Penalties and Fees Regulations

Art. 1 Penalties

Sec. 1. ENLI can impose penalties on a company if the company reports advertising activities or other activities that are considered to be in breach of the rules subject to control, see ENLI's Cooperation agreement section 2, paragraph 1, point (a), or if ENLI otherwise becomes aware of such activities, e.g., from a complaint.

a) ENLI may apply the following penalties:

1. Reprimand
2. Fine
3. Express a public reprimand of a company for breach of the rules

b) ENLI may also impose a pharmaceutical company to:

1. Correct incorrect information (cases concerning medical information)
2. Revoke illegal advertising material
3. Avoid using illegal promotional materials
4. Issue a corrective statement, e.g., by order of publishing the ad on this in a professional journal
5. Cancel or change a scheduled event (conferences, courses, etc.), including support for such event or the healthcare professional's participation in such

Sec. 2. If appropriate ENLI can, by breach of the Pharmaceutical Industry's Code of Practice on Promotion, etc. of Medicinal Products aimed at Healthcare Professionals (Promotion Code), impose upon the company to provide a signed commitment of its intention not to repeat the offence.

Sec. 3. ENLI shall decide on the application of penalties and the amount of any fine after an assessment of merits of the case, including the infringement, gravity, and extent.

Sec. 4. The Investigator Panel may not impose a company a penalty for an activity, which has been pre-approved, if all necessary and accurate information about the activity was available for the Investigator

Panel at the time the pre-approval was granted, and not afterwards have been changed in format, content, etc. If the Appeals Board dismiss a pre-approval, which is given by the Investigator Panel under the above assumptions, the Appeals Board can only impose a reprimand upon the company.

Art. 2 Penalties for breach of the obligation to report

Sec. 1. The reporting requirement is defined in Art. 21 of the Promotion Code. Violation of the reporting obligation will as a general rule be imposed a reprimand. If the infringement is committed egregiously, apparently deliberately, and is a repeated offence, ENLI can however, impose an administrative fine between 15,000 DKK – 30,000 DKK + VAT.

Sec. 2. If ENLI finds that a company has violated the reporting requirement, it must be imposed upon the company to cease the violations immediately.

Art. 3 Penalties in cases involving substantive offences

Sec. 1. Substantive offences are defined as a violation of the Rules laid down in the cooperation agreement, Art. 2, section 1 (a), as well as the obligation to report, cf. the Promotion Codes Art. 21.

Sec. 2. Reprimand is used for substantive infringements, if the violation concerns trivial matters, where the offense is minor or insignificant, and which is not a repeat violation. Please refer to Art. 4-6 for examples of cases. Fines for violation of the rules on medical information, are imposed in the range of DKK 60,000 – 250,000 DKK + VAT. In cases where a company has violated several rules at the same time, ENLI can impose a total fine, which penalties all infringements at once.

Sec. 3. By a company's repeated infringement of the same offenses of same character, e.g., unfair comparative advertising, or payment for accommodation in a luxury hotel, the amount of the fine is doubled, and by additional iterations multiplied by the recurring frequency, up to a maximum of DKK 500,000 + VAT. Offences committed more than two years after ENLI's decision, are considered new offences and does not trigger repetitive effects.

Sec. 4. If a company incorrectly informs healthcare professionals that medical information material, an arrangement, sponsorship or other conditions is pre-approved by ENLI, the company is imposed a fine of 25,000 DKK + VAT.

Sec. 5. Use of public reprimand is reserved to matters relating to coarser or repeated offences. A prerequisite for the use of public reprimand is that there has been imposed a fine of at least 100,000 DKK + VAT.

Sec. 6. Mandating rectification requires that medical information is provided with incorrect information, which involves a danger to patients, or which are otherwise a significant detriment of the market.

Art. 4 Penalties in cases involving medical information

Sec. 1. In cases concerning medical information, a fixed penalty in type-cases is as a starting point the following rates:

The following cases is imposed a reprimand:

a) Violations that have taken place on a basis where there was reasonable doubt about how the rules should be understood or interpreted, or which introduced a completely new practice or standard by which the company could not reasonably be expected to have been familiar with.

The following cases begins with a reprimand, while a fine of 60,000 DKK + VAT is imposed by the first repetition:

b) Formal errors, e.g., missing or incorrect indication of common name or chemical composition, lack of dating, etc.
c) Incomplete compulsory texts, including indication of such with severe or illegible types, and deficiencies regarding general documentation.
d) Incomplete or incorrect data relating to prices, reimbursements, dosage and dispensing.

The following standard fine of 60,000 – 100,000 DKK + VAT is imposed when:

e) Infringement of rules for objectivity as subject to ENLI's control, cf. the cooperation agreement Art. 2, sec. 1 (a).
f) Severe breaches of category b)-d) above in the same information material which make the entire material insufficient and, inter alia, violates the requirement that the material be sufficient and factual.

The following standard fine of 80,000 – 125,000 DKK + VAT is imposed when:

g) Incorrect indication of therapeutic indication, significant adverse reactions, special precautions, etc.

The following standard fine of 100,000 – 175,000 DKK + VAT is imposed when:

h) Unfair comparative advertising, including advertising, that do not provide a sufficient basis to assess each difference of the products, or which may bring other companies or their products into disrepute, including incorrect price comparisons.
i) Denigration of other companies or their products.
j) Advertising for a non-marketed medicinal product.

The following standard fine of 175,000 – 250,000 DKK + VAT is imposed when:

k) False or misleading information that could pose a danger to public health.

Sec. 2. In cases where the violation can only be determined after careful scrutiny of the information material, possibly after obtaining special expert opinions and where there is no reason to doubt that the company has acted in good faith, a fine will only be imposed, if the company fails to respect the decision and reprimand by ENLI. The announcement must not be repeated, while ENLI is considering the matter, if the company has received an order accordingly. For violation of such orders, a fine of 60,000 DKK + VAT per advertising will be imposed.

Sec. 3. The mentioned rates apply per advertising, per broadcast of medical letter etc. Repeating of the illegal information will be regarded as a repeat offence. If ENLI's decision comes so late that the advertising, etc., cannot be halted – e.g., since the letter is in print, the letter has been delivered to the post office etc. – arises no repeat offences for that advertising, etc.

Art. 5 Penalties in cases of professional events and economic benefits

In cases of professional events (where the company itself is the organizer/co-organizer or provides a sponsorship) and economic benefits to healthcare professionals, a fixed penalty in type-cases will as a starting point be imposed the following rates:

a) Following cases will be imposed a reprimand:

Violations that have taken place on a basis where there was reasonable doubt about how the rules should be understood or interpreted, or which introduced a completely new practice or standard that the company could not reasonably be expected to have been familiar. Reprimand is also imposed for choice of venue, which is not obviously in breach of the Promotion code.

b) As an example of cases, that begins with a reprimand, while a fine of 60,000 DKK + VAT will be imposed at the first iteration, include:

- Event of less than two hours, where the company have offered meals to the participants, beyond what is proportionate to the meeting.
- Gifts, but where the company could have reasonable doubt as to whether the individual gift is lawful to give, cf. the Promotion Code Art. 14.
- Lack of compulsory texts in cases where a specific medicinal product is indicated in connection with invitations for events, etc.
- Sponsorship provided from a pharmaceutical company, not mentioned in the invitation to healthcare professionals, and where the pharmaceutical company has not verified this in the contract with the third party.

- When buying/renting of exhibition stand, etc., as an example:
  - Insufficient professional program for the event
  - Location of the exhibition stand, etc., which is not separated from the professional activities.

c) Examples of cases leading to a fine in the range of DKK 60,000.-DKK 100,000 + VAT, include:

- Events with insufficient professional content
- Event of less than two hours, where the company egregiously have offered meals to the participants, beyond what is proportionate to the meeting.
- Gifts, but where the company could have no reasonable doubt as to whether the individual gift is lawful to give, cf. the Promotion Code Art. 14.
- The use of non-appropriate venues or venues that are obviously known for their entertainment facilities is extravagant and/or luxurious.
- Payment for hospitality that exceeds a reasonable level and is not strictly limited to the main purpose of the meeting.
- Events with some degree of entertainment.

d) Examples of cases leading to a fine in the range of DKK 80,000.-DKK 125,000 + VAT, include:

- Gifts, where the company egregiously have given in breach of the Promotion Code Art. 14.
- Payment for representation, which is not limited to travel, meals, accommodation and accurate registration fees.
- Payment for representation to persons who do not meet the conditions to participate in the event.
- Payment for representation that obviously are extravagant and/or luxurious.
- Events in Denmark with obvious content of entertainment.
- Events in Denmark with lack of professional content.
- Refund of healthcare professionals expenses for non-billed representation.
- For events abroad:
  1. Insufficient professional content, or where the location of the event isn't professionally motivated.
  2. Use of non-appropriate venues or venues that obviously are known for their entertainment facilities, is extravagant and/or luxurious.
  3. Payment for hospitality that exceeds a reasonable level and is not strictly limited to the main purpose of the meeting.
  4. Some degree of entertainment.

e) Examples of cases leading to a fine in the range of DKK 100,000.-DKK 250,000 + VAT, include:

- Gifts that the company exceptional egregiously have given in breach of the Promotion Code Art. 14.
- For events abroad:
    1. Significant absence of professional content.
    2. Obvious content of entertainment.
    3. Payment for representation that have been obviously extravagant and/or luxurious.

Art. 6 Penalties in cases regarding violation of other ethical rules

In cases concerning other ethical rules, e.g., other rules of the Promotion Code and other ethical codes subject to ENLI's control, fine sizes are fixed in the following intervals:

a) Following cases will be imposed a reprimand:

Violations that have taken place on a basis where there was reasonable doubt about how the rules should be understood or interpreted, or which introduced a completely new practice or standard that the company could not reasonably be expected to have been familiar with.

b) Examples of cases, beginning with a reprimand, while fines on 60,000 DKK + VAT will be imposed at the first iteration, include:

1. Invitations are not sent to the hospital at the relevant management level in accordance with the cooperation agreements with the individual regions.
2. Organization of hospital-related arrangements that are not approved by the hospital at the relevant level of management in accordance with the cooperation agreements with the individual regions
3. Where the identification by name and the name of the company facing a decision-maker has been done, but where it has not been clear, unsolicited and initially, cf. Ethical rules for dialogue and negotiations with decision-makers (Lobbying Code).

c) Examples of cases leading to a fine in the range of DKK 60,000.-DKK 100,000 + VAT, include:

1. Violation of the transparency requirements concerning publication on the corporate website, as they are contained in e.g.:
    a) Ethical Rules for Collaboration between Patient Organizations, etc. and the Pharmaceutical Industry, etc.
    b) Ethical Rules for dialogue and negotiations with decision-makers
    c) Ethical rules for the pharmaceutical industry's donations and grants (Donation Code).

2. Direct or indirect financial support of less than DKK 20,000 to individual decision-makers, political parties, etc., in the form of election campaign contributions, gifts, travel, etc., cf. Ethical rules for dialogue and negotiation with decision-makers.

d) Examples of cases leading to a fine in the range of DKK 80,000.-DKK 125,000 + VAT, include:

1. Collaborations with patient organizations, which clearly do not meet the requirements of professionalism, cf. Ethical Rules for Collaboration between Patient Organizations, etc. and the Pharmaceutical Industry, etc.
2. Donations and grants to hospitals, which does not have a professional and/or scientific purpose, cf. Ethical rules for the pharmaceutical industry's donations and grants (Donation Code).
3. Serious violations of the provisions on decent behaviour towards decision makers, cf. Ethical rules for dialogue and negotiations with decision-makers (Lobbying Code).
4. Financial support from DKK 20,000 to individual decision-makers, political parties, etc., in the form of election campaign contributions, gifts, travel, etc., cf. Ethical rules for dialogue and negotiation with decision-makers.

e) Examples of cases leading to a fine in the range of DKK 100,000.-DKK 250,000 + VAT, include:

1. Collaboration projects, where financial support to patient organizations is subject to the condition that they must "promote" specific medicinal products to patients or the public, cf. Ethical Rules for Collaboration between Patient Organizations, etc. and the Pharmaceutical Industry, etc.
2. Significant financial support to individual decision-makers, political parties etc. in the form of campaign contributions, gifts, travel, etc., cf. Ethical rules for dialogue and negotiations with decision-makers (Lobbying Code).
3. Significant financial support granted to individual healthcare professionals, cf. Ethical rules for the pharmaceutical industry's donations and grants (Donation Code).

Art. 7 Fee instructions

Reports

Sec. 1. For the reporting of an event or printed advertising material, a fee per report on of 525 DKK + VAT is paid.

Sec. 2. Reporting-fee is charged once every three months backward.

Pre-approval

Sec. 3. For the request of pre-approval of advertising material, a basic fee of DKK 9,000 + VAT is paid. For the request of pre-approval of activities, including events and other cases, a basic fee of DKK 7,000 + VAT is paid. If the Investigator Panel determines that the specific case will lead to work beyond two hours, the company is requested to pay an hourly rate of 2,000 DKK + VAT per started hour of case management in addition to the second hour. Before the proceedings commence, the company must confirm its acceptance of payment of fee in addition to the basic fee within an estimated maximum fee. The total fee must be paid, whether pre-approval is granted or not.

Sec. 4. On subsequent minor changes in an activity, which has previously been granted a pre-approval, an additional assessment of the activity can be made for a fee of 2,000 DKK + VAT.

Complaints

Sec. 5. It is free to complaint if the Investigator Panel is successful with the complaint. The party who is not successful with a complaint will be charged a fee of 6,000 DKK + VAT. If both parties are partially successful, the fee is shared with 6,000 DKK + VAT equally between the two parties.

Sec. 6. For the rapid processing of complaints, a fee of 25,000 DKK + VAT is paid.

Sec. 7. The Investigators Panel can in special cases choose to raise a case ex officio and without payment of fee, on the basis of a complaint from a healthcare professional or an authority, if there is an immediate justifiable reason for doing so.

Appeals

Sec. 8. A fee of 6,000 DKK + VAT is required to appeal a decision by the Investigator Panel.

Affiliation fee

Sec. 9. Pharmaceutical companies who have chosen to join ENLI, even though they are not members of the following associations: Lif, IGL or the Parallel Importers Association, pays an annual affiliation fee of 22,500 DKK + VAT.

Art. 8 Entry into force

This Penalties and Fees Regulations for ENLI shall enter into force on 1 April 2025 and replace the recently published Penalties and Fees Regulations of 1 January 2025.