

Newsletter 26 June 2023

Updated pre-launch guide

ENLI has updated its guide on Pre-launch - both the Danish and English versions. These are editorial changes and the addition of questions about:

- ◆ a new treatment (new mechanism of action) in progress, where the company has obtained a favourable opinion and an approval by the EU Commission questions, and
- ◆ continuing education event that is solely related to disease/health.

The updated guide is available at www.enli.dk in both the Danish and English versions.

Folkemøde - guide (People's Meeting)

Every spring, ENLI receives a number of questions in connection with pharmaceutical companies' planning of events at Folkemødet in June. They 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 before next spring. 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.

Michelin-starred restaurants

In connection with continuing education events, pharmaceutical companies can offer, for example, dinner when the professional event lasts a minimum of 2 hours. Some companies choose to hold the continuing education meeting in restaurants that have relevant meeting facilities where you can go straight to dinner after the meeting.

According to Art. 13(10) of the Promotion Code, you may not hold (neither continuing education nor sub-

sequent dinner) at a place that is known for its entertainment facilities, is extravagant and/or luxurious. The Appeals Board has previously considered when, for example, a restaurant can be considered luxurious/extravagant.

Here, the Appeals Board mentioned that it would be luxurious/extravagant to use "gourmet restaurants (understood as restaurants awarded one or more stars in the Michelin Guide or equivalent recognition in comparable independent quality ratings)".

For your information, the Michelin Guide recently awarded stars to restaurants in Denmark, and in this connection, Restaurant Domæne near Gødstrup Hospital was awarded a Michelin star.

Compliance is a mindset

The vast majority of organisations have expanded compliance as a company-wide mindset, but some companies still have compliance as a function for one



or two employees. Of course, it's useful for the company to have someone who knows the compliance rules and can guide the rest of the organisation, but it can also be vulnerable when an experienced compliance employee leaves the company.

ENLI's secretariat is ready to provide guidance every day by phone and email, and through this can see when companies change their compliance staff functions. For some organisations, a high level of compliance is directly related to the person who held the position. The secretariat therefore sees an increasing number of enquiries if an important employee leaves. And that's what the secretariat's guidance is for. The problem arises, for example, if (new) employees are not aware of the possibility of guidance from ENLI or are not properly familiarised with the rules. This can lead to some unfortunate cases if you are not familiar with the practice and rules.

So please use the secretariat for guidance - and make sure that (new) employees are familiar with ENLI's rules and practices. You can also use checklists and guides from ENLI's website.

Checklists

ENLI occasionally finds that the notification of cases can be deficient when it comes to documentation and consideration of individual points, or that, for example, new staff are not familiar with long-standing practices.

To help companies, including new employees, with a better procedure and consideration of activities' compliance with the rules, ENLI has checklists on the website in clear form, so that companies can ensure that they have been through relevant and essential considerations when assessing a given activity.

The checklists have recently been translated into English and the Danish version has been revised with few editorial changes. The checklists are available in both Danish and English at www.enli.dk.

References must be uploaded with the notification

It appears from Art. 21(4) of the Promotion Code that

pharmaceutical companies are obliged to make an online notification of advertising activities at www.enli.dk. In this connection, the company is obliged to ensure that the notification is fully informed and that all relevant attachments have been submitted.

Therefore, remember that all relevant references mentioned in the advertising material must be uploaded as attachments to the notification, so that the Investigator Panel has the opportunity to check references in the event of a random control.

Summer holidays and case management

For consultations over the summer, it is possible to extend the consultation deadline for ENLI if this is needed due to holidays. The secretariat can be contacted by phone or email if there is a need to extend the consultation deadline.

In the case of a large number of requests for pre-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, for example in connection with summer and Christmas holidays.

ENLI's secretariat is open throughout the summer for both telephone enquiries and emails, but with staffing at a low level in weeks 28-30.

ENLI wishes everyone a good summer.

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