Newsletter 20 March 2023

Appeals Board

The Appeals Board has made a decision in a case of pre-approval regarding the boundary between information material (covered by the exception in Art. 2(2)(c)(5) of the Promotion Code) and advertising.

A pharmaceutical company had applied for pre-approval of a submitted material, where the company wanted an opinion on whether the material was covered by Art. 14(1) of the Promotion Code (information material) and whether the material was in accordance with ENLI's guidance on the use of guidelines.

According to the information provided, the company experiences great demand for knowledge about treatment of the disease in question. In this connection, the company would like to be able to provide the general treatment algorithm from a medical society's guideline on the disease, as the figure outlines different treatment options in a disease course and is practically useful for the practitioner. The company stated that the material would only be provided in the context of general education about the disease (no product education) with the aim of serving as a support tool for the clinician.

The Investigator Panel had denied the request for pre-approval based on an overall assessment based on the form, content and use of the material. The Investigator Panel did not consider that the material constituted information and educational material that can legally be provided in accordance with Art. 14 (1) of the Promotion Code, just as the material was not considered to fulfil any specific exceptions to the advertising rules, cf. Art. 2 (2) (c) (1-8) of the Promotion Code. Instead, the Investigator Panel considered the material to be covered by the concept of advertising. The Investigator Panel stated, among other things, that when, at the initiative of the company, a figure from a treatment guide is highlighted where the company's medicines within various substance groups are emphasised as treatment recommendations, this must be considered to be an indirect claim of the company's medicines within the substance groups.

The Appeals Board's decision

"Advertising of medicinal products means "any form of information outreach, canvassing or influencing attitudes aimed at promoting the prescription, supply, sale or consumption of medicinal products", cf. Art. 3 (1) of the Promotion Code and Art. 1(1) of the Advertising Order. This very broad definition of advertising means that there are narrow limits to how pharmaceutical companies can inform healthcare professionals without this being considered advertising and thus covered by the advertising rules. The information must be objective and neutral both in relation to its content and its dissemination, so that it neither directly nor indirectly takes on the character of advertising for medicinal products.

The decision as to whether it is advertising depends

on a specific assessment in each individual case. In this case, based on an overall assessment of the relevant circumstances, the Appeals Board has found that the proposed information material has the character of advertising and therefore cannot be pre-approved.

In its decision, the Appeals Board has in particular emphasised that [the company] will provide the material unsolicited to healthcare professionals, that [the company] has chosen to reproduce a short - adapted - extract from the Danish [Medical] Society's 56-page treatment guide containing a number of essential information for healthcare professionals' treatment of [disease], concerning [x] and [y] inhibitors, that [x] inhibitors are among the medicines the company markets in Denmark, and that the choice of extract and its distribution to healthcare professionals with an immediate link to [the company] is neither objective nor neutral. This gives the material the character of indirect advertising for the company's [x] medicines.

The provision in Art. 2(2)(c)(5) of the Promotion Code exempts "information material about health and disease" from the advertising rules. The central area of the exemption is information about diseases - not the treatment of diseases. Information about disease must be the focus, while any information about disease treatment in the information material must be limited in scope and at a very general level. The [company's] material is centred on disease treatment and has a concrete, indicative character. For this reason alone, the material is not covered by the exception in Art. 2(2)(c)(5) of the Promotion Code.

The Appeals Board's decision is in accordance with the Board's previous practice in this area."

The decision is not published as it is based on a request for pre-assessment. However, ENLI will soon revise the guidance to the Promotion Code, especially regarding the Appeals Board's comments on the exception in Art. 2.2(2)(c)(5), where it is clarified that the focus should be on the disease and not the treatment of the disease.

Clarification regarding presentations at continuing education meetings regarding climate/environment

In 2023, the Board of Appeal expanded the professional requirement to also cover the environmental consequences of the use of medicines, as "*Focus on sustainability and climate-friendly solutions must be expected to become a necessary and integral part of healthcare professionals' daily lives as the global climate crisis continues to grow [...]. The concept of professionalism for healthcare professionals must reflect this development.*"

In this context, criteria for presentations on climate/environment and sustainability were specified:

- The primary purpose of such posts should be to provide healthcare professionals with relevant facts in order to better understand the impact of climate effects on healthcare work,
- No reference to specific medicines may be made in the context of such presentations; and
- The review of environmental conditions in general must neither directly or indirectly have the character of or be perceived as advertising for medicinal products.

Subsequently, questions have been raised about the mention of pharmaceuticals in connection with climate/environment posts.

It is the Investigator Panel's assessment that it will not be possible to combine a presentation on the environmental impact of a medicinal product with a presentation on one of the pharmaceutical company's other medicinal products (which is not related to the presentation on climate/environment), as there is a significant risk that participants will get the impression that all the company's medicinal products in other presentations at the continuing education meeting are climate-friendly.

News at www.enli.dk

ENLI has published the companies' reporting of donations and collaborations with patient associations for 2022. ENLI has also published its annual report for 2022.

Both lists and the annual report can be found at www.enli.dk.

Revised guidelines for the Promotion Code

ENLI is putting the finishing touches on the revision of the guidelines for the Promotion Code, which is expected to be available on the website during the month of April. So please keep an eye on www.enli.dk or register at sekretariat@enli.dk. You will then receive an email every time ENLI updates the website with new information.

Regional agreements - invitation to management

ENLI has been made aware that some companies, in connection with information about upcoming continuing education events, e.g. posts on LinkedIn, state something like: "contact your department head for further information about the symposium and registration".

After discussing the issue with Lif (which is a party to the agreement with the regions), it is ENLI's immediate opinion that such a formulation would be contrary to (the purpose of) the regional agreements, as it could be perceived as circumventing the agreement when the companies call on healthcare professionals to contact their department manager for registration.

In this way, the companies encourage the employees to push for participation in the company's training. The pharmaceutical companies must use the procedure described in the regional agreement, ie. send invitations to the provided email addresses, after which the management itself decides whether the employees are to be offered further training.

Supply of equipment to patients - with a healthcare professional as an intermediary

ENLI has dealt with a case concerning an request for pre-approval for the supply of cooler bags in accordance with section 14, subsection of the Promotion Code. 2, for patients.

The Investigator Panel stated on that occasion that § 14, subsection of the Promotion Code. 2, relates to medical equipment that is issued to individual healthcare professionals.

Of the guidance to the Promotion Code § 14, subsection 2, it is stated that medical equipment includes: "*equipment that is suitable for improving the healthcare professional's medical or pharmacy business and patient treatment, and which has no personal value for the healthcare professional. Examples of this could be medical equipment for e.g. inhalation (without active ingredient) as well as equipment intended to help the patient learn, e.g. self-injection.*"

Based on the above description, the Investigator Panel did not find that the supply of a cooling bag was to be regarded as medical equipment according to Section 14 (2), subsection of the Promotion Code. Equipment that must be handed out to patients via a general practitioner is regulated according to article 12 of the Promotion Code.

Of the guidance to the Promotion Code art. 12, subsection 1, it appears, among other things, that the supply of medicine cooling bags to individual healthcare professionals with a view to subsequent supply to patients must meet four criteria: 1) The medicine cooling bags are aimed at the patients' needs; 2) is of unexpensive value; 3) is without product branding (neither name nor logo for product) and 4) does not constitute an inducement to recommend, prescribe, buy, supply, sell or administer specific medicines.

The company stated in the request that the cooling bag was to be delivered to a hospital, which could then pass on the cooling bag to patients. As the cooling bag had to be handed over to patients via a hospital, and not via the patient's own doctor, it was the Donations Code's rules, and not the Promotion Code's rules, that applied.

This appears from Section 4(1) of the Donations Code, that a pharmaceutical company may provide support to a hospital if the support is used for a healthcare purpose, i.e. a donation can be given if the support goes to an activity/project that can be considered an integral part of either prevention, examination, diagnosis, treatment or the subsequent control of the patient.

In contrast to the guidance for art. 12(1) of the Promotion Code, the Donations Code does not directly address pharmaceutical companies' donations to hospitals, which are provided with the aim that the donation can be passed on to patients. The Investigator Panel must note, however, that the same assessment is made when onward distribution to patients takes place, regardless of whether it is from a hospital or a general practitioner.

Since the Donations Code does not contain provisions or a prohibition against hospitals passing on donations to patients, combined with the fact that it appears from the guidelines for the Donations Code that it is the hospital that has the right to dispose of the donation received, it is the Investigator Panel's assessment that it is basically possible for a hospital to pass on donations received from pharmaceutical companies, if the hospital so wishes.

Branding of equipment

It should be noted that according to section 66 of the Medicines Act, subsection 1, no. 1, prescription medicines may not be advertised to the public, which is why donations that are passed on to patients may not be branded, unless it is concretely assessed to serve a patient safety purpose.

In the case in question, the cooler bag had to be provided with the product name on the outside, along with the QR code for patient information material.

The company stated in the request that it is an advantage that the product name is written on the cooler bag, as it prevents any errors and doubts when dispensing the medicine, as the healthcare staff can identify this on the cooler bag. The company also stated that in this way the cooling bag will only be dedicated to the medicine and not used in the home for anything else.

The Investigator Panel found that since only one medicine is dispensed, there is no immediate risk of confusion when passing on to the patient. In relation to the patient's use of the cooling bag for anything other than the medicine, it must be assumed that it is the size of the cooling bag and not the printed medicine name that limits the patient's use.

The Investigator Panel therefore did not find that the medicine's name on the cooler bag served a patient safety purpose. It would therefore not be possible to donate cooler bags etc. if these contained the company's name, logo or special and common name, if the cooler bag etc. had to be passed on to patients.

Continuing education and planning activities

A pharmaceutical company had requested a pre-approval for sponsorship of a podcast on a disease area. The podcast itself was assessed to be comparable to a continuing education event.

The question in this connection was whether the company could also sponsor expenses for advice on the choice of platform, launch and strategy in connection with the creation of the podcast.

This appears from the instructions for art. 13(1) of the Promotion Code, that the companies' sponsorships may only cover the direct costs in connection with the continuing education arrangement, i.e. that it is not possible to cover expenses in connection with, for example, planning meetings.

On the basis of the information in the case, the Panel Investigator Panel found that advice on choosing a platform, launch and strategy was more in the nature of planning and thus cannot be considered to be direct expenses in connection with the continuing education arrangement.

Advice on the choice of platform, launch and strategy was thus found not to have the necessary health professional aim, which is required according to the professional criterion in art. 13(1) of the Promotion Code. The company was thus refused to be able to provide support for these expenses in the budget.

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