPONSE

Alexion stated that it had escalated the matter internally in the UK and in the US where its parent company (which issued the LinkedIn post in question) was based. Whilst the company was reviewing its position, subject to receiving further information, it had taken the immediate and precautionary measure of taking the post down from LinkedIn. The company was also reviewing its social media policy to consider whether any changes were needed to deal more specifically with such instances in the UK.

Alexion noted that the post and press release were international in nature, wholly attributable to the US-based parent company, Alexion Pharmaceuticals Inc., with no involvement of the UK affiliate, and did not target UK users, nor indeed directly mention the UK. Therefore, the company considered that the activity did not fall within the scope of the Code and asked for the complaint to be dismissed as such.

That said, Alexion responded to the complaint. In summary, Alexion submitted that it was clear that the post and press release in question were factual, non-promotional, corporate announcements relevant, in their entirety, to the investor community. Such communications were permitted under the Code. Moreover, given the highly specialised nature of Alexion's products, the company did not understand how the posts could, even inadvertently, have a promotional effect. As such, it did not see grounds to support the alleged breaches. Moreover, the company had developed a robust social media policy for its employees and considered that it had maintained high standards at all times.

B**ackground and context**

Alexion was a US-headquartered group that focused on the development and sales of products for orphan and ultra-orphan conditions such as paroxysmal nocturnal hemoglobinuria (PNH). Alexion Pharma UK Ltd (Alexion UK) was the group's UK affiliate. Alexion UK's promotional activities were limited to the very small number of specialist centres and clinicians that diagnosed and treated patients with rare diseases; it did not target GPs with any kind of promotional material, since they would not usually be in a position to prescribe Alexion products and/or be directly responsible for the diagnosis and treatment of very rare diseases. Alexion submitted that because of the specialist nature of its products, and their classification as prescription only, it did not promote its products on open social media platforms.

The post in question came from a LinkedIn account operated by Alexion Pharmaceuticals Inc. based in the US. This account exclusively contained general information relevant to investors, the financial community and others with an interest in Alexion

Pharmaceuticals Inc. It did not contain product promotional materials of any kind.

When Alexion was advised of the complaint, the post had received over 300 'likes' on LinkedIn largely from users who were not employees of, nor associated with, Alexion. Of those that were from Alexion, only a small handful were employees of Alexion UK; the rest were Alexion employees based outside the UK and would not be expected to have any professional dealings with UK-based clinicians and certainly not UK GPs. It was therefore not clear whether the complainant received the post in his/her feed as a result of following the Alexion LinkedIn account, being linked to a person not employed by Alexion who 'liked' the post, or being linked to an Alexion UK employee or ex-employee who 'liked' the post.

Jurisdiction and scope of Code

Alexion noted that Section 14 of the PMCPA Digital Guidelines effectively confirmed that UK companies should not be held responsible for information placed on the Internet outside the UK by a parent company unless: (i) such activities were on the instigation or authority of the UK company; and (ii) the information referred to the availability of a product in the UK.

According to the above test, the post and the press release would not be attributable to Alexion UK and would fall outside the scope of the Code because:

- The source of the post was Alexion Pharmaceuticals Inc., the US-based parent company. The LinkedIn account of Alexion Pharmaceuticals Inc. had a global audience, predominantly based in the US. Source of feed was 'news.alexion.com'. The press release was from Alexion.Inc, to NASDAQ – a US-based stock exchange. The press release had US-based contact addresses. Publishing such content was clearly under the authority and at the instigation of Alexion Pharmaceuticals Inc. without involvement of the UK company.
- The LinkedIn post and press release were addressed to the global investor community and not specifically to UK users. Both the feed and the press release focused on US, EU and forthcoming Japanese regulatory filings, and the mention of the EU was simply part of that continuum.

Based on advice and information received about previous PMCPA cases, Alexion submitted that the LinkedIn post in question clearly fell outside the scope of the Code.

Non-promotional nature of post

As noted above, the post originated from a corporate LinkedIn account, containing general company and investor-relations news at an international level. Consistent with this, the post itself and the press release provided factual, non-promotional information about an important corporate update. The contents were, in their entirety, relevant to investors and the financial community.

Alexion noted that Alexion Pharmaceuticals Inc. was under obligation under various securities laws to bring such news to the attention of markets in full.

Alexion referred to the Supplementary Information to Clause 26.2 of the Code:

> 'Information made available in order to inform shareholders, the Stock Exchange and the like by way of … announcements etc. may relate to both existing medicines and those not yet marketed. Such information must be factual and presented in a balanced way….'

The LinkedIn post clearly adhered to these requirements, as follows:

- The post accurately summarised and provided a link to a press release made to the NASDAQ. The nature and purpose of the communication, as a corporate announcement, would be abundantly clear to the average user. For example: the press release (i) mentioned NASDAQ ticker; (ii) and contained a 'Forward Looking Statements' disclaimer. Alexion did not understand how this could be interpreted as product-promotional material.
- No product claims were made. The press release only mentioned clinical trial results in the context of updating corporate news, as supporting the marketing authorization application.
- No product name was mentioned – ALXN1210 was not a brand name. The post did not stimulate patient or health professional interest in a specific product, as no product with that name existed. No marketed product would be available for a number of years, as the EU marketing authorisation application was very recent.
- The risk of the post being misconstrued as promotional, or inadvertently having a product promotional effect, was virtually zero. PNH was an ultra-rare condition and the handful of patients with the disease or few clinicians operating in that field were already likely to be aware of Alexion's products and pipeline. The post simply provided that information to the wider financial and investor community, which might not have such awareness, but in any event, would not be in a position to prescribe, recommend, use, request etc treatment with any Alexion product. While it remained unclear to Alexion how a GP would have received the post, its receipt could not possibly have a promotional effect since GPs would not be in a position to prescribe or recommend its products.
- Under general principles set out in the Code, companies might mention an indication in a non-promotional context so long as they did not also mention a product by name (analogy with 'Reply Paid Cards', per Supplementary Information to Clause 9.8 of the Code). A proportionate approach had been taken here, since it might be misleading to the market not to be clear about which indication and which development molecule was in question.

Complainant's receipt of content

It was unclear as to how the complainant received the post in his/her LinkedIn feed. There was a suggestion that this was because the post received a 'like' from an Alexion employee to whom Alexion assumed the complainant was connected through LinkedIn, however, the complaint did not elaborate. As a general observation, Alexion noted that LinkedIn users would have consented to receiving posts from their contacts, except where users had disabled such a setting, so the post could have been liked by anyone in the complainant's network. Nonetheless, Alexion maintained that the intention and content of the post was not promotional and so it denied a breach of Clause 9.9.

Social media activities of employees

Alexion understood that the PMCPA addressed the responsibility of a company with respect to the social media activities of its employees on a case-by-case basis. With respect to Clauses 2 and 9.1 of the Code, a key factor was whether companies had appropriate social media policies in place for their employees.

Alexion was aware of the sensitivities of the use of social media by its employees and took its responsibilities very seriously in this regard. For instance, the Alexion Global Social Media Policy required that employees:

- were 'expected to act responsibly and professionally, exercise good judgement …' (Section A)
- were expected not to speak on the company's behalf on social media (Section C.III)
- were permitted to 'like' Alexion's social media posts but might not provide further comment (Section C.V.i)
- should have awareness of interactions with professional acquaintances over social media (Section C.V.ii).

Alexion considered that the company had strong policies in place to guide employees on the appropriate use of social media and had maintained high standards. Without understanding how the complainant received the LinkedIn post in question, it was difficult to comment further at this stage. However, Alexion was reviewing the social media policy to see whether changes were necessary for the UK. Alexion might, for example, guide UK employees not to 'like' certain posts on social media in future.

Conclusions

Subject to receiving further information, Alexion's interim conclusions were as follows:

- Alexion's position was that the post in question fell outside the scope of the Code as there was no relationship with the UK.
- Notwithstanding this, the materials were clearly corporate announcements relevant, in full, to the investment community. As such they were a form of general communication permitted under the Code and acknowledged to be non-promotional. As such, it was Alexion's position that it had fully complied with the requirements of Clauses 9.9, 26.1 and 26.2.
- Alexion had maintained high standards by establishing a clear social media policy for employees, which discouraged any comment on materials posted. This ensured employees did not make promotional claims as a follow-up to non-promotional information. Alexion therefore believed that it had complied with the requirements of Clause 9.1.
- In light of the above, Alexion submitted that it had always complied with the requirements of Clause 2 in not bringing discredit upon, or reducing confidence in, the pharmaceutical industry.

Alexion had not been provided with any evidence to support the suggestion that the actions of a specific Alexion employee might have triggered the complaint. Even if the LinkedIn post appeared in the complainant's feed because it was liked by an Alexion employee, Alexion maintained that the post was not promotional. LinkedIn users who received items in their LinkedIn feed had consented to this by agreeing to the terms of use. Alexion did not have any control over the use of 'likes' by non-Alexion employees, and the social media actions of its own employees were managed by the Alexion social media policy. The liking of the post by any LinkedIn user (Alexion employee or not) did not make a non-promotional post become promotional.

Alexion had taken, and would take; the measures outlined above and might take further remedial actions following the PMCPA's investigation if required.

PANEL RULING

The Panel noted that Alexion referred to the complainant as a general practitioner (GP) in its response. The Panel noted that the company had been advised by the case preparation manager at the outset that the complainant was a GP. That was not so, the contactable complainant described themselves as a 'concerned HCP'. The Panel noted that the complaint concerned alleged promotion to the public rather than to health professionals and thus his/her professional status was not relevant to the subject matter of the complaint.

The Panel noted the complainant's allegation that the LinkedIn post, which led to a press release, appeared in his/her LinkedIn feed because Alexion UK employees had liked it which then presented it to their connections. The Panel noted that the complainant had not named or otherwise referred to a specific Alexion UK employee that was in his/her network on LinkedIn. The Panel further noted Alexion's submission that when it was advised of the complaint, the post had received over 300 'likes' on LinkedIn including a 'small handful' of likes from Alexion UK employees.

The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, including 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 his/her connections LinkedIn feeds thereby disseminating the material. 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. The Panel considered it was likely that Alexion UK employees' connections would include UK members of the public and might include UK health professionals. The Panel noted that the LinkedIn post and associated press release was 'liked' by a number of Alexion UK employees. In the Panel's view the act of liking the material amounted to proactive dissemination of the material within the UK and brought it within the scope of the 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. In the pharmaceutical industry, the Panel noted that an individual's network might, albeit not exclusively, be directly or indirectly associated with the healthcare industry. In the Panel's view, it was of course not unacceptable for company employees to use personal LinkedIn accounts and the Code would not automatically apply to all activity on a personal account; whether the Code applied would be determined on a case-by-case basis taking into account all the circumstances including: the content, any direct or indirect reference to a product, how the information was disseminated on LinkedIn, the company's role in relation to the availability of the content and whether such activity was directed or encouraged by the company. If activity was found to be within the scope of the Code, the company would be held responsible.

The Panel noted Alexion's submission that the post and press release in question were factual, non-promotional, corporate announcements relevant, in their entirety, to the investor community and that they originated from a LinkedIn account operated by Alexion Pharmaceuticals Inc. based in the US no involvement of the UK affiliate. The Panel noted Alexion's submission that the post did not target UK users or directly mention the UK. The Panel noted, however, that in liking the post, Alexion UK employees had, on the balance of probabilities, proactively disseminated it within the UK to an audience far wider than the intended financial community. In the Panel's view, the broad dissemination of the material beyond the financial community meant that such dissemination was beyond that referred to in the supplementary information to Clause 26.2 Financial Information which, *inter alia*, permitted financial information within the scope of the supplementary information to relate to both existing medicines and those not yet marketed.

The Panel noted that the LinkedIn posting informed readers that Alexion had submitted an application for approval of ALXN1210 as a treatment for patients with paroxysmal nocturnal haemoglobinuria (PNH) in the European Union (EU). The US filing and Japanese submission were also referred to. The linked press release provided more detail. It described the results of two large Phase 3 studies and included statements such as 'We are excited about this next important step towards our goal of establishing ALXN1210 as the new standard of care for patients with PNH…' and 'Building on 10 years of proven efficacy and safety with Soliris and 25 years of leadership in complement biology...'. Soliris (eculizumab) was an Alexion prescription only medicine, available in the UK, indicated in adults and children for the treatment of PNH. Soliris was described in the press release as 'a first-in-class complement inhibitor ...' and ALXN1210 was described as an 'innovative, long acting C5 inhibitor discovered and developed by Alexion ...'. The press release also stated that 'Alexion and Soliris have received some of the pharmaceutical industry's highest honours for medical innovation in complement inhibition.
The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 stated that information about prescription only medicines which was made available either directly or indirectly to the public must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted its comments above and considered that on the balance of probabilities not all the Alexion UK employees' connections to whom the post might have been disseminated to by virtue of their 'like' would have been health professionals. Thus, in the Panel's view and on the balance of probabilities the LinkedIn post and associated press release had been disseminated to members of the public.

The Panel noted that the product, ALXN1210, was not classified as a prescription only medicine when the LinkedIn post and associated press release at issue were liked by the UK employee. Clauses 26.1 and 26.2 only applied to prescription only medicines. On this very narrow technical point the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code. However, the Panel considered that the Alexion UK employees' like of the LinkedIn post and associated press release regarding an unlicensed medicine and the potential subsequent dissemination to all of their connections meant that Alexion had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that the press release also referred to Soliris, which was a prescription only medicine available in the UK. There was no allegation with regard to Soliris and, therefore, the Panel could make no ruling in this regard.

The Panel noted that Clause 9.9 stated that the telephone, text messages, email, telemessages,

facsimile, automated calling systems and other electronic data communications must not be used for promotional purposes, except with the prior permission of the recipient. The Panel noted Alexion's submission that LinkedIn users would have consented to receiving posts from their contacts, except where users had disabled such a setting. There was no evidence before the Panel detailing what information was provided to users when signing up to use LinkedIn and to existing users when new functionalities were introduced. It was thus unclear whether prior permission had been given to receive such posts. The Panel considered that Clause 9.9 required companies that wished to rely on prior permission to be able to demonstrate that recipients had agreed to receive promotional material by such means. Such consent should be explicit and the nature of the material to be sent electronically made clear. Clause 9.9 applied to all medicines within the scope of the Code. Nonetheless, the Panel noted that the complainant bore the burden of proof and considered that he/she had not provided evidence to show that there had been a breach of Clause 9.9 and no breach was ruled.

The Panel was mindful of the complex issues that had to be addressed by companies when advising staff about social media use. The increasing use of social media, both in the personal and business capacity, presented compliance challenges. In addition, many social media platforms used algorithms and had settings which individuals and companies might not be fully aware of. In the Panel's view, companies should remain vigilant and ensure that they took reasonable steps to highlight the potential compliance issues that might arise from interacting on social media including 'liking' certain posts on LinkedIn given such posts could thereby potentially be pushed to their connections' feeds. The Panel was aware that the types of activity performed by the Alexion UK employees on LinkedIn was not uncommon across the industry.

In the Panel's view, employees might feel inclined to endorse posts that were published by their company's corporate social media account or which related to their company and depending on the content such activity may or may not fall within the scope of the Code. Companies therefore needed to issue specific and unambiguous guidance on use of social media including relevant personal use. This was particularly important if 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. It was therefore critical that companies provided clear and tailored guidance for its employees which was frequently reviewed. In the Panel's view it was important that companies regularly reviewed such guidance.

The Panel noted Alexion's submission that the Alexion Global Social Media Policy stated, *inter alia*, that employees were permitted to 'like' Alexion's social media posts but might not provide further comment. The Panel noted that Alexion was, however, reviewing the social media policy to see whether changes were necessary for the UK and might guide UK employees not to 'like' certain posts on social media in future. The Panel was concerned that there appeared to be no UK specific guidance at the time of the complaint. The Panel considered that the lack of adequate UK specific social media guidance at the time of the complaint meant that Alexion had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

Complaint received **28 June 2018**

Case completed **14 February 2019**