CASE AUTH/3493/3/21

COMPLAINANT v ABBVIE

Promotion of Durysta on social media

A contactable complainant provided screenshots from LinkedIn and alleged that a named employee of AbbVie Limited had promoted Durysta (sustained release bimatoprost implant) to the public. The senior UK employee had 'liked' a LinkedIn post from a US eye surgeon which stated that June 23 2020 would go down as a banner day as he/she was among the first in the US to use Durysta after Food and Drug Administration (FDA) approval. In referring to the Durysta implant, the eye surgeon stated:

> **'…This implant slowly releases a medicine in the eye to lower eye pressure and treat glaucoma without eye drops. There is no pain and there are no restrictions after implantation. These are exciting times to be an eye surgeon, and a new era for our patients with glaucoma! #durysta #glaucoma.'**

The complainant alleged that the sharing of this information by an AbbVie employee was pre-licence promotion to the public and to doctors within the named employee's connections.

The detailed response from AbbVie is given below.

The Panel noted AbbVie's submission that contrary to the allegations raised in the complaint, there was no pending application at the time of AbbVie's response for a marketing authorisation for Durysta either with the MHRA or with the EMA. In the Panel's view, the medicine was still, nonetheless, unlicensed in the UK.

The Panel noted, from the screenshot provided by the complainant, that the employee in question was a senior employee and had over 500 connections on LinkedIn. The Panel considered that his/her connections would likely include both health professionals/other relevant decision makers and members of the public.

The Panel noted that the LinkedIn post at issue included the name, indication and claims for the unlicensed medicine Durysta. The Panel considered that the employee's 'like' would have, on the balance of probabilities, proactively disseminated the post to his/her LinkedIn connections which would likely predominantly be within the UK and therefore brought the matter within the scope of the UK Code. The Panel considered that the employee's activity on LinkedIn constituted the promotion of Durysta prior to the grant of its marketing authorisation and that high standards had not been maintained; breaches of the Code were ruled.

The Panel noted AbbVie's submission that when the named employee engaged with the relevant social media content, he/she had been trained on the relevant social media policy and had been provided with the social media reference guide. The Panel noted that the social media policy stated 'Users should not use Social Media in a manner that

could be seen as endorsing statements by third parties that may be inconsistent with this Policy or may be otherwise unlawful'. There was, however, no reference in this policy, nor in the quick reference guide, to the activity of 'liking' posts on LinkedIn which might subsequently disseminate the information to one's LinkedIn connections.

The Panel noted that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2. The Panel noted its comments and rulings above, including its concerns with the lack of clear guidance in the company's social media policy at the time of the activity, the seniority of the named employee, and the clearly promotional claims about Durysta within the 'liked' post, and considered that promoting Durysta prior to the grant of its marketing authorisation had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

A contactable complainant provided screenshots from LinkedIn and alleged that a named employee of AbbVie Limited had promoted Durysta (sustained release bimatoprost implant) to the public. The senior UK employee had 'liked' a LinkedIn post from a US eye surgeon which stated that June 23 2020 would go down as a banner day as he/she was among the first in the US to use Durysta after Food and Drug Administration (FDA) approval. In referring to the Durysta implant, the eye surgeon stated:

> '…This implant slowly releases a medicine in the eye to lower eye pressure and treat glaucoma without eye drops. There is no pain and there are no restrictions after implantation. These are exciting times to be an eye surgeon, and a new era for our patients with glaucoma! #durysta #glaucoma.'

COMPLAINT

The complainant stated that he/she had seen a complaint already about the company on the PMCPA platform so would have expected everyone in the company to have learnt from this issue and understand what could be talked about.

The complainant noted that Durysta was approved in the US and that a UK licence was being applied for. In that regard, the complainant alleged that the sharing of this information by an AbbVie employee was pre-licence promotion to the public and to other doctors within the named employee's connections.

When writing to AbbVie, the Authority asked it to consider the requirements of Clauses 3.1, 9.1 and 2 of the Code.

RESPONSE

AbbVie stated that it was fully committed to strict adherence to the Code and all applicable laws and regulations. As a member of the ABPI, AbbVie was dedicated to applying high standards at all times across all areas of its business and, similarly to the PMCPA, AbbVie took any complaint seriously.

Abbvie submitted that shortly before the occurrence of the social media engagement mentioned in the complaint, on 8 May 2020, AbbVie publicly announced the acquisition of Allergan. At that time, a complex process of integrating the two global organisations was initiated [and was ongoing; details were provided].

AbbVie submitted that the individual named in the complaint was employed by Allergan when the social media activity in question took place but was functionally reporting into the AbbVie organisation and therefore AbbVie would respond to the complaint.

AbbVie noted that the complainant referred to having seen a complaint already on the PMCPA platform which it took to be a reference to Case AUTH/3291/12/19, which was about certain social media matters involving Allergan rather than AbbVie and which occurred before AbbVie's acquisition of Allergan.

AbbVie strongly rejected the complainant's suggestion/allegation that AbbVie/Allergan had not learnt from past social media cases considering that in the context of the ongoing AbbVie/Allergan integration, significant strides forward had been made in terms of the standards of social media conduct adhered to by both organisations. AbbVie strongly believed that a nine-month old 'like' on social media was historic behaviour that was not indicative of the meaningful progress that the companies and its employees had made in the meantime, and therefore, in AbbVie's view, this matter should not be further escalated.

AbbVie stated that in June 2020, when the named employee engaged with the relevant social media content, he/she had been trained on the Allergan social media policy and had been provided with the social media reference guide.

As part of the ongoing process of integrating the AbbVie and Allergan businesses, and in the context of the annual global refresher training on high standards for social media, the AbbVie corporate social media policy had been rolled-out to all employees across AbbVie and Allergan legal entities in February 2021. That, together with other local awareness measures, was aimed at ensuring that the integrating business would operate with the same standards as the AbbVie legal entity was operating in the area of social media.

AbbVie stated that upon receipt of the complaint, it investigated the timing and circumstances of the named individual's engagement with the relevant social media content and was confident that such engagement occurred around the time that the original content was initially posted (June 2020), and that there was no related activity by the same individual. The matter had been addressed with the individual and AbbVie had also not identified other activity of a similar nature on his/her social media profile which strongly suggested that this was an isolated one-off occurrence, and not evidence of a systemic issue. Therefore, AbbVie believed its policies and procedures in relation to social media were robust and up-to-date, and, as such, it denied a breach of Clause 9.1.

AbbVie confirmed that, contrary to the allegations raised in the complaint, there was currently no pending application for a marketing authorisation for Durysta, either with the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). The post that was 'liked' by the named individual included an opinion of a US health professional related to a product which was available in the US. Therefore, AbbVie believed that, when considering that the relevant social media interaction took place over nine months ago and was related to a product that had been, and remained for the foreseeable future, unavailable in the UK, this could not reasonably be considered a strategic attempt at stimulating interest from a UK audience in a prescription only medicine. AbbVie noted that past PMCPA cases reinforced the fact that mentioning the name of a product that was only available overseas was not tantamount to unlicensed promotion, for example Case AUTH/2853/6/16. As such, AbbVie denied a breach of Clause 3.1.

AbbVie stated that it took its responsibility for compliance with the Code very seriously as it continuously endeavoured to maintain these high standards in all its activities. AbbVie remained available to answer any further questions the Panel might have, but trusted that its response was sufficient for the Panel to confirm that AbbVie was not in breach of Clauses 3.1 and 9.1 in relation to social media activities and governance, and by extension, given that relatively high threshold has not been met, AbbVie was also not in breach of Clause 2.

PANEL RULING

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. The Panel noted that compliance challenges arose when the personal use of social media by pharmaceutical company employees overlapped with their professional responsibilities or the interests of the company. The Panel noted that material could be disseminated or highlighted by an individual on LinkedIn in a number of ways, 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, appearing as '[name] likes this'. In the Panel's view, activity conducted on social media that could potentially alert one's connections to the activity might be considered proactive dissemination of material. In addition, an individual's activity and associated content might appear in the individual's list of activities on his/her LinkedIn profile page which was visible to his/her connections; an individual's profile page was also potentially visible to others outside his/her network depending on the individual's security settings. Company employees should assume that such activity would, therefore, potentially be visible to both those who were health professionals or other relevant decision makers and those who were members of the public. In that regard, it was imperative that they acted with extreme caution when using all social media platforms, including LinkedIn, to discuss or highlight issues which impinged on their professional role or the commercial/research interests of their company. 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. Companies must have comprehensive and up-to-date social media policies that provide clear and unequivocal guidance on what was, and what was not, acceptable and it was extremely important that employees were trained upon them and followed them.

The Panel noted AbbVie's submission that contrary to the allegations raised in the complaint, there was no pending application at the time of AbbVie's response for a marketing authorisation for Durysta either with the MHRA or with the EMA. In the Panel's view, the medicine was still, nonetheless, unlicensed in the UK and the circumstances of this case were different to those in Case AUTH/2853/6/16 which involved a malaria vaccine for use in the Sub-Saharan African countries where malaria was highly endemic and the company in that case had submitted that use in the UK was precluded as there would be little, if any, therapeutic need.

The Panel noted that whilst it was not clear from the screenshot submitted by the complainant when the post had been 'liked' by the named employee, it noted AbbVie's submission that the post had been 'liked' at the time the original content had been posted in June 2020.

The Panel noted, from the screenshot provided by the complainant, that the employee in question was a senior employee and had over 500 connections on LinkedIn. The Panel considered that his/her connections would likely include both health professionals/other relevant decision makers and members of the public.

The Panel noted that the LinkedIn post at issue included the name, indication and claims for the unlicensed medicine Durysta. The Panel considered that the employee's 'like' would have, on the balance of probabilities, proactively disseminated the post to his/her LinkedIn connections which would likely predominantly be within the UK and therefore brought the matter within the scope of the UK Code. The Panel considered that the employee's activity on LinkedIn constituted the promotion of Durysta prior to the grant of its marketing authorisation. A breach of Clause 3.1 was ruled. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted AbbVie's submission that when the named employee engaged with the relevant social media content, he/she had been trained on the Allergan social media policy and been provided with the social media reference guide. The Panel noted that the Allergan social media policy (COMP-CORP-POL-104) was dated 15 December 2016 and stated 'Users should not use Social Media in a manner that could be seen as endorsing statements by third parties that may be inconsistent with this Policy or may be otherwise unlawful'. There was, however, no reference in this policy, nor in the quick reference guide, to the activity of 'liking' posts on LinkedIn which might subsequently disseminate the information to one's LinkedIn connections.

The Panel noted that promotion prior to the grant of a marketing authorisation was an example of an activity likely to be in breach of Clause 2. The Panel noted its comments and rulings above, including its concerns with the lack of clear guidance in the company's social media policy at the time of the activity, the seniority of the named employee, and the clearly promotional claims about Durysta within the 'liked' post, and considered that promoting Durysta prior to the grant of its marketing authorisation had brought discredit upon, and reduced confidence in, the pharmaceutical industry and, on balance, a breach of Clause 2 was ruled.

Complaint received **22 March 2021**

Case completed **10 January 2022**