

Newsletter 21 June 2024

Appeals Board

At a meeting earlier in June, the Appeals Board made decisions in two appeal cases. One stems from a request for pre-approval, which is why it is not published, but only described here. The other decision stems from a sample case and is published on www.enli.dk.

Incorrect catering amount stated in notification to ENLI

The Investigator Panel had selected a sponsorship for sampling, which related to catering amounts in Sweden.

In May 2024, the Investigator Panel decided on a fine of SEK 50,000 as a result of the pharmaceutical company's violation of Art. 13.8 of the Promotion Code, as the pharmaceutical company's stated amount for dinner of DKK 650 and 700 corresponding to SEK 1013.72 and SEK 1091.70 respectively was not in accordance with the amount cap in Sweden of SEK 950, incl. taxes and charges, and as the amount for meals stated in the contract between the pharmaceutical company and the healthcare professional of EUR 114 maximum, corresponding to SEK 1326.49, also exceeded the ceiling in Sweden.

The pharmaceutical company stated that they are aware of the maximum amounts in Sweden and intend to comply with the maximum amounts, and they also stated that the reported catering amounts are due to an error, as the notifier has stated the amounts in SEK. To support the above, the pharmaceutical company has submitted an order confirmation for catering for day 2, which shows that catering has been ordered for SEK 495.

Based on the documentation provided, the Investiga-

tor Panel found that the catering amount for day 2 was in accordance with Art. 13.8 of the Promotion Code, but that the catering amounts for days 1 and 3 were not in accordance with Art. 13.8 of the Promotion Code, as no documentation was provided.

The Appeals Board notes in their decision:

"In order for the Investigator Panel to be able to enforce the rules in the Promotion Code, it is essential that the Panel's assessment can be based on the reported circumstances. This is a fundamental element of ENLI's self-justice system and also in accordance with a long-standing and well-known practice, cf., among other things, the clarification in the Guide to the Promotion Code Art. 21 (4), various newsletters sent to ENLI's membership, and the Appeals Board's decisions in AN-2018-0650, AN-2011-1927 and AN-2011-1480. To avoid unfairness in connection with typing errors and the like, it is possible to correct errors in notifications to ENLI during the working day on which the notification is made. The right to correct typing errors on the day of notification applies without the need for documentation and without the pharmaceutical company incurring sanctions.

The starting point for assessing [the pharmaceutical company's] sponsorship for participation in the "26th European Congress of Endocrinology" is therefore the declared amounts for dinner on days 1 and 2 at DKK 650 and on day 3 at DKK 700. For dinner on day 2, an order confirmation dated December 12, 2023 has been submitted for a 3-course menu at a price of 495

SEK excluding taxes and duties. The dinner thus complies with the maximum amount for meals in Sweden (950 SEK). The order confirmation, which was issued before the time of notification, must be considered sufficient documentation for this. For dinner on days 1 and 3, [the pharmaceutical company] has at the time of notification stated amounts of DKK 650 and DKK 700 respectively. The Appeals Board does not consider it sufficient documentation for the intention to provide meals at a lower amount than menus from restaurants with a different price level than originally notified are now presented during the appeal proceedings.

As the maximum amount for an evening meal in Sweden is 950 SEK (approx. 610 DKR), the notified sponsorship is in violation of Art. 13(8) of the Promotion Code."

The case thus ended with a confirmation of the Investigator Panel's decision and a fine of DKK 50,000 to the pharmaceutical company. The decision can be viewed at www.enli.dk.

Comparative advertising

The decision from the Appeals Board stems from a request for a pre-assessment, which is why the decision is not published.

The case concerned whether a pharmaceutical company could make a comparative advertisement based on the study on which their medicinal product was approved. The study contained a comparison with a medicinal product not approved for sale in Denmark.

The Appeals Board upheld the Investigator Panel's refusal of pre-approval and mentioned the following: *"[The pharmaceutical company's] planned use of data from the [XX] study in connection with the marketing of the medicinal product [...] will, in the opinion of the Appeals Board, be in clear violation of Art. 8(2) of the Promotion Code, as it is not permitted to compare a medicinal product with a medicinal product without marketing authorization in Denmark.*

Overall, the Appeals Board agrees with the Investigator Panel's decision of April 30, 2024 and the additional comments in the consultation response of May 22, 2024.

In relation to the use of data from the [XX] study and the extension study in a marketing context, reference is made to the Investigator Panel's additional comments of May 22, 2024, page 3, last paragraph: "... Since the [XX] study forms the basis for the [medicinal product's] SmPC and the results of the subsequent extension study clarify/confirm the information in the SmPC for the [medicinal product], data from the study can be used as reference for statements regarding the effect of the [medicinal product]."

Guide to handing out information material and medical equipment - now in English

Earlier this year, ENLI launched a new guide on the provision of information material and medical devices. This is now also available in an English version at www.enli.dk/en.

Summer holidays and case management

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

For a large number of requests for pre-assessment, there may be a need to postpone the case processing deadline, cf. ENLI's Code of Procedure 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 will be open throughout the summer for both telephone inquiries and emails, but with staffing at a low level in weeks 28-30. Telephone and emails will be completely closed for answering on Fridays 12 and 26 July 2024.

ENLI wishes everyone a great summer.

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