Newsletter 28 November 2025

Appeals Board

At its meeting on 25 November 2025, the Appeals Board ruled on two cases concerning claims of being "the only one" on the market with a specific mechanism of action and an image.

Claim to be "the only one" with a specific mechanism of action

The appeal arose from a complaint between two pharmaceutical companies.

The Appeals Board upheld the Investigator Panel's decision and stated in its reasoning:

"The statement in [company]'s advertisement, 'The only selective IL-23 inhibitor with dual action. [Medicine] blocks both IL-23, which drives inflammation, and binds to CD64 on immune cells that produce IL23,' is based on laboratory data (in vitro). The mechanism of action of the medicinal product is described in more detail in the summary of product characteristics. Other IL-23 inhibitors, including [A] and [B], do not claim a similar dual action, even though the summaries of product characteristics for these medicinal products also describe a mechanism of action involving both blocking and binding (dual action).

Summaries of product characteristics are drafted by the individual pharmaceutical companies (with subsequent approval by the Danish Medicines Agency or the EMA). The content of the summaries of product characteristics therefore reflects, to a not insignificant extent, the companies' own priorities and assessments of what information should be included. In light of this, and since the statement in [the company]'s advertisement is based solely on laboratory data and is not supported by human trials, the Appeals Board agrees that the differences in the product descriptions do not sufficiently document a relevant difference between the medicinal products. The advertising statement is therefore misleading and in violation of Section 4(2) of the Promotion Code, cf. Section 7(1) and (3).

The Appeals Board also agrees that the illustration in the advertisement of a tree stump with roots and the text 'IL-23' at ground level and 'CD64+' below ground illustrates the mechanism of action of [the medicinal product] without creating the impression that the medicinal product cures the disease. The illustration complies with Section 4(2) of the Promotion Code.

The pre-approval of [the company]'s advertisement was based on [the company]'s statement that the claim 'the only selective IL-23 inhibitor with dual effects' was correct. As stated in Section 6(2) of the ENLI Code of Procedure, it is the company's responsibility to provide the necessary and accurate information in connection with the approval. As information subsequently emerged that would have been relevant and significant for the processing of the pre-approval, this was no longer valid and the Investigator Panel was able to reassess the case."

The decision can be read in its entirety at www.enli.dk. (Danish only)

Use of mood picture

The appeal arose from a refusal to pre-approve advertising material, including the use of a mood image. The Appeals Board upheld the Investigator Panel's decision and stated, among other things, the following in its decision regarding the requirement for objectivity in pharmaceutical advertising:

"According to Section 4(2) of the Promotion Code, advertising for a medicinal product must be sufficiant-

ly complete and objective and must not be misleading or exaggerate the properties of the medicinal product. The requirement of objectivity means, among other things, that advertisements for medicinal products must provide objective, relevant information about the nature, effect and appearance of the product in order to ensure the correct use of the medicinal product. This general requirement applies to both text and illustrations in the advertisement.

In other words, advertisements for medicinal products must be characterised by a certain sobriety without the use of the consumption-stimulating effects known from advertisements for ordinary consumer goods. Advertisements with evocative illustrations and colour schemes do not meet the requirement of objectivity in Section 4(2) of the Promotion Code."

As the case arose from a request for a pre-approval, the decision will not be published on ENLI's website.

Revised fees and fine levels in 2026

The steering committee has decided to change both the level of fines and fees from 1 January 2026.

Fees applicable from 1 January 2026

- Notification fee: DKK 575 + VAT per notification
- Fee for pre-assessment of advertising material: DKK 10.000 + VAT
- Fee for pre-assessment of events and other activities: DKK 8.000 kr. + VAT
- Fee for supplementary pre-assessment: DKK 3.000 + VAT
- Annual fee for affiliated conpanies: DKK 23.500 kr. + VAT

The steering committee has decided that fees will be adjusted at the end of each year in line with the price index (net price index). Amounts will be rounded to the nearest whole number.

Level of fines as of 1 January 2026

The steering committee has decided to adjust the level of fines for cases reported to ENLI after 1 January 2026. Thus, from 2026, the minimum level will be DKK 45,000 +VAT and the maximum level DKK 200,000 +VAT, with a ceiling of DKK 400,000 +VAT for repeating infringements.

New advertising material after adding handwritten notes

The Investigator Panel has assessed a complaint concerning advertising material to which handwritten notes had been added by the company's pharmaceutical consultant when it was handed to the doctor during a meeting.

The promotional material had been reported to ENLI in its original form, but as the promotional material had subsequently been changed and thus appeared with altered information and a different overall impression, the Investigator Panel assessed that the revised material was subject to reporting requirements.

The handwritten addition consisted of information about the medicine's subsidy, which is factual information about the medicine that can be disclosed in a secondary, objective and neutral manner in a medicine advertisement. The question was whether this was the case.

In its decision, the Investigator Panel stated that *"Section 5.3 of the Danish Medicines Agency's guidelines states that the summary of product characteristics is considered the basic documentation for the properties of a medicinal product. However, other documentation may be used if it meets the requirements for this. Sources that do not meet the documentation requirements in section 7(5) of the Promotion Code may not be used to document the properties of the medicinal product, including its efficacy and safety profile. Such sources may therefore only be used to provide factual information about the medicinal product.*

If factual information is given such prominence in advertising material that it appears as a highlighted element in the advertisement and constitutes a claim about the medicinal product, this may constitute a violation of Section 7(5) of the Promotion Code (5), as information about, for example, the medicinal product's subsidy status will not be included a source that meets the reference requirements in section 7(5).

In addition, it may constitute inappropriate advertising, which may contravene section 4(2) of the Promotion Code.

The Investigator Panel agrees with the complainant's argument that the 'OBS' notation in the thought bubble written in ballpoint pen in a conspicuous place at the top and beginning of the material causes it to stand out in relation to the overall graphic expression of the material and its other content.

Conversely, however, the Investigator Panel also agrees with the respondent's arguments that factual information about subsidies is added, which does not significantly alter the overall message of the advertisement, which otherwise deals exclusively with the recently approved extended use and related information and data.

However, the Investigator Panel assesses that the information is so significant and important in the communication between the pharmaceutical representative and the doctor that the information is not only kept to the verbal dialogue, but is also included on the material, not by the recipient healthcare professional, but by the pharmaceutical representative on the front page in a prominent position and with graphic nuance.

After an overall assessment, this circumstance appears to be prominently and conspicuously emphasised, whereby the handwritten notes appear to be promotional, and the note takes on the character of a central promotional advertising statement. This is considered to constitute a violation of Section 7(5) of the Promotion Code, cf. Section 4(2). The complaint is thus upheld with regard to the complaint about lack of objectivity and neutrality concerning factual information."

The decision can be read in its entirety at www.enli.dk. (Danish only)

Notification of sponsorships

The Secretariat notes that some continue to report sponsorships at a very early stage, without all relevant information being available.

Following the change to the deadline for reporting sponsorships in April 2025, this will no longer be necessary, as reports must be submitted no later than 10 days prior to the start of the event.

Pharmaceutical companies must therefore only report the sponsorship to ENLI once all relevant information needed to assess the case is available, cf. section 21(4) of the Promotion Code.

Revised guides and guidelines

ENLI has published its guide to the People's Meeting (Folkemødet), now also available in English.

ENLI has also revised the guidelines for the Donation Code, both in Danish and English.

All guides and guidelines can be found at www.enli.dk/EN.

Opening hours during Christmas and New Year

ENLI is open for telephone calls and emails up to and including December 19, 2025. ENLI is closed for inquiries from December 20, 2025 up to and including January 4, 2026.

ENLI will answer phones and emails again from January 5, 2026.

For consultations over Christmas, it is possible to extend the consultation deadline to ENLI if this is needed due to the holidays. The secretariat can be contacted by phone or email before December 19, 2025, if there is a need for an extension of the consultation deadline.

For a large number of requests for pre-approval, there may be a need to postpone the case processing deadline, cf. Section 6, paragraph 5, in fine, according to which ENLI may in special cases extend the case processing deadline beyond the 10 working days, for example in connection with summer and Christmas holidays.

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