Newsletter 13 January 2025

Complaint - Unfair and disloyal comparative advertising

A company had complained about another company's advertising material that included a comparison between the medicinal products based on information from the products' American SPCs - information that did not appear in the products' Danish SPCs.

The investigator panel agreed with the complainant that this was an unfair and disloyal comparison and noted, among other things:

"The complainant generally points out that the comparative advertising element is unfair, as the "potency" of the medicines is compared on the basis of BAU (Bioequivalent Allergy Unit), which is not used in the medicines' current Danish summaries of product characteristics. A number of other supporting factors are linked to this point.

In general, the respondent argues that the comparison has been made on the basis of applicable comparative documentation in the form of SmPCs for the medicinal products at the FDA and a peer-reviewed publication.

The investigator panel notes that comparative advertising for medicinal products must be based on the medicinal products' SmPCs, cf. Art. 8(2) of the Promotion Code. This implicitly means that it is based on the summaries of product characteristics that apply to medicinal products approved for the Danish market.

[…]

It is the Investigator Panel's assessment that although a regulatory authority such as the FDA considers the BAU measurement method and device to be necessary, other recognized regulatory authorities internationally, including in particular Denmark, have not currently endorsed it. The requirement for use of the method and unit by the FDA (and thus anchoring and inclusion in US SmPCs) does not mean that the method or unit can necessarily be considered to be of a supplementary or clarifying nature to the Danish summary of product characteristics, just as it does not necessarily enable comparative use or promotion thereof in marketing material in Denmark.

The investigator panel is aware that reference is made to a peer-reviewed publication that, among other things, discusses the method, the unit and lists it for a number of medicinal products in the product class in relation to their manufacturer-specific allergenicity units. The fact that a piece of information appears in a peer-reviewed article does not mean, however, that it can be used freely in a pharmaceutical advertisement, cf. the guidelines to Art. 7(1) of the Promotion Code, which states the following, among other things "The fact that a study is peer-reviewed and published in a journal that formally complies with Art. 7 (5) does not mean that the reference can be used completely uncritically. For example, if the reference contains information about conditions that contravene the SPC, the reference cannot be used even if it complies with section 7(5), as it also contravenes other provisions of the advertising rules. See also the Appeals Board's decision in AN-2017-1490".

[…]

In the specific material, the BAU unit is primarily used as a differentiating and comparative element and in a very eye-catching and emphasized manner. The unit is not presented in a factual, objective, informative and complementary manner analogous to a "factual" information, which is contrary to the criteria for factual (comparative) advertising, as the overall impression of the use appears particularly intrusive in light of the overall circumstances, cf. Art. 8 (1) and in particular the guidance to the provision, where it specifically states that "[...] The objectivity criterion in Art. 4 (2) of the Promotion Code must ensure that an advertisement always as a primary purpose contains professional, adequate and relevant information about medicines, which ENLI considers essential, especially for comparative advertisements. This is particularly important to avoid advertisements where medicinal products with possibly poorer/lower efficacy than the medicinal product being compared with are marketed on parameters that are irrelevant when the healthcare professional has to assess the therapeutic effect of the medicinal product in relation to the patient".

[…]

The investigator panel therefore notes that even if the BAU unit could be used to clarify or confirm information in the Danish SPCs, the way in which the respondent has set up the comparison to the complainant's medicine is found to be contrary to the requirement of objectivity in the circumstances and is assessed as unfair comparative advertising, see above."

A fine of DKK 60,000 was imposed on the respondent. The decision can be read in full (only in Danish) at www.enli.dk.

Complaint - Repitition of unfair and disloyal comparative advertising

The companies from the aforementioned complaint case were also involved in this complaint case, as the decision was not complied with. In addition, the case concerned the distribution of promotional material in connection with a continuing education event.

The investigator panel found in favor of the complainant and settled the case with a fine of DKK 150,000. The decision, which can be read in full (only in Danish) at www.enli.dk, states, among other things

"The investigator panel assesses that [the company] has violated Sections 8(1) and (2), cf. Sections 4(2) and 7(1) of the Promotion Code by using the promotional material assessed in KO-2024-3608 on 15 November 2024 at the annual meeting of the Danish ENT doctors' Organization (DØNHO). In a decision dated October 29, 2024, [the company] was ordered to stop using the promotional material, and [the company] was fined DKK 60,000 + VAT.

From [the company]'s consultation response of December 9, 2024, it appears that [the company] is of the opinion that the Investigator Panel's decision only comes into force from the time [the company] complies with the decision.

The Investigator Panel must note that the decision takes effect from the day the decision is made and thus has immediate effect, which is why any complaint to the Appeals Board as a starting point does not have suspensive effect, cf. Section 11(2) of the Rules of Procedure for ENLI. In special cases, the Appeals Board may grant a complaint suspensive effect if the purpose of the complaint would otherwise be wasted.

[The company] has thus repeated the violation by using advertising material on 15 November 2024 at the annual meeting of the Danish ENT doctors' organization DØNHO."

In addition to repeating the violation from the previous complaint case, this case also included the issue of handing out the material in the classroom itself.

Here, the Investigator Panel noted, among other things:
"*Based on an assessment of [complainant]'s complaint and [respondent]'s response of December 9, 2024, the Investigator Panel has found that [respondent]'s exhibition stand does not comply with the relevant rules.*

In this regard, the Investigator Panel has emphasized both parties' information that [Respondent] was in the conference room with promotional material and

distribution of promotional material took place at the entrance.

The investigator panel has in particular emphasized that [respondent] in their consultation response of 9 December 2024 admits that they are aware that their exhibition activities are in violation of Art. 18 (1) of the Promotion Code, but despite this they choose to have an exhibition stand in the classroom, as this is the only alternative offered by the congress organizer.

The investigator panel notes that advertising must be separate from the professional content of the event. An exhibition stand that is located in the classroom and where the distribution of promotional material takes place at the entrance, where participants do not have the opportunity to avoid a forced exposure of promotional material, is thus not in accordance with the rules that there must be no exhibitions in the classrooms. Promotional activities must be separate from the academic part of the event, for example in a foyer outside the classroom. Compliance with the rules is the responsibility of the pharmaceutical company - regardless of whether the congress organizer instructs the company to have their exhibition stand in the classroom.

On this basis, the investigator panel finds that [the respondent]'s exhibition activities are in violation of Art. 18 (1) of the Promotion Code."

New reporting system - "ENLIsag"

In 2024, ENLI has been working on the development of a new case management system, including a new notification system for the affiliated companies. The development work has gone very well, and therefore we are already ready for all affiliated companies to switch to the new system, ENLIsag.

On **Thursday, January 16, 2025**, all existing users of the "old" notification system will be transferred to ENLIsag with their contact information. Users will receive a welcome email with information about ENLIsag. From January 16, 2025, access to ENLIsag will be via ENLI's website (the same place you currently access the notification system). Access to the "old" system will be closed at the same time.

Please note that even though the user profile has been transferred to ENLIsag, you will need to create a new password the first time you log in. If you have not logged in before the end of March 2025, the user profile will be deleted from the system. After that, you can of course sign up again, but will then have to wait for approval from the person(s) with administrator rights in the company in question.

As mentioned in previous newsletters, ENLIsag allows you to have one or more administrators in the company who can see all colleagues' notifications of activities to ENLI, so that the company can get a complete overview. New users in the company, or consultants working for the company, can register as a user in the system and request a sign up to the company. The user will only be able to report activities for the company once the user creation has been approved by an administrator in the company.

In ENLIsag, you can create drafts so that you can start a notification and come back to it later if you need more information. In addition, it is possible to specify currency when reporting catering, and to upload larger files and multiple file formats.

ENLI will publish user guides during the transition to ENLIsag, and the secretariat is ready with help and guidance by phone and email.

Information about donations and collaborations with patient organisations

ENLI has sent out forms for affiliated companies to complete regarding reporting of donations and collaborations with patient associations.

The reporting to ENLI must be made no later than **January 23, 2025**. If the pharmaceutical company has not made donations or collaborated with patient organizations, this must also be reported to ENLI.

In the first quarter of 2025, ENLI will publish the reports in combined forms at www.enli.dk.

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