

## COMPLAINANT v ALK-ABELLÓ

### Alleged promotion of Itulazax on Instagram

A contactable complainant who worked for an agency complained about advertisements for Itulazax (*Betula verrucosa*) on Instagram by ALK-Abelló Ltd and a creative agency.

Itulazax was used in certain adults for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group.

The complainant alleged that ALK-Abelló and the creative agency had breached the Code by placing advertisements for an allergy medicine on their social media (Instagram). The complainant stated that the product, claims and company were clearly readable when one paused and zoomed in and alleged a breach of the Code as it was promotion of a prescription only medicine where the general public could view.

The detailed response from ALK-Abelló is given below.

The Panel noted that a UK based creative agency posted an Instagram story on its account regarding its success at a named advertising awards competition in 2021. The 'story' included 10 frames, of which frames 3 and 4 (the material at issue) were related to Itulazax.

The Panel noted that frame 3 featured, *inter alia*, a picture of a female who appeared to be dressed as a tree with a hat made of catkins. The top right of the picture had the ALK-Abelló corporate logo and the bottom right had the Itulazax brand logo with the tagline 'Reconnect with nature'. The picture was overlaid with the headline claim 'This season's must have' beneath which was a further claim which stated, 'Finally, a new highly effective and convenient treatment option for tree pollen allergy sufferers. Just one daily SLIT-tablet can provide clinical benefits across the extended tree pollen season'. The Panel noted that frame 4 was similar to frame 3, with the same claims, but included a picture of a male in what appeared to be a suit made from tree bark and catkins.

The Panel noted ALK-Abelló's submission that the creative agency was contracted by ALK-Abelló Global marketing to develop promotional imagery in preparation of the European launch of Itulazax in 2019 and that the contract ended in 2020.

The Panel noted that the contract was between the creative agency, a UK registered company, and ALK-Abelló A/S in Denmark. The agreement was effective between 2017 and 2020 and according to ALK-Abelló was not extended.

The Panel noted that the confidentiality clause in the contract stated that the creative agency was to treat all information concerning or relating to the services and to ALK-Abelló, its affiliates or its commercial partners as strictly confidential during or

subsequent to the agreement and therefore not to disclose it to any third party or make any commercial use of it without the prior written and express consent of ALK-Abelló.

The Panel noted ALK-Abelló's submission that, unbeknown to the company, the creative agency entered the Itulazax press advertising imagery for the advertising awards; at no point leading up to the submission, or for the subsequent social media post on Instagram, did the creative agency seek any permissions or consent from ALK-Abelló. The Panel noted ALK-Abelló's submission that under the contract between the parties, any use of ALK-Abelló imagery had to be agreed before use.

In the Panel's view, although the contract between the parties had ended by the time the social media post in question was made, the creative agency was still considered a third party to ALK-Abelló in relation to the material at issue.

The Panel noted that the creative agency Instagram account had over 2000 followers, of which over 50% were based in the UK. The Panel considered that as the Instagram story was directed mainly to a UK audience, the proactive provision of the promotional material was within the scope of the ABPI Code.

The Panel considered that ALK-Abelló had been badly let down by its third-party agency which appeared to have acted contrary to the written agreement between the parties. The material was taken down promptly upon receipt of notification of the complaint.

The Panel considered that the creative agency Instagram account followers would have likely included individuals who did not meet the Code's definition of a health professional or other relevant decision makers. The 2021 Code stated that prescription only medicines must not be advertised to the public. The Panel considered that the frames of the Instagram story that referred to Itulazax, a prescription only medicine in the UK, and included claims about that medicine, meant that Itulazax had been promoted to the public and a breach of the Code was ruled which was appealed by ALK-Abelló.

The Appeal Board noted ALK-Abelló's submission that the creative agency was contracted by ALK-Abelló Global marketing to develop promotional imagery in preparation of the European launch of Itulazax in 2019 and that the contract ended in 2020. The contract stated that the creative agency was to treat all information concerning, or relating to, the services and to ALK-Abelló, its affiliates or its commercial partners as strictly confidential during, or subsequent to, the agreement and therefore not to disclose it to any third party or make any commercial use of it without the prior written and express consent of ALK-Abelló.

The Appeal Board noted that the contract stated, *inter alia*, that documents, data, disclosed confidential information and other records must be promptly returned to ALK-Abelló upon expiry or termination of the agreement. At the cessation of the contract, ALK-Abelló Global had, according to ALK-Abelló, received confirmation from the creative agency that all copies of the promotional imagery produced during the contract had been returned/deleted. ALK-Abelló's investigation following receipt of the complaint found that the creative agency had retained imagery on an old server which a junior member of the creative agency team had accessed.

**The Appeal Board accepted ALK-Abelló's submission that, unbeknown to ALK-Abelló, the creative agency had entered the Itulazax press advertising imagery into the 2021 advertising awards competition in question; at no point leading up to the submission or for the subsequent social media post on Instagram, did the creative agency seek any permissions or consent from ALK-Abelló.**

**The Appeal Board noted that the definition of promotion given in the 2021 Code included that 'Promotion' meant any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.**

**The Appeal Board considered that given the contract between ALK-Abelló and the creative agency had ended over 16 months prior to the creative agency's Instagram post at issue in this case, and that the creative agency had failed to gain consent or notify ALK-Abelló of its submission to the advertising awards or its subsequent Instagram post, the creative agency had not acted with ALK-Abelló's authority as defined in the Code.**

**The Appeal Board considered that in the particular circumstances of this case, ALK-Abelló had not promoted Itulazax to the public and no breach of the Code was ruled. The appeal on this point was successful.**

A contactable complainant who worked for an agency complained about advertisements for Itulazax (*Betula verrucosa*) on Instagram by ALK-Abelló Ltd and a creative agency.

Itulazax was used in certain adults for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group.

## **COMPLAINT**

The complainant alleged that ALK-Abelló and the creative agency had breached the Code by placing advertisements for an allergy medicine on their social media (Instagram). The complainant stated that the product, claims and company were clearly readable when one paused and zoomed in and alleged a breach of Clause 3.2 as it was promotion of a prescription only medicine where the general public could view. The complainant provided screenshots of the Instagram advertisements.

When writing to ALK-Abelló, the Authority asked it to consider the requirements of Clause 3.2 of the 2021 Code.

## **RESPONSE**

ALK-Abelló Ltd submitted that, as a member of the ABPI, it strove to fully adhere to the Code and, as such, refuted the allegation that it promoted Itulazax on Instagram contrary to Clause 3.2.

Itulazax (*Betula verrucosa*) was a sublingual immunotherapy treatment for moderate to severe allergic rhinoconjunctivitis caused by an allergy to tree pollens from the birch homologous group. Itulazax received UK marketing authorisation in June 2021 and, following the grant of the NHS List Price, was launched in September 2021.

During preparations for the European launch of Itulazax in 2019, the creative agency, was contracted in 2017 by ALK-Abelló Global Marketing to develop promotional imagery and documentation. This contract ended in 2020 and was not extended by either party.

As part of the creative agency's corporate strategy, unbeknown to ALK-Abelló, they entered the Itulazax press advertising imagery into a named advertising awards competition in 2021. These awards were entered by creative agencies across different sectors and entries were judged on creativity and design. The creative agency entered without any consent, permission or approval for the Itulazax imagery for the awards which won several categories.

The creative agency posted on Instagram on 18 November 2021 that they had won several categories and included the associated documents which included the Itulazax imagery.

At no point leading up to the submission to these advertising awards, or for the subsequent social media post on Instagram, did the creative agency seek any permissions or consent from ALK-Abelló. Further, until the PMCPA complaint was received on 19 November 2021, ALK-Abelló had absolutely no knowledge of the actions of the creative agency (separate communication to the PMCPA from the creative agency was provided).

Within the active contract between the creative agency and ALK-Abelló (2017-2020) any use of ALK-Abelló imagery had to be agreed before use to ensure the correct and proper use of all its materials aligned to the ABPI Code. An example of such communication was given from March 2020 for a previous submission for a different award competition.

ALK-Abelló submitted, therefore, that as it was not involved with the awards or subsequent Instagram posts and the creative agency was operating outside of contract, no breach of Clause 3.2 could have been made by ALK-Abelló.

In addition, ALK-Abelló stated that it was a pity that due process was not followed as this matter could have been swiftly resolved if the complainant had contacted ALK-Abelló directly without the unnecessary need to directly involve the PMCPA.

### **Response from the creative agency**

The creative agency confirmed that ALK-Abelló had no prior knowledge or involvement in the awards submission in question made by the creative agency or indeed the creative agency Instagram 'Story' post that took place on 18 November 2021 from which this complaint had arisen.

The creative agency took full responsibility for this issue and apologised to the PMCPA and ALK-Abelló for the inconvenience caused. The creative agency fully appreciated the seriousness of this issue and the importance of regulation and compliance within the industry. The creative agency was committed to complete transparency in this process and would support, in any way possible, to ensure that ALK-Abelló bore no responsibility or faced any serious consequences as a result.

The creative agency stated that it took matters like this very seriously and wanted to reassure the PMCPA that this situation would not happen again. As a result, the creative agency was auditing its internal awards submission process to ensure greater robustness and accountability in its sign-off procedures from both a client and internal agency perspective. Importantly,

adding this topic specifically to its internal compliance training. Coupled with this, the security and access rights to any ALK-Abelló work would be restricted to three executive level personnel which would prevent any work being accessed without prior approval from this senior leadership team.

In order to support the PMCPA and ALK-Abelló in response to this complaint, the creative agency provided supporting evidence as outlined below:

- A PDF of the creative agency Instagram 'Story' content in which the ALK-Abelló Itulazax advertisements were featured. The 'Story' was posted at 10.37am on Thursday, 18 November 2021 and removed immediately on notification at 14.33pm on Friday, 19 November 2021. The total 'Story' view count was 481. The 'Story' was not shared via other followers or on other social channels. The creative agency had provided the PDF content in a mobile device setting to replicate the scale that the content would have been viewed .
- The creative agency Instagram account had over 2000 followers of which over 50% were female and in 24-35 age range. Over 50% were based in the UK. The creative agency were aware that a large number of its followers were current and previous employees of the creative agency.
- The creative agency stated that its two entries were submitted by the creative agency without prior approval from ALK-Abelló. Each entry was submitted as 'closed' which prevented the work being shown on any external advertising awards competition platforms. In addition, the awards were judged by senior creative figures who were, as expected, bound by strict non-disclosure and confidentiality agreements during the judging process.
- The creative agency provided email confirmation of receipt of the awards entries in question which showed that one representative from the creative agency was included and no representative(s) included from ALK-Abelló.

Following a request for further information, ALK-Abelló provided a copy of the contract between the creative agency and ALK-Abelló A/S. ALK-Abelló submitted that the contract was for a three year period expiring in July 2020 and was not extended.

## PANEL RULING

The Panel noted that a UK-based creative agency, posted an Instagram story on its account regarding its success at a named advertising awards competition in 2021. The 'story' included 10 frames, of which frames 3 and 4 (the material at issue) were related to Itulazax.

The Panel noted that frame 3 featured, *inter alia*, a picture of a female who appeared to be dressed as a tree with a hat made of catkins. The top right of the picture had the ALK-Abelló corporate logo and the bottom right had the Itulazax brand logo with the tagline 'Reconnect with nature'. The picture was overlaid with the headline claim 'This season's must have' beneath which was a further claim which stated, 'Finally, a new highly effective and convenient treatment option for tree pollen allergy sufferers. Just one daily SLIT-tablet can provide clinical benefits across the extended tree pollen season'. The Panel noted that frame 4 was similar to frame 3, with the same claims, but included a picture of a male in what appeared to be a suit made from tree bark and catkins.

The Panel noted ALK-Abelló's submission that the creative agency was contracted by ALK-Abelló Global marketing to develop promotional imagery in preparation of the European launch of Itulazax in 2019 and that the contract ended in July 2020.

The Panel noted that the contract was between the creative agency, a UK registered company, and ALK-Abelló A/S in Denmark. The agreement was effective between 2017 and 2020. The Panel noted ALK-Abelló's submission that the contract was not extended.

The Panel noted that the confidentiality clause in the contract stated that the creative agency was to treat all information concerning or relating to the services and to ALK-Abelló, its affiliates or its commercial partners as strictly confidential during, or subsequent to, the agreement and therefore not to disclose it to any third party or make any commercial use of it without the prior written and express consent of ALK-Abelló.

The Panel noted ALK-Abelló's submission that unbeknown to them, the creative agency entered the Itulazax press advertising imagery into the advertising awards competition in question; at no point leading up to the submission to these awards, or for the subsequent social media post on Instagram, did the creative agency seek any permissions or consent from ALK-Abelló. The Panel noted ALK-Abelló's submission that under the contract between the parties, any use of ALK-Abelló imagery had to be agreed before use.

The Panel understood that creative agencies and individuals would want to be able to showcase their work and/or refer to the campaigns in which they had been involved, however, in doing so, they must ensure that prescription only medicines were not advertised to the public.

The Panel noted that it was an established principle that pharmaceutical companies were responsible for the acts and omissions of their third parties which came within the scope of the Code, even if such acts and omissions were contrary to the instructions which they had been given. Furthermore, UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. It therefore followed that ALK-Abelló UK would be responsible for any acts or omissions of ALK-Abelló A/S and/or its third parties that came within the scope of the Code.

In the Panel's view, although the contract between the parties had ended by the time the social media post in question was made, the creative agency was still considered a third party to ALK-Abelló in relation to the material at issue.

The Panel noted that the creative agency Instagram account had over 2000 followers, of which over 50% were based in the UK. The Panel considered that as the Instagram story was directed mainly to a UK audience, the proactive provision of the promotional material was within the scope of the ABPI Code.

The Panel considered that ALK-Abelló had been badly let down by its third-party agency which appeared to have acted contrary to the written agreement between the parties. The material was taken down promptly upon receipt of notification of the complaint.

The Panel considered that the creative agency Instagram account followers would have likely included individuals who did not meet the Code's definition of a health professional or other relevant decision makers. Clause 3.2 of the 2021 Code stated that prescription only medicines must not be advertised to the public. The Panel considered that the frames of the Instagram

story that referred to Itulazax, a prescription only medicine in the UK, and included claims about that medicine, meant that Itulazax had been promoted to the public and a breach of Clause 3.2 was ruled.

## **APPEAL FROM ALK-ABELLÓ**

ALK-Abelló submitted that as a member of the ABPI, it strove to fully adhere to the Code and, as such, wished to appeal the ruling of a breach of Clause 3.2.

ALK-Abelló stated that Itulazax was a sublingual immunotherapy treatment for moderate to severe allergic rhinoconjunctivitis caused by an allergy to tree pollens from the birch homologous group. Itulazax received UK marketing authorisation in June 2021 and, following the grant of the NHS List Price, was launched in September 2021.

ALK-Abelló stated that during preparations for the European launch of Itulazax in 2019, a creative agency was contracted in 2017 by ALK-Abelló Global Marketing, based in Denmark, to develop promotional imagery and documentation. This contract ended in July 2020 and was not extended by either party.

ALK-Abelló stated that in 2021, unbeknown to it, the creative agency entered a named advertising awards competition. This competition was entered by creative agencies across different sectors and entries were judged on creativity and design. The creative agency entered the competition without any instruction, consent, permission, or approval of the use of the Itulazax imagery for the awards which then won several award categories.

ALK-Abelló submitted that the creative agency, again without any knowledge by ALK-Abelló, posted on its corporate public Instagram account on 18 November 2021 that it had won several categories and included the Itulazax imagery from the awards.

ALK-Abelló submitted that at no point leading up to the submission to these awards, or for the subsequent social media post on Instagram, did the creative agency seek any permission or consent from ALK-Abelló. In addition, the creative agency did not even inform ALK-Abelló that the imagery had been submitted or Instagram posts distributed. Therefore, the creative agency acted without authority. This was confirmed by the creative agency in a letter to the Authority.

ALK-Abelló submitted that the contract between it and the creative agency ended in July 2020 and the Instagram posts were made on 18 November 2021; over 16 months after cessation of the contract. Clause 1.17 defined promotion as 'any activity undertaken by a pharmaceutical company or with its authority'. ALK-Abelló submitted that there was no supplementary information given in the 2021 Code of Practice to define the scope of 'its authority'. Further, there was no case precedent to define a statute of limitation on what was considered 'its authority' following cessation of a contract between a pharmaceutical company and a third party.

ALK-Abelló submitted that without reference to previous case precedent, it was reasonable to consider that 16 months following the ending of a contractual agreement, the creative agency was no longer acting with ALK-Abelló's authority.

Clause 3.2 stated that the advertising of prescription only medicines to the public was also prohibited by the relevant regulations relating to advertising. In this case, ALK-Abelló submitted

that a breach of Clause 3.2 was ruled by the Panel as it considered that Itulazax, a prescription only medicine, was promoted to the public. However, under Clause 1.17, as the creative agency was no longer acting with the authority of ALK-Abelló, then by definition, ALK-Abelló could not have promoted Itulazax and hence did not breach Clause 3.2.

ALK-Abelló submitted that the breach of Clause 3.2 should be overturned based on the fact that the creative agency was not acting with its authority, either implicitly or explicitly.

## **RESPONSE FROM COMPLAINANT**

The complainant had no comments on the appeal.

## **APPEAL BOARD RULING**

The Appeal Board noted ALK-Abelló's submission that the creative agency was contracted by ALK-Abelló Global marketing to develop promotional imagery in preparation of the European launch of Itulazax in 2019 and that the contract ended on 5 July 2020. The confidentiality clause in the contract stated that the creative agency was to treat all information concerning, or relating to, the services and to ALK-Abelló, its affiliates or its commercial partners as strictly confidential during, or subsequent to, the agreement and therefore not to disclose it to any third party or make any commercial use of it without the prior written and express consent of ALK-Abelló.

The Appeal Board noted that the contract stated, *inter alia*, that documents, data, disclosed confidential information and other records must be promptly returned to ALK-Abelló upon expiry or termination of the agreement. At the cessation of the contract, ALK-Abelló Global had, according to ALK-Abelló, received confirmation from the creative agency that all copies of the promotional imagery produced by the creative agency during the contract had been returned/deleted. ALK-Abelló's investigation following receipt of the complaint found that the creative agency had retained imagery on an old server which a junior member of the creative agency team had accessed.

The Appeal Board accepted ALK-Abelló's submission that, unbeknown to ALK-Abelló, the creative agency had entered the Itulazax press advertising imagery into the 2021 advertising awards competition in question; at no point leading up to the submission or for the subsequent social media post on Instagram, did the creative agency seek any permissions or consent from ALK-Abelló. The Appeal Board accepted the company's submission that when ALK-Abelló had previously been asked for permission by the creative agency to use material in relation to a different competition it had asked the agency to amend the material to be Code-compliant.

The Appeal Board noted that the definition of promotion given in Clause 1.17 of the 2021 Code included that 'Promotion' meant any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Appeal Board considered that given the contract between ALK-Abelló and the creative agency had ended over 16 months prior to the creative agency's Instagram post at issue in this case, and that the creative agency had failed to gain consent or notify ALK-Abelló of its submission to the advertising awards or its subsequent Instagram post, the creative agency had not acted with ALK-Abelló's authority as defined in Clause 1.17 of the Code.



The Appeal Board considered that in the particular circumstances of this case, ALK-Abelló had not promoted Itulazax to the public and no breach of Clause 3.2 was ruled. The appeal on this point was successful.

**Complaint received**      **18 November 2021**

**Case completed**        **16 June 2022**