CASE AUTH/3758/4/23

COMPLAINANT v ALK-ABELLÓ

Alleged promotion of Jext on Facebook and conduct of a representative

CASE SUMMARY

This case related to an ALK-Abelló representative's Facebook status which made reference to the company's prescription only medicine Jext (adrenaline tartrate) and contained a link to the Jext website.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 17.2	Representative failing to maintain a high standard of ethical conduct
Breach of Clause 26.1	Promoting a prescription only medicine to the public

This summary is not intended to be read in isolation. For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant about ALK-Abelló Ltd.

COMPLAINT

The complainant complained that a representative had posted information about a prescription only medicine on their Facebook page and had asked all of their friends to share it. This was a public post which any member of the public could access. They did not think it was legal to advertise to the public and to ask people to share the advertisement and hoped the representative was dealt with appropriately. The complainant stated the representative had posted other stuff too.

When writing to ALK-Abelló, the Authority asked it to consider the requirements of Clauses 17.2, 26.1 and 5.1 of the Code.

ALK-ABELLÓ'S RESPONSE

ALK-Abelló began by extending its deepest apologies on behalf of ALK and its UK employee [named] for the complaint received of the alleged promotion of Jext on a private Facebook post. This complaint had been reviewed with the utmost sincerity and importance, and ALK-Abelló had worked swiftly to deliver the most appropriate and compliant course of action. As members of the ABPI, ALK stated it was extremely committed to remaining compliant to the Code and

adhering to all relevant laws, regulations, and codes to safeguard both the public and the industry.

Furthermore, the named employee was very apologetic and deeply regretful of their actions. In their apology letter, the named employee stated that they could not provide any justification for creating the post and was profoundly remorseful of this. ALK-Abelló believed that this demonstrated that this single post was an error of judgement and not a deliberate unethical act.

Upon receiving the complaint on the 5 April 2023, the named employee took screenshots and then immediately deleted the Facebook post from their account. In addition, the named employee reviewed all other Facebook posts on their account for any relation to ALK and ALK products.

Furthermore, an independent review of the employee's personal Facebook was conducted on the 6 April 2023 by ALK. Results from both reviews indicated that no other Facebook posts mention ALK products and no other issues had been identified. ALK-Abelló believed that the named employee did not use Facebook as a promotional or professional tool, and the review of their profile had confirmed that they had always maintained their content as personal updates for friends and family.

ALK stated that it strove to maintain high standards of compliance within the company, and employees were required to conduct appropriate training at regular timepoints. Prior to and following the complaint received by the PMCPA, ALK had completed various actions to maintain these standards.

Please see examples below:

- ➤ The ALK Social Media Guidelines (August 2017) had been developed to ensure employees had the required training and knowledge to use social media compliantly and correctly.
- ALK had required all UK employees to read and understand the ALK Social Media Guidelines (August 2017) by the 21 April 2023 and to record that they had read and understood the document via email voting buttons. Evidence of completion of this training by UK and ROI employees was provided.
- > From the 13 March 2023 a platform was introduced to ALK to better manage all training and record keeping.
- From the 18 October 2022 all content creation, review, approvals, and archiving (in addition printed content was still wet signed and archived physically) were moved into Veeva Vault PromoMats to ensure efficiency and compliance. Evidence of completion of training was provided.
- ➤ It had always been mandatory for all ALK employees to complete the Code of Conduct Training annually.
- ➤ It was mandatory for all appropriate ALK employees to complete the Company Social Media Management Corporate SOP CSOP72130 Training.
- ➤ The UK team were asked to complete an external PMCPA Social Media update training module on the 13 March 2023 with a completion date set as the 31 May. On the 20 April 2023 it was extended to include all UK based employees (including global teams), & the ROI team. Evidence of training completion as of the 21 April 2023 was provided.

The additional steps ALK had now put in place were:

- ➤ It was now mandatory for all ALK employees to read and confirm they had understood the ALK Social Media guidelines (August 2017) annually with confirmation filed with ALK-Abelló's QA Officer.
- ➤ It was now mandatory for all ALK employees to complete and pass an external PMCPA Social Media training module annually with certificates filed with ALK-Abelló's QA Officer to ensure the company remained up to date with any PMCPA changes.

Below was the response to the referenced Clauses below:

Clauses 17.2, 26.1 and 5.1

Following the recommendation of the PMCPA, Clauses 17.2, 26.1 and 5.1 had been reviewed in context to this case.

Clause 17.2: Representatives must maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code.

ALK stated it understood and upheld the requirement for its employees to maintain a high standard of ethical conduct in their duties and comply with all requirements of the code. The named employee completed the Code of Conduct training to ensure ethical behaviour in their duties and responsibilities. A record of the completion of their training in 2017, prior to creating the Facebook post in question, and a record of their completion of training in 2018 had been provided. However, ALK acknowledged the Facebook post created by their employee, the named employee, did not comply with Clause 17.2. The post was not intended to be promotional and/or to promote ALK medicines, but it contained personal opinions alongside product details.

ALK and the named employee were regretful of these events and understood that the post should not have been made from a personal Facebook account in this format and it was not an appropriate way to raise awareness about the allergy therapy area to neither patients nor the general public. So, upon receiving the complaint, the Facebook post was immediately taken down.

Clause 26.1: Prescription only medicines must not be advertised to the public. This prohibition did not apply to vaccination and other campaigns carried out by companies and approved by the health ministers.

In accordance with the Summary of Product Characteristics (SPC), Jext 150 and 300 microgram solution for injection in pre-filled pen was a prescription only medicine licensed for use in the UK since 2010.

The Facebook post was shared with both patients and members of the public who were connected to the employee as Facebook friends. The post was neither approved by ALK nor certified for patients and members of the public before posting. In addition, the landing page linked did not include alternative information for the general public. Therefore, ALK acknowledged the Facebook post created by their employee did not comply with Clause 26.1.

According to ALK Social Media Guidelines the pathway on pages 6 & 7 clearly stated that individuals should not post content from their social media account containing a product name, especially where those contain personal comments. Additionally, the Company Social Media Management Corporate SOP CSOP72130 stated under Section 5.3: Approval of a social media post, it was the 'working group leads responsibility to assess requirement for material to be signed off by Global Medical Affairs or delegate.' The named employee believed they had read and understood the Company Social Media Management Corporate SOP CSOP721302018 when they initially received it via email on 27 February 2018. Additionally, the named employee believed they had read and understood the ALK Social Media Guidelines (August 2017) when they initially received it via email on the 23 February 2018. However, on this occasion, the guidance provided by ALK was not followed.

Clause 5.1 High standards must be maintained at all times.

ALK stated that it was deeply committed to maintaining high standards throughout the company and its employees. ALK had provided the required Code of Conduct training, the Company Social Media Management Corporate SOP CSOP721302018 training and the ALK Social Media Guidelines (August 2017) training which the named employee believed to have read and understood in 2017 and 2018 prior to making the post at issue. Upon updating the Company Social Media Management Corporate SOP CSOP72130, ALK retrained the named employee and other employees periodically in 2019 and 2021 which the named employee also believed to have read and understood at the time upon receiving. Furthermore, ALK had responded to this complaint ethically and compliantly by accepting where breaches were made, and immediately removed the Facebook post when brought to their attention.

However, ALK believed that it had failed to maintain high standards in a number of areas. Whilst the evidence of completion of the Code of Conduct training in 2017 and 2018 by the named employee had been appropriately recorded and provided. ALK had not been able to locate evidence of completion of training by the named employee for the Company Social Media Management Corporate SOP CSOP72130 and the ALK Social Media Guidelines (August 2017). ALK acknowledged that it had failed to maintain high standards by not being able to provide evidence of the completed training and were committed to ensuring that a record for all future mandatory training was completed.

ALK-Abelló stated that it had also since discovered that the Jext website landing page was not certified at the time the Facebook post was made, although it had no product claims, it had been updated and certified many times since and the company believed it should have been certified at the time.

Furthermore, a new medical signatory recently identified that the Jext website landing page did not provide alternative information for members of the public. ALK was made aware of this issue on the 21 March 2023 (prior to receiving this complaint) and immediately rectified this matter by re-certifying a new version of the landing page which included information for members of the public which was now live.

Therefore, ALK-Abelló felt that the issues stated above indicated that high standards were not maintained, and ALK accepted a breach of Clause 5.1.

As requested by the PMCPA, ALK-Abelló provided the following:

Details as to the intended audience of the Facebook post and the Jext.co.uk website.

The intended audience of the Facebook post were the employee's personal Facebook friends – these include colleagues, allergy patients and members of the public.

The intended audience of the Jext.co.uk website was:

- Healthcare Professionals
- Adult Patients (19+ years)
- Teen Patients (13-18 years)
- Kid Patients (7-12 years)

Details of whether the post is currently active and when the post was taken down.

The post was no longer active and was taken down on the 5 April 2023.

Confirmation of whether this was a personal Facebook account or a Company account.

ALK and the named employee confirmed that the post was created via a personal Facebook account. A letter of admission and apology from the named employee was also provided for review.

Details of the number and make-up of the individual's connections on Facebook (e.g., health professionals/members of the public).

The named employee had 282 Facebook connections which include personal friends, acquaintances, and relatives. Of those connections who interacted with the post in question, details of those individuals (their role and relation to the employee) had been provided.

PANEL RULING

The complaint related to an ALK-Abelló representative's Facebook status posted on 31 July 2018:

'This is where the last 6 months of my life have gone... check out the new Jext website...hands down the best patient support for AAI's [adrenaline auto injector]. Translation in 22 languages, travel abroad section, and much more... share share ESP[ecially] MY ALLERGY FRIENDS!!'.

The post concluded with a link to the Jext.co.uk website, the landing page for which had four sections: for a health professional, 'adult patient (19+)', 'teen patient (12-18)' or 'kid patient (7-11)'. The Panel noted there was no section for members of the public.

ALK-Abelló submitted that the named employee had 282 connections; their Facebook friends and individuals that reacted to the post, consisted of health professionals, patients and members of the public. Contrary to ALK-Abelló's submission that the post was private, the Panel noted that the screenshot of the post had a globe icon, indicating that the post could have been viewed by individuals that were not the named employee's Facebook friends.

In the Panel's view, the post's reference to the prescription only medicine Jext (adrenaline tartrate), along with its link to the Jext website and overtly promotional language, such as 'hands down the best patient support', meant the post could not be considered as anything other than promotion of a prescription only medicine to the public. **The Panel ruled a breach of Clause 26.1** as acknowledged by ALK-Abelló.

The Panel noted the Facebook status post had been published contrary to the company's guidance and without its prior approval or certification. The Panel considered the representative's use of Facebook to promote Jext and instruction to share the post, in particular to their Facebook friends that were allergy patients, was such that they had failed to maintain a high standard of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code; a breach of Clause 17.2 was ruled as acknowledged by ALK-Abelló.

The Panel noted ALK-Abelló's admission that it was not able to locate evidence of completion of training by the named employee for the Company Social Media Management Corporate SOP and the ALK Social Media Guidelines although the Panel noted that the company provided copies of emails dated 23 and 27 February 2018 sent to the representative prior to the post in question providing copies of the relevant SOP and Guidelines. ALK-Abelló further acknowledged that the Jext website landing page was not certified at the time the Facebook post was made and that it had no alternative information for members of the public.

The Panel took into account its rulings and ALK-Abelló's admission above, and considered ALK-Abelló had failed to maintain high standards; **a breach of Clause 5.1 was ruled**.

Complaint received 4 April 2023

Case completed 10 May 2024