

Newsletter 10 January 2023

The Appeals Board

The Appeals Board has made a decision in an appeal case regarding the use of presentations on the environment in connection with a continuing education event. The decision itself is not published as the case concerns a pre-assessment case.

Environmental and climate-related speeches

A company had applied for prior authorisation to hold meetings/symposia for healthcare professionals with a programme item on the environmental consequences of using greenhouse gases in inhalation therapy.

In connection with the request, the company stated, among other things, that these meetings will not include presentations from the company in any form other than a welcome. At no time will brand-specific medicines be mentioned - neither the company's nor other manufacturers'. In the presentation, inhalers will only be referred to as either HFC-free or HFC-containing, focusing on the different climate footprints of the two groups. The company stated that many pharmaceutical companies produce inhalation medicine in both groups, and therefore the company perceived the presentation as neutral and assessed that it was not covered by the Promotion Code.

It follows from Art. 13(1) of the Promotion Code that when pharmaceutical companies hold their own educational events for healthcare professionals, the programme must be 100% professional, which means that there must not be elements of the programme that do not meet the professional requirement. Health policy and health economics areas can, under the circumstances, be considered to be in accordance with Art. 13(1) of the Promotion Code, as long as the focus remains on the treatment of a disease area with the aim of ensuring patients the best medical treatment, cf. the Guide to the Promotion Code Art. 13(1). It was therefore the Investigator Panel's assessment that the presentation did not have the necessary spe-

cific healthcare and continuing education purpose, as the main purpose of the presentation was to inform about climate aspects of HFC spray and HFC-free dry powder inhalers respectively.

The Investigator Panel's decision was appealed, and the Appeals Board decided to expand the professionalism criterion in Art. 13 (1) of the Promotion Code. The Appeals Board states in their reasoning:

"Focus on sustainability and climate-friendly solutions must be expected to become a necessary and integral part of healthcare professionals' daily lives in line with the ever-growing global climate crisis, cf. the quotes from the Danish Medical Association and Danish regions cited above by [the company]. The concept of professionalism for healthcare professionals must reflect this development.

The Appeals Board can therefore agree to a certain expansion of the professionalism criterion, cf. Art.



13.1 of the Promotion Code, so that the criterion will also include presentations at continuing education events regarding environmental issues relevant to the healthcare sector. The Appeals Board assumes that such presentations must primarily aim to provide healthcare professionals with relevant facts in order to better understand the significance of climate effects for healthcare work, that specific medicines must not be mentioned in connection with presentations of this kind, and that the review of environmental conditions must otherwise neither directly or indirectly have the character of or be perceived as advertising for medicines."

The Investigator Panel will soon update the guidance to Art. 13.1 of the Promotion Code regarding the extension of the professionalism criterion for continuing education events, but pharmaceutical companies can already now adapt to the decision, in particular the Appeals Board's criteria for the use of presentations on environmental issues relevant to the health sector:

- ◆ that such presentations must primarily aim to provide healthcare professionals with relevant facts in order to better understand the impact of climate effects on healthcare professionals' work,
- ◆ that no reference to specific medicinal products may be made in the context of such submissions; and
- ◆ that the review of environmental conditions must not directly or indirectly have the character of or be perceived as advertising for medicinal products.

ENLI's secretariat is looking for a lawyer

ENLI is looking for a professionally skilled and independent legal reviewer for 30 hours per week.

As a legal reviewer, you will be part of ENLI's Investigator Panel, which consists of two other lawyers in the secretariat (one of whom is head of secretariat), a law student and three external medical reviewers. As a reviewer, you will be responsible for checking and sanctioning pharmaceutical companies' compliance with the ethical code of conduct, as well as performing pre-assessments and authorisations of pharma-

ceutical companies' activities and advertisements targeting healthcare professionals.

You will also be responsible for communicating decisions, practices and news to the affiliated companies, answering general questions, drafting guidelines and updating current regulations. Training in rules and practices will also be part of your work.

The full job advert can be found at www.enli.dk.

The application deadline is 27 January 2023.

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 26 January 2023. In the first quarter of 2023, ENLI will publish the reports in complete forms at www.enli.dk.

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