

# Newsletter 8 December 2023

## Fee increases

At a meeting on 24 October 2023, the ENLI steering committee decided to increase the notification fee.

ENLI is a user-financed self-regulatory organisation with a focus on preventing violations of ethical codes of conduct. At the same time as prices in society in general are rising, the costs of running ENLI are also increasing. In addition, there is a decrease in the number of pre-assessments.

Based on the above, the Steering Committee has decided that the price of reporting activities to ENLI as of 1 January 2024 will increase to DKK 475 + VAT per notification.

The changes are made in ENLI's Sanction and Fee Regulations with effect for notified activities from 1 January 2024.

## Anonymous complaints and press enquiries

The year was characterised by an increased number of inquiries from the press and anonymous complaints regarding issues that were relevant for the Investigator Panel to look into.

### *Anonymous complaint - catering for a hospital event*

The Investigator Panel received an anonymous complaint about two different pharmaceutical companies that had provided lunch and dinner for an event at a hospital without sponsoring other activities in connection with the event.

Both companies were of the opinion that they were on a pharmaceutical sales-rep visit and had therefore brought catering.

Both companies therefore offered catering in the form of lunch and dinner in connection with a sales

representative visit where the professional content lasted less than two hours.

It should be noted that the hospital's event from 12:00 to 18:00 did not affect the assessment of the duration of the professional content, as it was only the companies' own event, i.e. the pharmaceutical representative visit itself, that had to fulfil the condition of two hours of professional content. The hospital meeting could only be included in the assessment if the companies had been involved in the meeting as either sponsor or co-organiser.

### *Enquiries from the press*

During the year, the Investigator Panel has received a number of enquiries from the press regarding possible violations of the codes that fall under ENLI's competence.

One of the cases concerned a collaboration with a patient organisation. The media had listed a number

of issues that could be problematic. However, after consultation with the pharmaceutical company, it was clear that the conditions were in accordance with the Patient Organisation Code. However, a meeting (workshop) had not been reported, where the company had contributed with knowledge. The company had only reported the financial benefit it had given the patient organisation.

The case was appealed, and the Appeals Board stated in this connection, among other things:

*"The consideration of transparency is of central importance for pharmaceutical companies' cooperation with patient organisations. The Appeals Board therefore sees no reason to change the previous restrictive practice, according to which there is no de minimis limit for the obligation to report non-financial support to patient organisations, cf. section 6(8) of the Patient Organisation Code, cf. section 7(3) and the Guide to the Patient Organisation Code regarding section 6.*

...  
*Against the above background, the Appeals Board does not find that [the company's] service in the form of referral to publicly accessible websites known to the patient organisation is in the nature of "support" that must be reported, cf. Section 6(8), cf. Section 7(3), of the Patient Organisation Code. On the other hand, [the company] has been obliged to report the company's participation in the workshop with [the patient organisation] and [agency], cf. Section 7(3) of the Patient Organisation Code, according to which pharmaceutical companies must submit an annual overview to ENLI of their collaborative projects in the past year. Section 2(5) of the Patient Organisation Code defines "collaboration" as "any form of contact between pharmaceutical companies and one or more organisations." In accordance with the rules, [the company] has reported the financial collaboration in the form of the sponsorship of DKK 500,000, but participation in the workshop goes beyond the financial support and should therefore have been reported separately.*

*The decision does not imply any change compared to previous practice in the area."*

Another case involved a company handing out a trophy to a minister in connection with an event at Folke-

mødet.

Section 15 of the Lobbying Code states that a pharmaceutical company may not in any way offer or give gifts to decision-makers.

In this specific case, the Investigator Panel considered the presentation of a trophy to be a gift in relation to section 15 of the Lobbying Code. The Investigator Panel noted that in addition to having a symbolic value, the trophy also constituted a financial value in itself.

The decisions are published on [www.enli.dk](http://www.enli.dk).

### **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 organisations.

The reporting to ENLI must be made no later than 25 January 2024. In the first quarter of 2024, ENLI will publish the reports in complete forms at [www.enli.dk](http://www.enli.dk).

If the pharmaceutical company has not made donations or collaborated with patient organisations, this must also be reported to ENLI.

### **Updated guides on congresses and financial sponsorship**

ENLI has updated its guides on international congresses and the guide for external partners on financial sponsorship - both the Danish and English versions. There are editorial changes and the addition of a few sections and questions.

The updated guides are available at [www.enli.dk](http://www.enli.dk) in both the Danish and English versions.

### **People's Meeting - guide (Folkemødet)**

As previously mentioned in a newsletter, ENLI receives a number of questions every spring in connection with pharmaceutical companies' planning of events at Folkemødet in June. These usually concern when the event is covered by, for example, the Promotion Code, the Patient Organisation Code or the Lobbying Code.

At the request of companies, ENLI will prepare a guide with Q&As specifically for Folkemødet. In this connection, ENLI encourages pharmaceutical companies to submit questions that they want addressed in the guide. Questions can be sent to: [sekretariat@enli.dk](mailto:sekretariat@enli.dk).

### **New guide on providing information material and medical equipment**

ENLI is in the process of preparing a new guide on information material and medical equipment that can be provided under Section 14 of the Promotion Code. The guide is structured in the same way as ENLI's other guides, with a Q&A section.

The guide will be available at [www.enli.dk](http://www.enli.dk) before Christmas in a Danish version and will be published in an English version during 2024.

### **Newsletter - also in English in 2024**

ENLI has decided that newsletters from 2024 will also be sent out in an English version, so that non-Danish-speaking employees in pharmaceutical companies can also stay informed about new cases etc.

### **Kilometre reimbursement**

ENLI has recently received questions about sponsorship contracts that include sponsorship of transport in own car, where it appears that the transport is covered according to the state tariffs.

In this connection, it should be noted that reimbursement according to the state tariffs would not be in accordance with Section 13 of the Promotion Code, according to which certain direct expenses can be covered by pharmaceutical companies.

Only expenses actually incurred can be reimbursed (on account). When travelling in your own car, ferry and bridge expenses can be covered on account. As only direct expenses are covered, kilometres driven in your own car cannot be reimbursed according to government rates. The pharmaceutical company can only cover the healthcare professional's direct expenses. See further details in the guidance to Art. 13(7) of the Promotion Code.

### **Opening hours for Christmas and New Year**

ENLI will be open on the phones and for emails up to and including 20 December 2023. ENLI will be closed for enquiries from 21 December 2023 and until after the New Year.

ENLI will answer phones and emails again from 2 January 2023.

For consultations over Christmas, it is possible to extend the consultation deadline for ENLI if needed due to holidays. The secretariat can be contacted by phone or email before 21 December 2023 if an extension of the consultation deadline is needed.

In the event of a large number of requests for prior assessment, it may be necessary 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, e.g. in connection with summer and Christmas holidays.

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