

Newsletter 19 March 2024

Guide regarding the Folkemødet (Peoples Meeting)

ENLI has published a guide about Folkemødet on Bornholm.

Every spring, ENLI receives a number of questions in connection with the pharmaceutical companies' planning of events at Folkemødet in June. ENLI has therefore prepared a guide specifically for Folkemødet.

The purpose of the guide is to summarize relevant information for pharmaceutical companies that organize or support events at Folkemødet.

As the events at Folkemødet can be aimed at health-care professionals, politicians, patient associations and the general public, the guide contains provisions from the Promotion Code, the Patient Organizations Code and the Lobbying Code. In addition, there will be events that do not fall under ENLI's jurisdiction as they are targeted at the general public.

In line with other ENLI guides, a Q&A is included.

The Danish version of the guide can be found at www.enli.dk. The guide will later be published in an English version.

Newsletters - now also in English

As you may have already noticed in the email, an English version of the newsletter is also attached.

With the increased globalization and centralization of compliance functions in companies, it is a goal for ENLI to translate all relevant information into English. Therefore, newsletters will now also be available in an English version, which you have the opportunity to share with non-Danish speaking colleagues.

Newsletters in English will be published on the English version of www.enli.dk/en.

Information about donations and collaborations with patient organizations

ENLI has received reports from the affiliated companies about their donations to hospitals and collaborations with patient organizations. These are now published in an aggregated version on www.enli.dk.

Annual report for 2023

ENLI has published the annual report, which can be found at www.enli.dk. (though only in Danish)

The number of cases where a violation has resulted in a fine remains low. In 2023, pharmaceutical companies reported 4,806 activities to ENLI, and random checks were carried out in approx. 35% of all reported activities. Of these, 25 cases ended with a fine and 25 cases ended with a reprimand. The number of reprimands is for the most part administrative reprimands (late notification, missing documents, etc.).

Complaint about promotional material on an exhibition stand

Just before Christmas, ENLI received the first (and only) complaint case of the year. The case was settled at the end of January 2024.

The case concerned questions about the adequacy of the mandatory text in a leave-behind, the use of documentation (data-on-file and market research) and reference to the mandatory text in a roll-up.

The Investigator Panel found in favor of the complainant and the case was settled with a fine of DKK 50,000. The decision can be found at www.enli.dk. (though only in Danish)

Opening hours for Easter

ENLI is open for phone calls and e-mails up to and including March 27, 2024. ENLI is closed for inquiries from March 28 and up to and including April 1, 2024.

ENLI will answer inquiries again from April 2, 2024.

For hearings over Easter, 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 telephone or e-mail no later than March 27, 2024, if there is a need to postpone the consultation deadline.

In the case of a larger number of requests for pre-approval, there may be a need to postpone the case processing deadline, cf. Case Processing Rules for ENLI § 6.5, according to which ENLI may in special cases extend the case processing deadline beyond the 10 working days, e.g. in connection with summer and Christmas holidays.

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