

Newsletter 31 March 2025

Change of rules in the Promotion Code and the Patient Organisation Code

At a meeting in March 2025, based on a recommendation for a rule change from Lif, the steering committee changed the Promotion Code and the Patient Organization Code, respectively.

The changes are as follows:

- ◆ Art. 13 (7) and (8) of the Promotion Code have been amended to allow for a 'light' meal allowance of DKK 100 for shorter professional meetings (up to two hours - e.g. pharmaceutical sales reps visits).
- ◆ Art. 13 (10) of the Promotion Code has been amended so that the rule is clarified in order to support a balanced and flexible practice that takes into account both reputational considerations and the specific circumstances of the venue.
- ◆ Articles 6 and 7 of the Patient Organisation Code have been amended so that it is no longer all types of contacts with patient organizations that are covered by the requirement that a written contract must be drawn up and published.
- ◆ Art. 21(5) of the Promotion Code has been amended so that notification of sponsorships (both to HCP and to organizers) must be made no later than 10 working days prior to the opening day of the event.

The changes will enter into effect from April 1, 2025.

ENLI has adapted guidelines and made consequential changes in derived guides etc. In addition, guidelines etc. have been reviewed and updated in relation to new practice in the recent period. Both amended codes, guidelines and guides are now available on the website in both Danish and English versions.

The following codes, guidance, guides, etc. have changed:

- ◆ Promotion Code and its guidance
- ◆ Patient Organisation Code and its guidance
- ◆ Guide on financial support
- ◆ Guide about Folkemødet (only in Danish at the moment)
- ◆ Guide on reporting activities to ENLI
- ◆ Checklists for own events and sponsorships
- ◆ Overview slides regarding the Promotion Code
- ◆ Intro guide to ENLI
- ◆ Penalties and fee regulations for examples of meals under two hours

Annual report 2024

ENLI published its annual report on March 27, 2025, which can be found at www.enli.dk.

The number of cases where a violation has resulted in a fine remains low. In 2024, pharmaceutical companies reported 4,713 activities to ENLI, and random checks were carried out in approximately 40% of all reported activities. Of these, 13 cases ended with a fine and 13 cases ended with a reprimand. The number of reprimands is mostly administrative reprimands (late notification, missing documents, etc.).

In addition, ENLI processed two complaints in 2024, both of which ended with fines. Thus, 15 fines were issued in 2024 compared to 25 in 2023.

Information about donations and collaborations with patient organizations

ENLI has received reports from the affiliated companies about their donations to hospitals and collaborations with patient associations. These are now published in a single version on www.enli.dk.

Appeals Board

As of April 1, 2025, there will be changes in the Appeals Board, as Lars Almbloom has chosen to step down after 14 years on the board.

The Board of Appeal consists of three people; a lawyer as chairman (Strange Beck), a doctor with clinical pharmacological knowledge (Sisse Rye Ostrowski), and a member who has previously worked in the pharmaceutical industry. The steering committee has discussed candidates for the latter position, and Ghita Astrup has been chosen.

Ghita Astrup has many years of experience from the pharmaceutical industry, including as CEO and regional director of Takeda A/S. Ghita has also held positions of trust as Vice Chairman of the Board of Directors of the Danish Pharmaceutical Industry Association (Lif), Chairman of the Board of Directors of Danish Medicines Information (DLI) and board member of Dansk Erhverv.

Together with Strange Beck and Sisse Rye Ostrowski, Ghita Astrup has been appointed to the Appeals Board for a two-year period.

Private homes as a meeting venue

ENLI has decided in a case about a meeting venue.

Section 13(3) of the Promotion Code states that all promotional, scientific or professional meetings, congresses, etc. organized or sponsored by, or on behalf of, a pharmaceutical company must take place at a venue that is appropriate in relation to the main purpose of the activity.

In the case in question, the pharmaceutical company had invited to a continuing education meeting in a rental home via Airbnb belonging to a healthcare professional who helped organize the meeting. This was

based on the participants' request for a meeting place, and the pharmaceutical company did not have to pay for the meeting place.

In the decision, the Investigator Panel stated that *“holding professional events in private homes does not reflect that professionalism and ethics are paramount, as the purpose of the Promotion Code's rules are intended to ensure, cf. Art. 1.1 of the Promotion Code. In general reputation, it must be considered to send a signal of family and/or friendly relations if you meet in a private setting, and thus not a signal of a professional relationship. Such a signal reduces the professional credibility of the events and, in the opinion of the Investigator Panel, could risk reducing trust in the pharmaceutical industry.”*

The decision can be read in full at www.enli.dk.

Contacting hospital employed physicians

ENLI has received an inquiry from a hospital department in the Region Midtjylland, as the department experiences that there is a tendency for some pharmaceutical companies to either make agreements directly with employees, who then ask the department management to “keep an eye out for an invitation”, or the company seeks participants so narrowly that very few employees can actually participate.

The regional agreements are concluded between Lif and the five regions, but apply to all companies affiliated with ENLI and are enforced by ENLI.

ENLI would like to refer to the common principles in the agreement with the Region Midtjylland, which states, among other things, that pharmaceutical companies *“may state in the invitation whether continuing education events are targeted at employees with special authorities, specialties or subspecialties. It must not be the case that the professional training event is targeted at specific individuals, either directly or indirectly. In exceptional cases, the pharmaceutical company may decline the management's choice of participant if this is justified by applicable legislation, company- or industry-specific compliance or impartiality rules, or by the person's lack of relevance in relation to the training event offered.”*

Therefore, the FAQ for the agreement also recommends that companies do not become too narrow in their targeting so that the invitation can be perceived as person-specific.

Reportingsystem - "ENLIsag"

In January, all companies affiliated with ENLI transitioned to the new notification system, ENLIsag.

The transition has gone well and based on inquiries from pharmaceutical companies, a few things have been adjusted.

In previous years, ENLI has been contacted by some pharmaceutical companies requesting information about the number of notifications including PO number in a given quarter or year.

With the new system, the companies' administrators in ENLIsag can now get an overview of this themselves, as they have access to see all reported cases from the company in a given period. You can also search specifically for a given PO number to see how many activities have been reported under it.

Easter

ENLI is available on the phones and for emails up to and including Wednesday, April 16, 2025. ENLI will be closed for inquiries from April 17 up to and including Monday, April 21, 2025.

ENLI will answer phones and emails again from April 22, 2025.

For consultations over Easter, it is possible to extend the consultation deadline to ENLI if there is a need for this due to holidays. The secretariat can be contacted by email or phone before April 16, 2025, if there is a need for an extension of the consultation deadline.

For a large number of requests for pre-assessment, 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.

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