

Newsletter 27 June 2025

Appeals Board

In April and June, the Appeals Board ruled on two cases concerning professionalism and banner advertising, respectively.

The criterion of professionalism

In April, the Appeals Board ruled on a case concerning the professional criteria in Section 13(1) of the Promotion Code. The case concerned the question of whether Section 13(1) of the Promotion Code provides a legal basis for a pharmaceutical company to offer healthcare professionals training in legal aspects within a specific healthcare field.

The Appeals Board upheld the investigator panel's decision on the violation and noted the following:

"It appears from Section 13(1) of the Promotion Code that pharmaceutical companies may provide or offer healthcare professionals professional information and training in the form of payment of the direct costs of professionally relevant courses, conferences, continuing education and similar events in which healthcare professionals participate or which they organise, provided that these activities include information about medicinal products or other professional information that is professionally relevant to the participants. According to established practice, this is interpreted to mean that events must have specific health-related content and a continuing education purpose for healthcare professionals, e.g. through professional presentations on diseases, disease areas, products and treatment methods. The Appeals Board has previously made a certain limited extension of the concept of professionalism to also include information and education on more general health policy and health economics issues, provided that the focus remains on treatment within a disease area with the aim of ensuring the best possible medical treatment for patients.

As the event [...] mainly comprises presentations concerning the legal framework for assisted reproduction, the requirement for professionalism in Section 13

(1) of the Promotion Code is not sufficiently met. The Appeals Board does not find that there is currently any basis for further expanding the concept of professionalism in Section 13(1) of the Promotion Code."

Banner advertisement

In June, the Appeals Board ruled on a case concerning the compliance of a banner advertisement with the Promotion Code.

The Appeals Board upheld the decision of the Investigator Panel and noted, among other things, the following:

"Advertisements aimed exclusively at healthcare professionals may be limited to the name and generic name of the medicinal product, cf. Section 12 of the Promotion Order and Section 6 of the Promotion Code. If other information is included, the advertisement falls outside the scope of the provision. However, the company name, address and logo identifying the sender of the advertisement may be included, cf. the Guidelines to the Advertising Order, section 5.2. If, as in [the company's] banner advertisement, a logo is included in the advertisement and the logo indicates the use of the medicinal product ('capsules') and the disease area ('oncology'), the general advertising rules apply, meaning that the indication for the medicinal product and all mandatory information must be

included, cf. Section 5(1)(3) and Section 6 of the Promotion Code Guidelines. Advertisements for medicinal products aimed at healthcare professionals must contain a number of mandatory information items as specified in Section 5 of the Promotion Code. According to paragraph 2 of the provision, this information must be presented so clearly that the natural target group for the advertisement can easily read it. In the case of electronic advertisements such as banner ads, it is acceptable that the text containing mandatory information can be found via a direct link from the advertisement stating that the compulsory information can be found here, cf. the Guidelines to the Promotion Code, section 5(2). [The company] has submitted email correspondence with Dagens Medicin documenting that [the company] had a clear intention that a link to the mandatory information for the medicinal product should be established via Dagens Medicin. The email correspondence shows that Dagens Medicin is responsible for the technical solution in this regard.

However, [the company] has not documented that the banner advertisements will contain a clear reference to the mandatory information. As [the company's] advertisement does not contain the required indication for the medicinal product or a relevant reference to the mandatory information, the advertisement is in violation of Section 5 of the Promotion Code."

Both decisions can be found at www.enli.dk.

Interpretation contribution to rule changes from April 2025

ENLI has received interpretative contributions from Lif regarding some of the rule changes from April 2025. This concerns Section 13(8) of the Promotion Code regarding catering abroad and the rule changes in the Patient Organisation Code.

The guidance on Section 13(8) of the Promotion Code is supplemented by a clarification that the two-hour rule continues to apply to meetings held abroad, with the addition that for meetings lasting less than two hours, catering may be offered up to a maximum of DKK 100. converted to the relevant currency.

The interpretation contribution to the rule changes in the Patient Organisation Code concerns when something is not considered significant in relation to whether the requirements for written agreements and publication must be complied with.

The interpretation contribution thus states that:

"In general, direct meetings between pharmaceutical companies and patient associations will be considered to represent insignificant non-financial value and will therefore not be subject to the requirements for written agreement and disclosure.

However, this presupposes that the company does not incur expenses in connection with the meeting that represent a genuine value for the patient association – for example,

- ♦ *a fee has been paid to an external speaker at the meeting,*
- ♦ *the company has paid fees to an external agency/consultant,*
- ♦ *the company provides health-related/educational material to the patient organisation, which the company has paid for and which represents a significant value,*
- ♦ *the company incurs expenses for an external meeting venue that represent a significant value and/or*
- ♦ *the company pays for catering (lunch/dinner) that are of significant value.*

It should be noted that direct meetings may well be an integral part of an overall collaborative project which, taken as a whole, constitutes value and is therefore covered by the requirements, but where the requirement may be met by the meeting being covered by an overall written agreement/disclosure.

Similarly, invitations from the company to patient organisations to participate in events on, for example, a health policy topic, and where other stakeholders participate (this may be conferences, debate events, round-table meetings, etc.) will also generally be considered to represent an insignificant non-financial value. However, this presupposes that there is no agreement/requirement/expressed expectation that the patient organisation must actively contribute before, during or after the event – and that the event is not otherwise an integral part of an overall collaboration project with the company.

However, the company should bear in mind that if there are only a few, exclusively invited participants at the event (e.g. 10 people at a closed round table meeting), this presupposes that the company does not incur any expenses in connection with the event (as mentioned above under the five bullet points) that represent a genuine value for the patient association."

As already mentioned in the guidelines for Section 6, there are no requirements for how a written agreement must be formulated, which means that the parties themselves decide whether the agreement should be formulated as an actual document or 'merely' an e-mail, e.g. confirming a verbal agreement or similar.

The interpretation contribution will be implemented in the guidelines for the Promotion Code and the Patient Organisation Code, respectively, as well as in the People's Meeting Guide, which will be published on www.enli.dk within the next few weeks.

Reporting of sponsorships

In connection with the change to the deadline for reporting sponsorships (where sponsorships must now be reported 10 working days prior to the start of the event), ENLI has received questions about whether a sponsorship must still be reported to ENLI if it turns out (before the notification deadline) that the company will not be sponsoring anyone after all, e.g. because no one is being sent to an international congress.

As stated in the guidelines for the Promotion Code, sponsorship must first be notified when all relevant information for assessing the case is available, cf. Section 21(4) of the Promotion Code, and no later than 10 working days before the event starts, cf. Section 21(5).

Every time sponsorship is offered to a healthcare professional or for the organisation of continuing education for healthcare professionals, it must be reported to ENLI, regardless of whether the sponsorship is ultimately realised, as the company has had the intention to sponsor and has also offered the sponsorship,

including the terms and conditions of the sponsorship. Based on the agreements with the five regions, ENLI assumes that the regions also expect ENLI to monitor and enforce the rules for the continuing education offers that pharmaceutical companies send to the regions, regardless of whether the sponsorship is realised or not.

Summer holidays and case processing

During consultations over the summer, it is possible to extend the consultation deadline to ENLI if necessary due to holidays. The secretariat can be contacted by telephone or email if there is a need to postpone the consultation deadline.

In the event of a large number of requests for preliminary assessment, it may be necessary to postpone the case processing deadline, cf. ENLI's case processing rules, section 6(5), in fine, according to which ENLI may, in special cases, extend the case processing deadline beyond the 10 working days, e.g. in connection with summer and Christmas holidays.

ENLI's secretariat will remain open throughout the summer for both telephone enquiries and emails, although staffing levels will be reduced in weeks 28-30.

ENLI wishes everyone a great summer.

—o0o—