

Newsletter 23 September 2024

Revised guides

ENLI has today published a revised guide to the Promotion Code and revised guides on documentation and market research respectively. All three revised guides can be found at www.enli.dk in both Danish and English versions.

Changes to the Guide to the Promotion Code

- ◆ Editorial changes of a linguistic nature and the addition of new case references in relevant places.
- ◆ Clarification of the exemption provision on necessary specific information or documentation that serves safety and non-promotional purposes (section 2(2)(c)(3))
- ◆ Clarification of the placement of references (§ 7(3))
- ◆ Clarification of comparative advertising with medicinal products not approved for sale in Denmark. In addition, clarification of comparison on factual conditions regarding reimbursement status, as well as clarification to include clinically significant endpoints in comparative advertising. Furthermore, clarification that package leaflets cannot be used as documentation in comparative advertising. (§ 8, paragraph 1)
- ◆ Clarification of sponsorship to healthcare professionals where the financial benefit is given to the healthcare professional's business (section 12(1))
- ◆ Clarification regarding mileage reimbursement - possibility of "ENLI rates" (section 13(7))
- ◆ Clarification regarding unethical methods for obtaining a meeting with a healthcare professional (section 20(1)(g))

Changes to the guide on information material and documentation

- ◆ Editorial changes of a linguistic nature and the addition of new case references in relevant places.

- ◆ Addition of section under point 6.5, regarding health economic analyses
- ◆ Clarification of response to Q2 under point 9
- ◆ Clarification of answer to Q4 under point 9 (regarding when a study can be said to confirm or clarify information in SPC)

Changes to the market research guide

- ◆ Editorial changes of a linguistic nature and revision of legal references etc.

Binding commitments for sponsorships must be stated in the notification to ENLI

In a number of cases selected for random control, ENLI has found that there is a lack of documentation for when the company made a sponsorship commitment.

The date of commitment can be documented in the notification by either stating the date the company sent the contract or by a similar email.

It should be noted that the deadline for notification to ENLI is calculated from the company's submission of a binding commitment, i.e. when the company has sent an invitation to a hospital with a commitment to sponsor x number of healthcare professionals' participation in an international congress or similar.

ENLI to get a new case management system

ENLI is in the process - together with an external supplier - of developing a new and customized system for both the companies' notification of activities to ENLI and ENLI's case processing.

New features for pharmaceutical companies include the possibility of having an administrator in the company who can see all colleagues' notifications of activities to ENLI, so that the company can get a complete overview.

It will also be possible to create drafts so that you can start a report and come back to it later if you need more information.

In addition, it will be possible to specify currency when reviewing catering, as well as upload larger files and more file formats.

The new system is planned to be ready in early 2025. The system will be tested by both ENLI and external users before 2025. ENLI will continuously inform about the upcoming system.

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