CASE AUTH/3163/2/19

CONCERNED UK HEALTH PROFESSIONAL v ALEXION

Promotional material advertised on LinkedIn

A complainant who described him/herself as a concerned UK health professional, complained for a second time about a post received on his/her LinkedIn feed from Alexion Pharmaceuticals. The LinkedIn message was first brought to the Authority's attention in Case AUTH/3051/6/18. The message informed readers, *inter alia*, that Alexion had submitted an EU application for approval of ALXN1210 as a treatment for paroxysmal nocturnal haemoglobinuria (PNH) and included a link to a press release about Alexion and ALXN1210. In Case AUTH/3051/6/18, the complainant was concerned that the material would be seen by a variety of people including those who were not health professionals. In its ruling on the matter, the Panel had noted that the linked press release also referred to Soliris (eculizumab) which was indicated for the treatment of PNH.

The complainant stated that he/she had read the outcome for Case AUTH/3051/6/18 and noted that it appeared that the case had focused on promotion to the general public but now noted that the LinkedIn post also promoted an unlicensed medicine (ALXN1210) to health professionals. The complainant noted that Alexion had submitted that the material was not reviewed locally and so, in that regard, the company had not certified the material.

The complainant alleged that the associated press release's reference to Soliris was promotion of a medicine to the public. The material promoted Soliris to health professionals and there was no prescribing information.

This case was considered under the 2016 Code.

The detailed response from Alexion is given below.

The Panel noted that the complainant had not referred to Soliris in Case AUTH/3051/6/18, however, in that case the Panel referred to it in its ruling as in its view it contributed to why the Panel considered the press release to be promotional.

The Panel noted Alexion's submission that in Case AUTH/3051/6/18, no evidence was ever provided by the complainant that the Alexion US post seen on LinkedIn was because of the actions of an Alexion UK employee. Alexion had not appealed the Panel's rulings of breaches of the Code in Case AUTH/3051/6/18. Alexion's submission in that case included that a small number of Alexion UK employees had liked the US post. Therefore, in the Panel's view, it was highly likely, on the balance of probabilities, that the LinkedIn post and associated press release was seen by the complainant as a result of an Alexion UK employee liking the post as alleged. In that case the Panel decided that

the act of liking the LinkedIn post 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, in the current case (Case AUTH/3163/2/19), that clicking on the link in the post took the reader to a site where the press release at issue appeared rather than being taken directly to the press release. At the top of the page the reader was able to select his/her country. If the UK was selected, the press release at issue could not be accessed at all. In addition, at the bottom of the page, there was a statement in relation to the intended audience for the press releases contained on that page: 'This website is intended only for residents of the United States'. It was not clear to the Panel whether this was always there or whether it had been amended following Case AUTH/3051/6/18 as Alexion had made no such submission when responding to Case AUTH/3051/6/18. Alexion stated that the post was taken down on 3 July 2018.

The Panel considered that its comments in Case AUTH/3051/6/18 were relevant in the present case (Case AUTH/3163/2/19).

The Panel noted that the LinkedIn post at issue in Case AUTH/3051/6/18 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 Panel noted the statements made in the press release with regard to ALXN1210.

The Panel considered that, on the balance of probabilities, the Alexion UK employees' connections on LinkedIn would include health professionals as well as members of the public. In the Panel's view, the disseminated LinkedIn post and associated press release promoted ALXN1210 prior to the grant of its marketing authorization and a breach of the Code was ruled which was upheld on appeal by Alexion.

The Panel further noted that the press release referred to Soliris, which was a prescription only medicine available in the UK. The Panel noted the statements made with regard to Soliris above and considered that the disseminated press release promoted a prescription only medicine to members of the public who might be encouraged to ask for it and breaches were ruled.

The Panel noted that the Code only required a statement about reporting side effects to be included on material which related to a medicine and was intended for patients taking that medicine. Although it might have been helpful to include information about reporting side effects, as the disseminated press release was not intended specifically for patients taking Soliris it was not a requirement and the Panel therefore ruled no breach of the Code.

The Panel noted that in its view the material had not been restricted to the financial community to whom Alexion submitted it was intended nor was the promotional nature of the material appropriate for that audience and the Panel therefore ruled a breach of the Code.

The Panel noted that in liking the LinkedIn post and associated press release, an Alexion UK employee proactively disseminated it to his/her connections which, on the balance of probabilities, would include UK health professionals. In the Panel's view, Soliris had, therefore, been promoted to health professionals and prescribing information and a

prominent statement regarding the mechanism for reporting adverse events should have been included with the post sent to this audience and had not been. The Panel therefore ruled a breach of the Code including that the material had not been certified. Alexion appealed these rulings.

The Appeal Board did not consider that it was unacceptable for the ruling in Case AUTH/3051/6/18 to describe the material at issue in that case, including a reference to Soliris. Indeed, it was established practice for the Panel to describe the material at issue. It was unusual for information in the Panel's ruling to lead to a follow-up complaint. The Appeal Board noted that the previous case, Case AUTH/3051/6/18, concerned the alleged promotion of ALXN1210 to the public. The present case concerned ALXN1210 in relation to promotion of an unlicensed medicine to health professionals. The Appeal Board noted that whilst the material at issue, the LinkedIn post, was the same in each case, the matters raised were different. The Appeal Board saw no reason why the matters now raised by the complainant could not, therefore, be taken up as a new complaint under Paragraphs 5.1 and 5.2 of the Constitution and Procedure. The new matters raised in the present case, Case AUTH/3163/2/19, had not been the subject of a previous adjudication. In the Appeal Board's view, and contrary to Alexion's submission at the appeal, allowing the complaint to proceed would not set a dangerous precedent to permit multiple complaints on matters already considered. It appeared to the Appeal Board that Paragraph 5.2 of the Constitution and Procedure had been complied with on this point.

The Appeal Board noted Alexion's submission in Case AUTH/3163/2/19 that the press release did not fall within the scope of the Code as, *inter alia*, the complainant had failed to provide any evidence that the LinkedIn post was received in the complainant's feed as a result of an Alexion UK employee liking it. In this regard, the Appeal Board noted the complainant's comments and Alexion's acknowledgment that a small number of its employees had liked the post. In the Appeal Board's view, given the allegations made in Case AUTH/3163/2/19, the complainant, who described themselves as a health professional, did not necessarily need to establish whether or how the posting appeared in his/her personal feed – merely that, on the balance of probabilities, the post was disseminated to members of the UK public and/or UK health professionals.

The Appeal Board noted that the LinkedIn post in question was issued by Alexion Pharmaceuticals Inc., the US-based parent company. The post 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 Appeal Board noted Alexion's submission that a small number of Alexion UK employees had liked the post. The Appeal Board considered that Alexion UK employees had, on the balance of probabilities, proactively disseminated the post within the UK to an audience far wider than the intended financial community. The Appeal Board consequently considered that the LinkedIn post came within the scope of the Code. In the Appeal Board's view, the post had a promotional appearance due to its layout and wording. The Appeal Board considered that its proactive dissemination by UK employees was such that the LinkedIn post promoted ALXN1210 prior to the grant of its marketing authorization. The Appeal Board upheld the Panel's ruling of a breach of the Code. The appeal on this point was unsuccessful. As the LinkedIn post that had promoted ALXN1210 had not been certified, the Appeal Board also upheld the Panel's ruling of a breach in this regard. The appeal on this point was unsuccessful.

The Appeal Board noted Alexion's submission that when clicking on the link in the LinkedIn post, the reader was taken to the site news.alexion.com. At the top of the page the reader was able to filter the list of the press releases by selecting his/her country. When the UK was selected from the 'Select a country' tab at the top of the page, the press release at issue could not be accessed. If the US was selected, the press release at issue was visible and this was the default view. In addition, at the bottom of the webpage, there was a statement in relation to the intended audience: 'This website is intended only for residents of the United States'. The Appeal Board noted from Alexion's submission that the statement had appeared on the website since at least 2016. The LinkedIn post made no mention of Soliris; the only mention of Soliris was in the press release which was accessed by clicking on a link in the post which took readers to a list of press releases and not directly to the press release at issue. The Appeal Board considered that the arrangements for reaching the press release and its content were sufficient to ensure that readers knew the press release was for a US audience. Consequently, the Appeal Board considered that the press release did not come within the scope of the Code. The Appeal Board therefore ruled no breach of the Code. The appeals on this point were successful.

A complainant who described him/herself as a concerned UK health professional, complained for a second time about a specific posting received on his/her LinkedIn feed from Alexion Pharmaceuticals. The LinkedIn message was first brought to the Authority's attention in Case AUTH/3051/6/18. The message informed readers, *inter alia*, that Alexion had submitted an EU application for approval of ALXN1210 as a treatment for paroxysmal nocturnal haemoglobinuria (PNH) and included a link to a press release about Alexion and ALXN1210. In Case AUTH/3051/6/18, the complainant was concerned that the material would be seen by a variety of people including those who were not health professionals. In its ruling on the matter, the Panel noted that the linked press release also referred to Soliris (eculizumab) which was indicated for the treatment of PNH.

COMPLAINT

The complainant stated that he/she had read the outcome for Case AUTH/3051/6/18 and noted that it appeared that the case had focused on promotion to the general public but now noted that the LinkedIn post also promoted to health professionals. Given that the medicine (ALXN1210) was unlicensed, the complainant alleged a breach of Clause 3.1. The complainant noted that Alexion had submitted that the material was not reviewed locally and so, in that regard, the company had not certified the material. Breaches of Clauses 14.1, 14.5 and 14.6 were alleged.

The complainant alleged that the associated press release's reference to Soliris was promotion of a medicine to the public, in breach of Clauses 26.1, 26.2 and 26.3. As the material also promoted Soliris to health professionals and there was no prescribing information, the complainant alleged a breach of Clause 4.1 and also Clauses 4.4, 4.6 and 4.9. The complainant stated that as the LinkedIn message had been sent to 'one and all', he/she would like Clause 11.1 reviewed.

This case was considered under the 2016 Code.

RESPONSE

Alexion stated that the complainant did not appeal the previous Panel ruling in Case AUTH/3051/6/18 and Alexion signed the undertaking relating to that breach even though there were oversights on the part of the case preparation manager and it had concerns about the Panel's ruling. Alexion believed that it was procedurally unfair to allow a complainant to complain again about the same matter without any new evidence adduced, based solely on Panel concerns about unalleged matters that Alexion could not address in its original response. In Alexion's view, the spirit of self-regulation was intended to help companies continuously improve and it supported the PMCPA's efforts in administering the Code to that end. However, on this occasion, Alexion considered this case should be dismissed and it set out its position below. Whilst Alexion would not address the specific allegations, it would be happy to respond to any questions from the Authority.

Alexion's position on Case AUTH/3051/6/18

Alexion stated that in the previous case, the burden of proof lay with the complainant, yet no evidence was ever provided by him/her that the Alexion US post he/she saw on LinkedIn was because of the actions of an Alexion UK employee. This was only assumed and Alexion was not given details of further communication between the complainant and the case preparation manager.

The Code might not have applied, as per other LinkedIn cases where a specific employee was named and the companies involved were able to investigate the matter thoroughly (Cases AUTH/3019/2/18, AUTH/3020/2/18 and AUTH/3021/2/18).

As Alexion's own review had uncovered that Alexion UK employees had liked the US post, it responded to the complaint, noting that the case preparation manager cited Clauses 9 and 26, even though it was clear that:

- the complaint was specifically about an unlicensed medicine
- the complainant was a health professional.

Alexion stated that it was not fair for Alexion to have to now respond on the same matter because of mistakes made by the case preparation manager during the previous complaint.

In the Panel ruling, the Panel essentially unfairly judged aspects of the post that Alexion was never asked to address. There were no grounds for Alexion to have appealed on those matters as they formed the Panel's 'concerns' and not their ruling. Nevertheless, Alexion chose to draw a line under the matter and move on.

Alexion stated that it was not in line with the spirit of self-regulation for complaints to be raised based on Panel concerns, which were inevitably pre-determined to be breaches of the Code.

Alexion's position on Case AUTH/3163/2/19

Alexion stated that as the complainant could not have appealed and introduced new clauses, it believed that he/she lodged a new complaint based solely on the Panel's concerns in Case AUTH/3051/6/18.

There was precedent for the PMCPA to have followed Paragraph 17 of the Constitution and Procedure in raising a new complaint about its concerns eg the Panel had concerns about an item beyond those of the original allegation in Case AUTH/1921/11/06 and so the matter was taken up by the Director as Case AUTH/1936/12/06.

Furthermore, under Paragraph 5.2, this complaint was not based on new evidence adduced by the complainant so should not have been allowed to proceed. In Case AUTH/2790/8/15, the case did not proceed because 'in the Appeal Board's view the first sentence of the relevant section of Paragraph 5.2 … was a condition precedent, ie '… it may be allowed to proceed at the discretion of the Director if new evidence is adduced by the complainant …'. Alexion stated that whilst the PMCPA stated in its email of 25 February that the new complaint related to new matters, that definition did not meet the criteria under Paragraph 5.2.

Alexion stated that it was not procedurally fair for it to respond to a complaint about the same matter but with no new evidence adduced by the complainant.

With respect to the wider industry, it was Alexion's belief that allowing complaints based solely on Panel 'concerns' set a significant precedent if left unchallenged:

'
- Panel concerns, expressed at the start of each ruling, might be seen to 'advocate' additional areas to complain about.
- The Panel might start being viewed as 'complainants' if the case preparation manager accepted cases that the Panel had essentially helped create.
- Citing further clauses would be accepted rather than new evidence.
- Paragraph 5.2 of the PMCPA Constitution would need to change if new evidence included 'new clauses alleged'.
- Anonymous complaints might increase, as there would be very little evidence to provide other than the Panel's concerns.
- Complainants need never appeal rulings but might simply rely on the Panel's concerns as a source of 'new evidence'.
- Respondent companies might not provide information about matters beyond the alleged clauses in their responses if there was a risk that any reader of the ruling was going to complain about these areas afterwards.
- Respondent company responses might have to address points beyond the initial scope of the complaint, just in case the Panel decided to comment on these.
- If companies considered that the Panel's language might encourage further complaints, could they request that the information was not included in case reports? It was clear that without clarity in the PMCPA Constitution and Procedure, there was no guidance on what the Panel might or might not include as concerns in case reports or what companies could request was removed from draft case reports.
- If complainants considered that the case preparation manager's approach was not correct, would the PMCPA Constitution and Procedure be amended to allow them to check alleged clauses or introduce new clauses at appeal?
- There must be no perceived bias when the Panel included concerns for one company but not for another. This was especially important if case rulings were complex in themselves.'

Alexion stated that it was committed to self-regulation to improve the identification, correction and prevention of risk so that matters were resolved quickly. The company had learnt from the

previous complaint and drawn a line under the matter. If a further case about the same post (which was taken down on 3 July 2018) was later published, this would imply Alexion had ongoing issues, which was incorrect and potentially damaging. Therefore, Alexion reiterated that this case should be dismissed for the reasons outlined above.

Further information from Alexion

Alexion submitted that the aspects of this case were closely similar, if not the same, as those raised in Case AUTH/3051/6/18 and it was not procedurally fair, reasonable or proportionate to permit these elements to go forward as a second complaint, as per Paragraph 5.2 of the PMCPA Constitution and Procedure.

Alexion submitted that as noted by the Panel in Case AUTH/3051/6/18, the complainant was a health professional and the matter of his/her complaint was clearly in relation to information that appeared on his/her LinkedIn feed about an unlicensed medicine. Alexion stated that whilst an element of the complaint was in relation to promotion to the public, it did not consider that it was the sole focus of the matter. The case preparation manager should have raised Clause 3.1 in Case AUTH/3051/6/18 for Alexion to consider in relation to the promotion of a medicine to a health professional prior to the grant of the marketing authorization which permits its sale or supply. Alexion noted that the complainant made this point in an email sent to the Authority following its rulings in Case AUTH/3051/6/18 which stated 'First, it appears that the case has focused on promoting to the general public, but it also promoted to healthcare professionals'.

With that in mind, Alexion considered that that aspect of Case AUTH/3051/6/18 and the current case (Case AUTH/3163/2/19) were identical and should not proceed as part of the complaint in the latter, given that it had already been ruled upon by the Panel:

> '… the Panel considered that 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.'

Alexion stated that the case preparation manager not raising all the relevant clauses while determining the scope of a complaint should not permit the same matter to be considered in a second complaint.

Alexion was concerned about the Panel commenting on matters that it considered to be out of scope of a complaint; if a matter was considered outwith the scope of a complaint then the Panel should not provide comment at all in the case report, but rather raise these concerns with the responding company only (as had been done on an *ad hoc* basis in the past).

Alexion submitted that in Case AUTH/3051/6/18, the Panel appeared to consider reference to Soliris in the press release at issue as outwith the scope of the complaint, yet still made a comment in that regard. This clearly prompted the complainant to raise this as a further complaint in this case (Case AUTH/3163/2/19). Whilst it could be argued that Soliris was within the scope of the complaint in Case AUTH/3051/6/18 as it noted that in an email to the Authority the complainant stated that he/she had not signed up to receive material for Alexion products [plural], if the Panel considered that the medicine was not within the scope of the complaint it should not have commented on it in its ruling.

In response to Case AUTH/3163/2/19 Alexion stated that should the case proceed, it did not consider that there had been any breach of the Code.

Firstly, the complainant failed to provide any evidence that the LinkedIn post appeared in his/her feed as a result of an Alexion UK employee liking the post. With that in mind Alexion did not consider that the complainant had discharged the burden of proof placed upon him/her by the PMCPA Constitution and Procedure to demonstrate that, on the balance of probabilities, he/she viewed the post as a result of any action taken by Alexion UK. Thus, there had not been a breach of Clause 3.1 in relation to a reference in the LinkedIn post to ALXN1210.

Secondly, even if such proof was provided, when clicking on the link in the post, the reader was taken to the site news.alexion.com where the press release at issue appeared rather than being taken directly to the press release. At the top of the page the reader was able to select his/her country. If the UK was selected, the press release at issue could not be accessed at all. In addition, at the bottom of the page, there was a clear statement in relation to the intended audience for the press release contained on that page:

> 'This website is intended for residents of the United States.'

Thus, Alexion submitted that the press release fell outside the scope of the Code and denied that there had been any breach of the Code in relation to the content or approval of that press release.

Alexion concluded that it did not consider that it was procedurally fair for the complaint to be taken forward, however in the spirit of self-regulation, it had provided a full response in relation to the issues raised.

PANEL RULING

The Panel noted Alexion's concerns with regards to procedural fairness and the complaint being allowed to proceed.

The Panel noted that Paragraph 5.2 of the Constitution and Procedure stated, *inter alia*, that if the complainant is not a pharmaceutical company, the case preparation manager might suggest the clauses of the Code to be addressed. The Panel noted that these would be the clauses which in the case preparation manager's view were relevant to the allegations. It was for the complainant to prove their complaint on the balance of probabilities. The respondent company was informed of the complaint and the clauses identified by the case preparation manager and invited to comment. The Panel would only consider clauses cited by the case preparation manager when making its rulings. Either party could only appeal clauses ruled on by the Panel. The only way to address matters that had not been previously considered and ruled upon by the Panel was for them to be considered as a new complaint. The Panel noted that Alexion had been provided with all of the information sent by the complainant in Case AUTH/3051/6/18.

The Panel noted that in Case AUTH/3051/6/18 the subject line of the complaint was 'Apparent pre-approval of a drug promoted to the UK public' and the complainant, who described themselves as a 'concerned HCP', alleged that the LinkedIn post at issue would be seen by a variety of people beyond the small number of people who needed to receive updates about a compound before it had been approved. The complainant also referred to promoting to the public and the link being sent to many people in the UK who were not health professionals. The

Panel considered therefore that in its view the complaint concerned the alleged promotion to the public rather than to health professionals as stated in its ruling in Case AUTH/3051/6/18. The complainant did not mention Soliris. The case preparation manager had therefore only raised clauses with respect to ALXN1210 and the alleged promotion to the public and therefore did not raise Clause 3.1 which included a prohibition of promoting a medicine prior to the grant of its marketing authorization.

The Panel noted Alexion's reference to Paragraph 5.2 of the Constitution and Procedure which further stated that the Director should normally allow a complaint to proceed if it covers matters closely similar to one which had been the subject of a previous adjudication if new evidence was adduced or the passage of time or a change in circumstances raised doubts as to whether the same decision would be made in respect of the current complaint. The Director should normally allow a complaint to proceed if it covered matters similar to those in a decision of the Panel where no breach of the Code was ruled and which was not the subject of an appeal to the Appeal Board.

The Panel noted that the current complaint specifically referred to allegations of promotion of Soliris to health professionals and the general public and the pre-licence promotion of ALXN1210 to health professionals, all of which had not previously been considered and ruled upon by the Panel. The Panel therefore did not consider that Paragraph 5.2 of the Constitution and Procedure was relevant.

The Panel noted Alexion's comments with regard to the Panel's well-established approach regarding matters not covered by the complaint which came to light during the consideration of a case.

The Panel's approach was that if a matter was an integral part of a complaint and could be misunderstood as possibly acceptable then this was pointed out after the Panel had completed its consideration. Such matters would be included in the outcome letters to the parties and published in the case report in order that those studying the case reports would not be misled. If a matter identified was not an integral part of the complaint and there would be no misunderstanding of the Code's requirements then such information would generally only be provided to the respondent company and would not be included in the case report.

Case reports were provided to the parties prior to publication. It was important that case reports did not lead to misunderstandings. For example, if a complaint about a claim 'the best medicine for treating hypertension' was that the medicine was not licensed for hypertension, a breach of Clause 3.2 would likely be ruled. If there was no allegation about the use of the superlative 'best', its use would be covered in a 'during the consideration of this case' paragraph referring to the relevant Clause (7.10) and published in the case report, otherwise readers might conclude that the use of 'the best' was acceptable. If it transpired that the advertisement containing the claim had not been certified, this would be noted in a 'during the consideration of this case' paragraph sent to the respondent company but would not be published in the case report as readers would not be misled as they would not have been told that the advertisement was not certified.

The Panel noted that the complainant had not referred to Soliris in Case AUTH/3051/6/18, however, in that case the Panel referred to it in its ruling as in its view it contributed to why the Panel considered the press release to be promotional.

The Panel appreciated the difficulties for companies; previous arrangements in the PMCPA Constitution and Procedure under Paragraph 17 had given both the Panel and the Appeal Board the option to raise new matters identified during the consideration of a case. This was no longer the position so Alexion's reference to Case AUTH/1921/11/06 and Case AUTH/1936/12/06 were not relevant.

In general terms it was unusual for a complainant to raise as new complaints matters identified by the Panel during its consideration of a case. Such matters were usually addressed by respondent companies as part of the company's commitment to self-regulation. The Panel was very mindful when raising such matters informally as it might have to consider a subsequent complaint about them.

The Panel noted Alexion's submission that in the previous case (Case AUTH/3051/6/18), the burden of proof lay with the complainant, yet no evidence was ever provided by him/her that the Alexion US post he/she saw on LinkedIn was because of the actions of an Alexion UK employee. The Panel noted that Alexion had not appealed the Panel's rulings of breaches of the Code in Case AUTH/3051/6/18. Alexion's submission in Case AUTH/3051/6/18 included that a small number of Alexion UK employees had liked the US post. Therefore, in the Panel's view, it was highly likely, on the balance of probabilities, that the LinkedIn post and associated press release was seen by the complainant as a result of an Alexion UK employee liking the post as alleged. In that case the Panel decided that the act of liking the LinkedIn post 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, in the current case (Case AUTH/3163/2/19**)**, that when clicking on the link in the post, the reader was taken to the site news.alexion.com where the press release at issue appeared rather than being taken directly to the press release. At the top of the page the reader was able to select his/her country. If the UK was selected, the press release at issue could not be accessed at all. In addition, at the bottom of the page, there was a statement in relation to the intended audience for the press releases contained on that page: 'This website is intended only for residents of the United States'. It was not clear to the Panel whether this was always there or whether it had been amended following Case AUTH/3051/6/18 as Alexion had made no such submission when responding to Case AUTH/3051/6/18. Alexion stated that the post was taken down on 3 July 2018.

The Panel considered that its comments in Case AUTH/3051/6/18 were relevant in the present case (Case AUTH/3163/2/19) as follows:

The Panel noted that the LinkedIn post at issue in Case AUTH/3051/6/18 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. The press release 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, *inter alia*, 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 honors for the medical innovation in complement inhibition…'.

The Panel noted that in liking the LinkedIn post, Alexion UK employees had, on the balance of probabilities, proactively disseminated it and the linked press release within the UK to an audience far wider than the intended financial community.

Turning to the present case (Case AUTH/3163/2/19) the Panel considered that, on the balance of probabilities, the Alexion UK employees' connections on LinkedIn would include health professionals as well as members of the public. Noting its comments above, in the Panel's view the disseminated LinkedIn post and associated press release promoted ALXN1210 prior to the grant of its marketing authorization and a breach of Clause 3.1 was ruled.

The Panel further noted that the press release referred to Soliris, which was a prescription only medicine available in the UK. The Panel noted the statements made with regard to Soliris above and considered that the disseminated press release promoted a prescription only medicine to members of the public who might be encouraged to ask for it and breaches of Clauses 26.1 and 26.2 were ruled.

The Panel noted that Clause 26.3 of Code only required a statement about reporting side effects to be included on material which related to a medicine and was intended for patients taking that medicine. Although it might have been helpful to include information about reporting side effects, as the disseminated press release was not intended specifically for patients taking Soliris it was not a requirement and the Panel therefore ruled no breach of Clause 26.3.

The Panel noted that Clause 11.1 stated that material should only be sent or distributed to those categories of persons whose need for, or interest in, it could reasonably be assumed. The supplementary information stated material should be tailored to the audience to whom it is directed. As far as the Panel was aware it was possible to create closed groups within LinkedIn to ensure that material could be sent to the specific intended audience and within the requirements of the Code. The Panel noted that in its view the material had not been restricted to the financial community to whom Alexion submitted it was intended nor was the promotional nature of the material appropriate for that audience and the Panel therefore ruled a breach of Clause 11.1.

The Panel noted Alexion's submission in Case AUTH/3051/6/18 that the original LinkedIn post came from a LinkedIn account operated by Alexion Pharmaceuticals Inc. based in the US and the account exclusively contained general information relevant to investors, the financial community and others with an interest in Alexion Pharmaceuticals Inc. The Panel did not agree with Alexion's submission in Case AUTH/3051/6/18 that the post and press release in question were factual, non-promotional, corporate announcements.

The Panel noted that corporate announcements and press releases were meant to be non-promotional and not intended as advertising for a health professional audience and therefore would not require prescribing information or information about adverse event reporting. This was similar with regards to materials intended for members of the public.

The Panel noted that the nature of LinkedIn was such that posts could be broadly and quickly disseminated making them available to other LinkedIn users which would likely extend beyond the relevant media and financial and investment community. In the Panel's view, in these

particular circumstances, both the content of the LinkedIn post and associated press release and their proactive dissemination meant that they were promotional.

The Panel noted that in liking the LinkedIn post and associated press release, an Alexion UK employee proactively disseminated it to his/her connections which, on the balance of probabilities, would include UK health professionals. In the Panel's view, Soliris had, therefore, been promoted to health professionals and prescribing information and a prominent statement regarding the mechanism for reporting adverse events should have been included with the post sent to this audience and had not been. The Panel therefore ruled a breach of Clauses 4.1 and 4.9. The Panel noted that the complainant raised Clauses 4.4 and 4.6 and considered that these allegations were covered by its ruling of a breach of Clause 4.1.

The Panel noted that the post should have been certified for use with this audience and it had not been and a breach of Clause 14.1 was ruled. The Panel noted that the complainant raised Clauses 14.5 and 14.6 and considered that these allegations were covered by its ruling of a breach of Clause 14.1.

APPEAL BY ALEXION

Alexion submitted that it appealed the Panel's rulings of breaches of the Code on the grounds that the process followed in this case by both the case preparation manager and the Panel was procedurally unfair and the case should never have proceeded.

Matters similar to those raised in Case AUTH/3051/6/18

Alexion submitted that, as noted by the Panel, the complainant was a health professional and the matter of his/her complaint was quite clearly in relation to information that appeared on his/her LinkedIn feed about an unlicensed medicine. When considering the scope of the complaint, the case preparation manager and the Panel had placed undue emphasis on the title of the original complaint 'Apparent pre-approval of a drug promoted to the UK public' without taking into account the significance of the broader statement made by the complainant, that 'I imagine that there is a very small number of people that do need to receive updates about a compound before it has been approved, but this has gone well beyond this'.

In addition, the complainant stated that he/she, a health professional, had 'not signed up to receive promotional material for Alexions [sic] products'. This mistake, coupled with the fact that the complainant was a health professional, should have been a clear indication to both the case preparation manager and the Panel that Clause 3.1 was relevant, and this clause should have been raised for the Panel to consider. With this in mind, Alexion reiterated the position that it had taken from the outset of this new complaint; this aspect of the complaint was identical to that raised in Case AUTH/3051/6/18 and should not have proceeded (Paragraph 5.2 of the PMCPA Constitution and Procedure). Failure by the case preparation manager to raise all the relevant clauses while determining the scope of an initial complaint should not permit the same matter to be considered in a second complaint. To do so would be procedurally unfair and not in line with the spirit of the Code, as this ruling suggested that any complainant listing out the Panel's concerns in a new complaint met the definition of 'new evidence' under Paragraph 5.2.

Turning to the matter of Soliris, and reference to this medicine in the ruling for Case AUTH/3051/6/18, Alexion submitted that the Panel should not have made any reference to this medicine in its ruling and certainly not in the case report.

Alexion submitted that the complaint was about a press release and its alleged promotion of an unlicensed compound, ALXN1210. The Panel's justification for referring to Soliris in its ruling on this matter was that it 'contributed to why the Panel considered the press release to be promotional'. This did not make sense; if a press release was promotional in relation to one medicine it did not automatically mean that it was promotional in relation to all the medicines it referred to. The ruling in relation to ALXN1210 could have been made without any mention of Soliris whatsoever.

Alexion submitted that it reiterated that this unnecessary reference to Soliris by the Panel had led directly to the complainant making a further complaint about the same press release. Alexion noted that the PMCPA Constitution and Procedure no longer permitted the Panel to raise new matters identified during the consideration of a complaint, however *ad hoc* comments such as in this case seemed to be a 'back door' method of achieving the same end. If the Panel had concerns about the content of the press release in relation to Soliris, this was a matter that was not an integral part of the complaint and should have been raised with Alexion only, as it had been identified in a manner similar to that of scrutiny, as detailed in Paragraph 17 of the Constitution and Procedure.

Alexion submitted that in relation to the reference to Soliris in the case report, it noted the Panel's comment that this was a well-established approach regarding matters not covered by a complaint which came to light during the consideration of a complaint. It might be considered to be well-established but this did not render it fair or constitutional; moreover, the application of this principle by the Panel was grossly inconsistent.

Alexion submitted that, for example, the Panel referred to certification or lack thereof, and in fact made a ruling in relation to this, in Case AUTH/2842/4/16, despite the matter of the complaint being unrelated to certification, yet it made no reference to a similar matter in the case report for Case AUTH/2954/4/17. Furthermore, a company could not be expected to address unalleged matters in its response, just in case the Panel decided to communicate concerns (and judgement) in its subsequent ruling.

On the whole, Alexion considered that reference in a ruling by the Panel to a matter not covered by the complaint in Case AUTH/3051/6/18 had led directly to the complainant raising this matter as a further complaint. This seemed entirely unfair and went against the principles of scrutiny in Paragraph 17 of the Constitution and Procedure, which stated that no member of the Authority could carry out scrutiny and that companies should be informed of such matters and invited to comment; and there should be no administrative charge and no case report in relation to such matters.

Case AUTH/3163/2/19

Notwithstanding the above, Alexion submitted that the press release did not fall within the scope of the Code.

Alexion submitted that the Panel appeared to have ignored the position that it took in relation to the lack of evidence provided by the complainant that, on the balance of probabilities, he/she viewed the post as a result of any action taken by Alexion UK. The complainant had failed to discharge the burden of proof placed upon him/her by the PMCPA Constitution and Procedure.

This evidence would be quite easily obtained by providing a screen shot of the post at issue, which would identify the individual to whom the complainant was linked who shared the post.

Alexion submitted that the fact that the complainant had not been asked to provide this before the case was considered demonstrated a lack of understanding by the case preparation manager and the Panel in relation to social media – as noted in the successful appeal in Case AUTH/3010/1/18.

Alexion submitted that, in addition, the Panel also appeared to have ignored to a large extent the comments made by Alexion in its response to this complaint that related to the clarity of the target audience for the press release. As previously stated, when clicking on the LinkedIn post, the reader was taken to the site news.alexion.com where the press release at issue appeared rather than being taken directly to the press release. At the top of this page the reader was able to select his/her country. If the UK was selected, the press release at issue could not be accessed at all. In addition, at the bottom of this page, there was a clear statement in relation to the intended audience for the press releases contained on that page: 'This website is intended only for residents of the United States'.

Alexion submitted that, in its ruling in Case AUTH/3163/2/19, the Panel questioned when this statement first appeared on the website. Rather than asking Alexion to clarify this point, it appeared to have assumed that this was a recent addition as a result of Case AUTH/3051/6/18. It was unclear on what basis the Panel would make such a negative assumption but it was wholly incorrect. It might be that the Panel reviewed the pdfs of each webpage; if the dynamic content was viewed the disclaimer could quite clearly be seen on every page. This statement had been on the website since at least 2016.

Alexion asked that the Appeal Board review the applicability of the Code to the press release when considering this important matter.

In summary, Alexion considered it grossly unfair and an abuse of process that this complaint was permitted to proceed to this stage. As it stood, it established a dangerous precedent that would permit multiple complaints on matters effectively already considered and ruled upon, and the Panel to avoid the requirements of scrutiny as laid out in the Constitution and Procedure.

Alexion submitted that even if the matter should have proceeded, it considered that it fell outside the scope of the Code, a point that the case preparation manager and Panel had alarmingly failed to pursue with any reasonable due diligence.

COMMENTS FROM THE COMPLAINANT

The complainant had nothing more to add and he/she was sure that the Appeal Board was able to review the material on the case.

APPEAL BOARD RULING

The Appeal Board considered Alexion's submissions very carefully and did not consider that Alexion had been the subject of procedural unfairness as submitted by the company. It was important, nonetheless, that companies raised such concerns. In this regard, the Appeal Board noted the company's submission about procedural unfairness and that the Chair had asked the

company representatives at the outset to raise any further procedural issues as they arose during the course of the appeal hearing. None were raised.

The Appeal Board did not consider that it was unacceptable for the ruling in Case AUTH/3051/6/18 to describe the material at issue in that case, including a reference to Soliris. Indeed, it was established practice for the Panel to describe the material at issue. It was unusual for information in the Panel's ruling to lead to a follow-up complaint. The Appeal Board noted that the previous case, Case AUTH/3051/6/18, concerned the alleged promotion of ALXN1210 to the public. The present case concerned ALXN1210 in relation to Clauses 3.1 and 14, and Soliris in relation to promotion to the public (Clause 26.1, 26.2 and 26.3), prescribing information and other obligatory information (Clauses 4.1, 4.4, 4.6 and 4.9) and Clause 11.1. The Appeal Board noted that whilst the material at issue, the LinkedIn post, was the same in each case, the matters raised were different. The Panel had not previously considered Clause 3.1 in relation to ALXN1210. The Appeal Board saw no reason why the matters now raised by the complainant could not, therefore, be taken up as a new complaint under Paragraphs 5.1 and 5.2 of the Constitution and Procedure. The new matters raised in the present case, Case AUTH/3163/2/19, had not been the subject of a previous adjudication. In the Appeal Board's view, and contrary to Alexion's submission at the appeal, allowing the complaint to proceed would not set a dangerous precedent to permit multiple complaints on matters already considered. It appeared to the Appeal Board that Paragraph 5.2 of the Constitution and Procedure had been complied with on this point.

The Appeal Board noted Alexion's submission in Case AUTH/3163/2/19 that the press release did not fall within the scope of the Code as, *inter alia*, the complainant had failed to provide any evidence that the LinkedIn post was received in the complainant's feed as a result of an Alexion UK employee liking it. In this regard, the Appeal Board noted the complainant's comments and Alexion's acknowledgment that a small number of its employees had liked the post. In the Appeal Board's view, given the allegations made in Case AUTH/3163/2/19, the complainant, who described themselves as a health professional, did not necessarily need to establish whether or how the posting appeared in his/her personal feed – merely that, on the balance of probability, the post was disseminated to members of the UK public and/or UK health professionals.

The Appeal Board further noted that Alexion accepted that Clause 3.1 was relevant. The Appeal Board noted its comments above about Clause 3.1 and queried why Alexion considered it was prejudicial to Alexion to deal with it in this case. The Appeal Board did not consider that Alexion had been subjected to any procedural unfairness in this regard.

The Appeal Board noted that the LinkedIn post in question was issued by Alexion Pharmaceuticals Inc., the US-based parent company. The post 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 Appeal Board noted Alexion's submission that a small number of Alexion UK employees had liked the post. The Appeal Board considered that Alexion UK employees had, on the balance of probabilities, proactively disseminated the post within the UK to an audience far wider than the intended financial community. The Appeal Board consequently considered that the LinkedIn post came within the scope of the Code. In the Appeal Board's view, the post had a promotional appearance due to its layout and wording. The Appeal Board considered that its proactive dissemination by UK employees was such that the LinkedIn post promoted ALXN1210 prior to the grant of its marketing authorization. The

Appeal Board upheld the Panel's ruling of a breach of Clause 3.1. The appeal on this point was unsuccessful. As the LinkedIn post that had promoted ALXN1210 had not been certified, the Appeal Board also upheld the Panel's ruling of a breach of Clause 14.1. The appeal on this point was unsuccessful.

The Appeal Board noted Alexion's submission that when clicking on the link in the LinkedIn post, the reader was taken to the site news.alexion.com. At the top of the page the reader was able to filter the list of the press releases by selecting his/her country. When the UK was selected from the 'Select a country' tab at the top of the page, the press release at issue could not be accessed. If the US was selected, the press release at issue was visible and this was the default view. In addition, at the bottom of the webpage, there was a statement in relation to the intended audience: 'This website is intended only for residents of the United States'. The Appeal Board noted from Alexion's submission that the statement had appeared on the website since at least 2016. The LinkedIn post made no mention of Soliris; the only mention of Soliris was in the press release which was accessed by clicking on a link in the post which took readers to a list of press releases and not directly to the press release at issue. The Appeal Board considered that the arrangements for reaching the press release and its content were sufficient to ensure that readers knew the press release was for a US audience. Consequently, the Appeal Board considered that the press release did not come within the scope of the Code. The Appeal Board therefore ruled no breach of Clauses 4.1, 4.9, 11.1, 26.1 and 26.2. The appeals on this point were successful. The Appeal Board noted that as the press release was not within the scope of the Code, it could not be ruled in breach of Clause 3.1 for promoting ALXN1210 prior to the grant of its marketing authorization.

Complaint received **20 February 2019**

Case completed **12 November 2019**