

Newsletter 12 November 2024

Fees and fine levels in 2025

ENLI is a user-financed board that is primarily funded through the fees that pharmaceutical companies pay for notifying their activities, requesting pre-approvals, etc. and the annual affiliation fees paid by companies that are not members of one of the three industry organizations (Lif, IGL and Parallelimportørerne).

For many years, ENLI has focused on preventing violations of codes of ethics. The secretariat employs three lawyers on a daily basis who, among other things, provide guidance to companies by phone and email, and prepare written guidelines, which are available on the website.

The years of focus on prevention have paid off. There are fewer code violations, but also fewer requests for pre-approvals. This is probably due to a combination of more guidance being available to companies and a narrowing of the gray area over time.

Despite fewer requests for pre-approval and fewer notified activities, ENLI has not had its workload reduced. The requests for pre-approvals that do come in are often complex and time-consuming, and often involve the involvement of multiple investigators.

However, there is a decrease in the number of activities notified to ENLI - especially considering how many companies are now covered by ENLI's authority.

The steering committee of ENLI has decided that the notification fee and fees for requesting pre-approvals will increase in 2025.

As of January 1, 2025, the price of notification of an activity will be DKK 525 + VAT per notification, while requests for pre-assessment for advertising material will be DKK 9,000 + VAT and for other activities DKK 7,000 + VAT.

The steering committee has also discussed the level

of fines. As mentioned, there is ample opportunity for guidance from ENLI, and the Steering Committee has thus decided that the fine level should be raised for companies that violate the rules.

From January 1, 2025, the fine level will therefore be raised. The minimum level for a fine will be DKK 60,000 (where it is currently DKK 30,000) and the maximum level will be raised to DKK 250,000 (where it is currently DKK 150,000). The maximum for repeat offenses will be raised to DKK 500,000 (from DKK 300,000 today).

The changes are made to ENLI's Sanction and Fee Regulations with effect from January 1, 2025.

Appeals Board

At their meeting on October 29, 2024, the Appeals Board made decisions in two appeal cases.

Distribution of reprints containing off-label information about one of the company's medicines

The investigator panel had rejected a request for pre-approval for unsolicited disclosure of a scientific article (reprint). The reprint contained information about one of the pharmaceutical company's older

medicines, which in many countries is used off-label (i.e. outside the approved indication).

The Appeals Board reversed the decision of the investigator panel based on the specific circumstances of the case.

The Appeals Board notes in the conclusion:

"The concept of advertising as defined in Art. 3(1) of the Promotion Code, cf. Art. 1(1) of the Advertising Order, must be interpreted broadly in accordance with the main purposes of the advertising rules, especially the protection of public health. Whether the individual case is an advertisement for a medicinal product depends on a specific assessment of the circumstances.

The case in question has the character of a borderline case.

The Appeals Board finds it questionable that [the company] will unsolicitedly send healthcare professionals a scientific article with off-label mention of the company's medicinal product [the medicinal product]. Conversely, it is part of the Appeals Board's assessment that the patent for [the medicinal product] reportedly expires in 2020, that the market share for [the medicinal product] in Denmark according to [the company] is below 1%, that the market for [the medicinal product] has been taken over by biosimilar versions of the medicinal product, that [the medicinal product] is not mentioned in the Danish treatment guidelines for [the disease], that the mentioned scientific article does not contain any recommendation of [the medicinal product] and that [the company] has an approved medicinal product, [...], on the market for the treatment of [the disease], so that according to [the company] there is no commercial interest for the company in an increased consumption of [the medicine].

Under the circumstances, the Appeals Board does not find that there is sufficient basis to assume that the planned distribution of a scientific article to healthcare professionals will have the character of "... outreach information activities, canvassing or influencing attitudes aimed at promoting the prescription, dispensing, sale or consumption of medicinal products

to humans.", cf. Art. 3(1) of the Promotion Code, cf. Art. 1(1) of the Advertising Order. Therefore, the distribution does not constitute an off-label advertisement for [the medicine] in violation of Art. 4(1) of the Promotion Code.

The decision is specifically justified and does not imply any change compared to ENLI's previous practice in the area."

The case stems from a request for pre-approval, which is why the decision is not published.

Accommodation - Hotel

Based on a sample case, the investigator panel had found that a pharmaceutical company had violated the Promotion Code regarding offers of accommodation abroad, as the hotel was considered luxurious and in several places was described as 5-star.

The Appeals Board upheld the decision of the investigator panel and noted the following:

"Section 12 of the Promotion Code states the prohibition against financial benefits and gifts to healthcare professionals: "It is not permitted to give, offer or promise gifts or financial benefits to healthcare professionals,..." This is the main rule. Exceptions require a specific legal basis and are interpreted restrictively in accordance with the overall principle that pharmaceutical companies must maintain high ethical standards at all times, just as sales promotions must never be of such a nature that they discredit the pharmaceutical industry or reduce confidence in it, cf. Section 1(2) of the Promotion Code.

The principle of restrictive interpretation thus also and to a large extent applies to the provision in Art. 13 of the Promotion Code on pharmaceutical companies' possibility of payment of expenses in connection with healthcare professionals' participation in professionally relevant courses, conferences, etc. Section 13(7) specifies that all forms of hospitality provided to healthcare professionals "must be at a reasonable level and strictly limited to the main purpose of the promotional or professional activity. As a general rule, the hospitality provided must not exceed the amount that recipients employed in the healthcare sector would normally be prepared to pay themselves.

" Specifically with regard to venues, section 13(10) states that pharmaceutical companies "must avoid using venues that are known for their entertainment facilities, are extravagant and/or luxurious." The Guidance to section 13(10) states that, as a general rule, 5-star hotels cannot be used unless there are other special circumstances (e.g. location, facilities, or lack of alternative venues) that can justify their use in specific cases. The Guide to Section 13(10) recommends using "... booking sites such as Trivago.com, Booking.com and the VisitDenmark website as a contribution to the overall assessment of how the venue appears in general reputation." The quality ratings on these websites typically refer to the traditional star rating from 1 to 5 stars based on hotels' own feedback and objective criteria set by independent hotel rating organizations. User-based ratings such as TripAdvisor.com, on the other hand, are not given decisive weight as they reflect customers' often quite different subjective assessments of the hotel in question, without necessarily taking all relevant parameters into account.

If the quality search for a specific hotel gives an unclear result, e.g. a rating of 5-star according to the traditional star classification and a lower rating according to user ratings, the restrictive interpretation of Art. 13(10) of the Promotion Code means that the pharmaceutical company must refrain from using the hotel. The same applies to any other reasonably justified doubt as to whether a hotel is perceived as luxurious or extravagant in "general reputation".

Against this background, and as [the company] in connection with the notification of the sponsorship has not disclosed other special circumstances, e.g. in relation to location, facilities, or lack of alternatives in the local area that could objectively justify the choice of Hilton Cologne, the Appeals Board can agree that [the company] has violated Section 13(7), cf. Section 13(10) of the Promotion Code."

The decision in its entirety can be viewed at www.enli.dk.

New notification system i 2025 - "ENLIsag"

As mentioned in previous newsletters, ENLI is in the process of developing a new case management system, including a new notification system for the affiliated companies. The progress of the development is on schedule, and in the latter part of the year the system will be tested with the involvement of eight companies that will report in the new system and provide feedback to ENLI. The plan is for all affiliated companies to switch to ENLIsag by February 2025. Access to ENLIsag will take place from ENLI's website - just as it does today.

New features for pharmaceutical companies include the possibility of having one or more administrators in the company who can see all colleagues' notifications of activities to ENLI, so that the company can get a complete overview. New users in the company, or consultants working for the company, can register as a user in the system and request an association with the company. The user will only be able to report activities for the company once the user creation has been approved by an administrator in the company.

All users created in the current system will be transferred to the new ENLIsag system as users. If there is only one user associated with the company, they will automatically be assigned an "administrator" role. If there are several users in the company, ENLI's secretariat will contact the company for selection of administrators.

In ENLIsag, it will be possible to create drafts so that you can start a review 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 multiple file formats.

ENLI will publish user guides during the transition to ENLIsag, and the secretariat is ready with help and guidance by phone and email.

Nordic compliance

ENLI has today published a revised overview of selected topics comparing Nordic compliance. The Nordic FAQ has also been revised. No new questions are included, but some countries have chosen to clarify their answers to individual questions.

Both the Nordic Compliance Overview and Nordic Q&A's can be found at www.enli.dk.

Opening hours for Christmas and New Year

ENLI is available on the phones and for emails up to and including December 20, 2024. ENLI is closed for inquiries from December 21, 2024 until and including January 5, 2025.

ENLI will answer phones and emails again from January 6, 2025.

For consultations over Christmas, it is possible to extend the consultation deadline to ENLI if this is needed due to holidays. The secretariat can be contacted by phone or email before December 20, 2024, if there is a need for an extension of the consultation deadline.

For a large number of requests for pre-approval, 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, for example in connection with summer and Christmas holidays.

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