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Introduction to the Ethical Committee for the Pharmaceutical Industry (ENLI)

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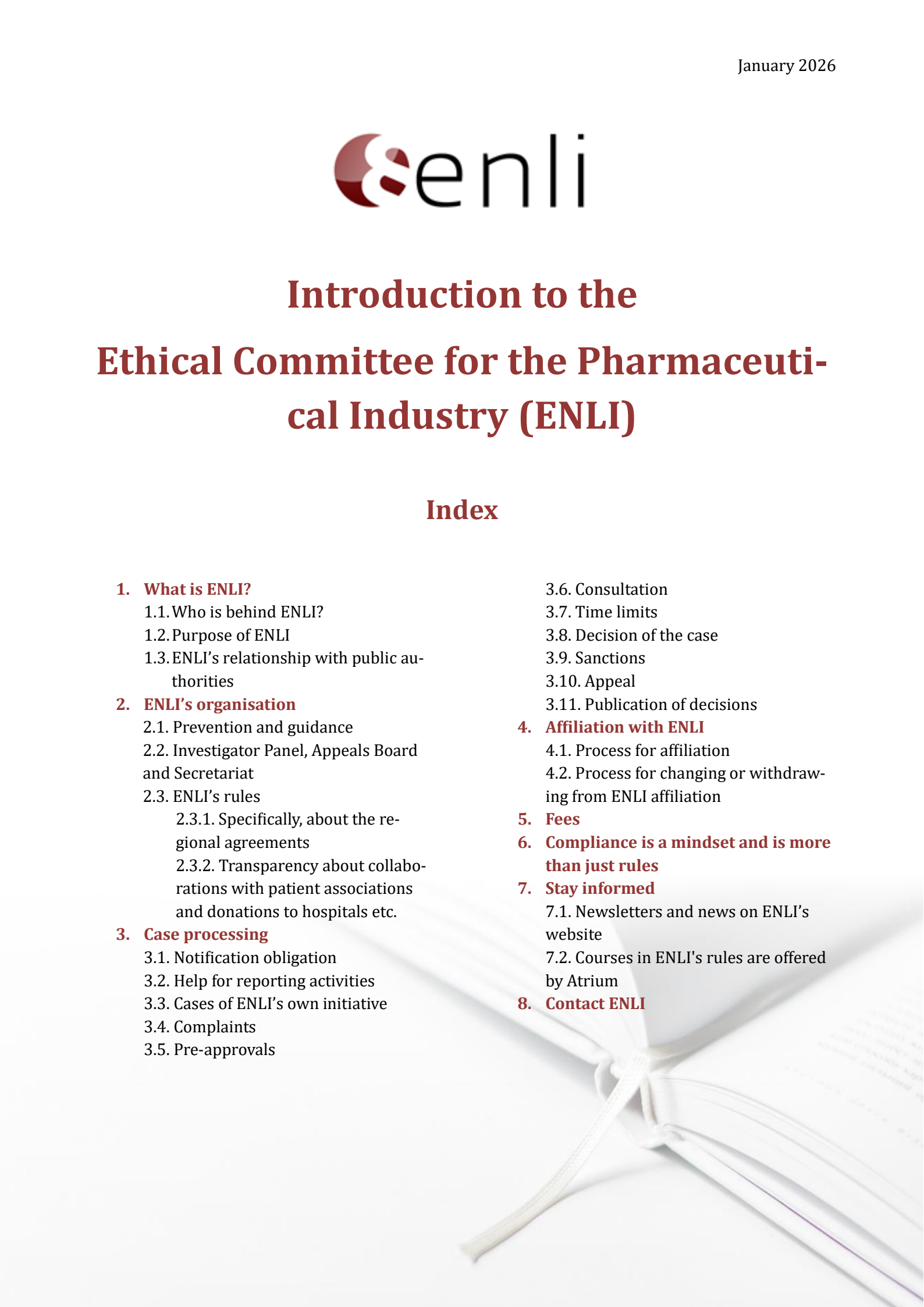

1. What is ENLI?

ENLI is the abbreviation for the Ethical Committee for the Pharmaceutical Industry. ENLI is the pharmaceutical industry's own self-regulatory body that ensures that the pharmaceutical industry's activities towards healthcare professionals and other stakeholders are conducted in a legal and ethical manner.

ENLI has existed since April 1, 2011, when it replaced the former Board for Self-Justice in the Pharmaceutical Sector (NSL). The pharmaceutical industry in Denmark has had its own self-regulatory system since 1973.

1.1. Who is behind ENLI?

ENLI was established by the Danish Pharmaceutical Industry Association (Lif), the Danish Association for Generic and Biosimilar Medicines (IGL) and the Association for Parallel Importers of Medicines (FPM).

In addition, associations and companies outside the three contracting parties can join ENLI for an annual affiliation fee.

On ENLI's website is an overview of the companies that are affiliated at any given time. By 2024, more than 100 pharmaceutical companies have joined ENLI.

The Danish Pharmaceutical Industry Association (Lif) has the financial ownership of and responsibility for ENLI. They do this through an independent limited liability company with Lif as the sole shareholder.

ENLI's operations are primarily financed through activity-based fees (such as notification fees and pre-approval fees) and secondarily through fines.

ENLI's steering committee decides the overall principles for ENLI's activities. The steering committee consists of representatives from the contracting parties behind ENLI (Lif, IGL and FPM).

1.2. Purpose of ENLI

Healthcare professionals and the pharmaceutical industry each have valuable knowledge about medicines and their use. Knowledge sharing is essential for the development of new medicines and benefits all stakeholders. However, it is clear that collaboration between the pharmaceutical industry and healthcare stakeholders must be conducted in an ethical manner with professionalism and patient safety as the focal point.

ENLI was established to ensure self-justice with the ethical framework for the companies that are affiliated with ENLI. ENLI thus acts as a voluntary supplement to the control exercised by the Danish Medicines Agency, just as ENLI's regulatory framework in many areas contains rules that go significantly further than Danish law requires.

The purpose of ENLI is to ensure professional, objective and independent cooperation between the affiliated pharmaceutical companies and other parties in the healthcare sector, and to ensure transparency about the affiliated companies' cooperation with their stakeholders.

In recent years, the pharmaceutical industry has focused on its ethical behaviour by, among other things, voluntarily affiliating with ENLI's industry code of conduct, which has meant even stricter standards than the comprehensive Danish legislation already requires. As a result, the pharmaceutical industry is now one of the most regulated industries in Denmark.

For the pharmaceutical industry, however, this has been a natural step to take, as the industry recognises that it has a special responsibility to ensure the credibility of its collaboration with stakeholders.

The goal of the comprehensive regulation is to ensure that the collaboration between the pharmaceutical industry and healthcare stakeholders is conducted in an ethical manner with professionalism and patient safety as the central point.

1.3. ENLI's relationship with public authorities

ENLI acts as a voluntary supplement to the control exercised by the Danish Medicines Agency. ENLI's regulatory framework in many areas contains rules that go significantly further than Danish legislation.

ENLI is a private industry board and not part of the public system - and therefore not a court of justice - but reflects a desire from the industry itself to take a closer look at itself. ENLI's authority to enforce the rules is also due to the fact that the companies affiliated with ENLI have granted ENLI the authority to monitor.

The authorities recognise ENLI's role, and thus the guidance to the Advertising Order states:

"The Danish Medicines Agency's control activities in the field of advertising are supplemented by industry self-regulatory bodies that monitor the legality of advertising activities alongside the Danish Medicines Agency and cooperate in this connection. There are four self-regulatory bodies: the Danish Pharmaceutical Industry Ethical Committee (ENLI), the Danish Pharmacy Board, the Medical Ethics Committee and the Health Industry Suppliers Association's Ethical Committee."

ENLI's starting point is that it is always the strictest rules that apply. ENLI inspects both legislation and the industry's own ethical rules, including the European and international industry ethical rules, the strictest of which are found in the codes that are subject to ENLI's control.

In recent years, agreements have been signed between the five regions and Lif, which means that pharmaceutical companies must now be affiliated with ENLI in order to interact with healthcare professionals at the Danish hospitals under the regions in relation to e.g. continuing education activities. Learn more on this under 2.3.1.

2. ENLI's organisation

2.1. Prevention and guidance

A large part of ENLI's work is focused on preventing violations of the rules. ENLI's secretariat provides guidance both by phone and email on understanding the rules. In addition, ENLI provides training in understanding the rules for both companies and their affected partners.

ENLI also regularly produces guides that can help you understand the rules. All guides can be found at www.enli.dk - in both Danish and English.

2.2. Investigator Panel, Appeals Board and Secretariat

ENLI consists of two bodies: the Investigator Panel and the Appeals Board.

The Investigator Panel consists of a number of investigators with legal expertise and doctors with clinical pharmacological knowledge. One of the legal investigators is responsible as Head of Secretariat.

The Investigator Panel makes decisions in what is called the 1st instance.

The Investigator Panel are also the ones who sit in the secretariat and provide information and guidance on understanding the rules.

The Appeals Board, which is the 2nd instance, processes and decides on all cases that are appealed after a decision by the Investigator Panel. The Appeals Board consists of three members: a lawyer as chairman, a doctor with clinical

pharmacological knowledge and a member who has previously worked in the pharmaceutical industry.

The Appeals Board meets three-four times a year. In the event of disagreement between the members of the Appeals Board in connection with a decision, the chairman's vote is decisive. A practice decided by the Appeals Board cannot be changed by the Investigator Panel.

ENLI's assessments must be made independently of the pharmaceutical industry. Therefore, no employees of ENLI may be affiliated with the pharmaceutical industry at the same time. ENLI follows an arm's length principle, which means that the pharmaceutical industry can in no way influence the decisions that ENLI makes. This applies to both the Investigator Panel in the first instance and the Appeals Board in the second instance.

2.3. ENLI's Rules

ENLI monitors the following codes:

- The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals" (Promotion Code)
- Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry (Patient Organisations Code)
- Ethical rules for the pharmaceutical industry's donations and grants (Donation Code)
- Ethical rules for dialogue and negotiations with decisionmakers (Lobbying Code)

You can find the current versions of the ENLI codes at www.enli.dk.

Each code consists of a number of clauses (§) that specify different rules under the individual code. Both Danish legislation as well as European and international industry rules are implemented in the ENLI set of rules. In addition, the regional agreements and joint declaration on clinical drug trials and non-interventional trials between the Danish Association of the Pharmaceutical Industry (Lif), the Danish Medical Association (LVS) and the Danish Medical Association (LF) also apply.

2.3.1. Specifically about the regional agreements

Agreements has been entered into between the five regions and Lif regarding cooperation between the industry and hospital healthcare professionals in the regions. The regional agreements apply to all companies affiliated with ENLI.

The regional agreements cover cooperation between the pharmaceutical industry and the regions' hospitals, mainly regarding continuing education for healthcare professionals. For example, when offering continuing education to healthcare professionals employed by hospitals, the pharmaceutical companies must contact the relevant management team at the regions, which then selects the healthcare professional(s) who can receive sponsorship from the pharmaceutical industry for participation in, for example, an international scientific congress.

The term "Healthcare professionals" only includes doctors, dentists, pharmacists, nurses, pharmaconomists, midwives, bioanalysts, clinical dieticians, radiographers, social and healthcare assistants and students within these professions. "Danish healthcare professionals" means healthcare professionals employed in Denmark, or healthcare professionals who are self-employed in Denmark, e.g. general practitioners with a clinic in Denmark.

2.3.2. Transparency about collaborations with patient associations and donations to hospitals etc.

Pharmaceutical companies affiliated with ENLI are required to submit an annual overview of the company's collaboration with patient organisations and donations to hospitals etc. ENLI publishes a complete overview annually at www.enli.dk.

3. Case processing

ENLI monitors that affiliated companies comply with the rules and sanctions if a company violates the rules. The Promotion Code, which deals with advertising and communication to healthcare professionals, is the most comprehensive set of rules and the code ENLI spends most of its resources on monitoring.

3.1. Notification obligation

According to the Promotion Code, pharmaceutical companies are obliged to submit a notification to ENLI about

1) Events where a pharmaceutical company is the organiser or co-organiser, and the event is wholly or partly aimed at Danish healthcare professionals.
2) Events where a pharmaceutical company, without being an organiser or co-organiser, provides financial (sponsor) support for a so-called third-party event that is wholly or partly aimed at Danish healthcare professionals or for Danish healthcare professionals' participation in the same.
3) Events where the pharmaceutical company buys an exhibition stand at a congress in Denmark.
4) All forms of promotional material about medicines targeted at healthcare professionals on the Danish market.

The Investigator Panel checks that pharmaceutical companies comply with the rules through the activities that are reported. The control is carried out through random checks, where the notified events or advertisements are assessed based on whether they comply with the applicable rules.

Notification of the above activities is done at www.enli.dk. The website also contains a guide to the reporting system itself, which shows how to create a user, ect.

3.2. Help for reporting activities

To help companies, including new employees, with a better procedure and consideration of activities' compliance with the rules, ENLI has checklists on the website in a manageable form, so that companies can ensure, in the assessment of a given activity, that they have been through relevant and essential considerations.

The checklists are available in both Danish and English at www.enli.dk.

3.3. Cases of ENLI's own initiative

The Investigator Panel can initiate a case against an affiliated company on its own initiative if there is reason to do so, e.g. cases that have been covered in the press or that others have brought to its attention. Here it is not only the Promotion Code that is looked at, but also ENLI's other codes.

3.4. Complaints

Moreover, there is a possibility to file a complaint about the activities of an affiliated company. Those entitled to complain are:

a) Companies subject to ENLI's control
b) Authorities

c) Healthcare professionals
d) Others with a significant and recognisable interest in the matter

3.5. Pre-approvals

A company subject to ENLI's control may, upon payment of a fee, request a pre-approval from the Investigator Panel for any activity subject to the rules. This pre-approval is valid if the company does not subsequently change the format, content, etc. of the activity.

It may be particularly relevant to request a pre-approval if, for example, you want to launch a new medicine or new results and are in doubt about key elements of the promotional material or event. In this case, it will be possible to submit the material to ENLI for closer scrutiny.

3.6. Consultation

If a case is initiated against a company, the Investigation Panel writes a consultation letter. This contains, among other things, information about the parties to the case, the background to the case/complaint, an indication of what violations may be involved with reference to the relevant provisions of the rules, an explanation of why the conduct in question may constitute a violation of the rules, conclusion and recommendation of sanction.

3.7. Time limits

A maximum of 10 working days must pass from the time the Investigator Panel receives a notification or complaint until the respondent company receives a consultation letter (in urgent cases, the consultation letter must be sent immediately, i.e. maximum two working days).

Once the company receives the consultation letter, the company can submit a response to the hearing. The company must ensure that it contains the information that the company considers relevant to the case. The deadline for this (the consultation deadline) is normally ten working days after receipt of the consultation letter. In urgent cases, however, the deadline is four working days.

Once the written hearing has been completed, the Investigator Panel will make a decision on the case. This is done no later than ten working days after the Investigator Panel has received the last hearing response. In the case of an urgent case, the decision will be made immediately (i.e. maximum two working days).

In some cases, the Investigator Panel can make an immediate decision, omitting the hearing phase. This applies when a case is raised on the basis of a random check and the Investigator Panel considers that the case is of such a nature that a consultation letter will have no influence on the outcome of the decision (for example, if the notification was not made on time). In this case, the violation will only result in a reprimand.

3.8. Decision of the case

The final decision made by the Investigation Panel, or the Appeals Board must at least contain specified information on:

a) The parties to the case.
b) Background to the case/complaint.
c) Information on how the case was raised.
d) Exact specification of the rule allegedly violated.
e) Summary of the parties' submissions.
f) Conclusion/decision, including a precise indication of which elements in the case were decisive for the outcome, as well as information about any sanction.
g) Standard appeal instructions, if necessary (does not apply to decisions from the Appeals Board).

The Appeals Board's decisions must also contain the Appeals Board's assessment of the decision made by the Investigator Panel and the content and grounds for the appeal.

In special cases, the Investigator Panel may reopen a case if the Investigator Panel considers that new information may lead to a change in the decision. However, a change in the decision cannot lead to additional or more onerous sanctions.

Similarly, the Appeals Board may in special cases reopen a decided appeal case if the Appeals Board considers that new information may lead to a change in the decision. However, a change in the decision cannot lead to additional or more onerous sanctions.

3.9. Sanctions

If an affiliated company violates the rules, ENLI can impose a sanction in the form of a reprimand, a fine or a public reprimand of the company. Fines are given in the range of DKK 45,000 - 200,000.

The above can be doubled in the event of a repeat offense within 2 years - but max. 400,000 DKK.

ENLI can also order a pharmaceutical company to:

1) Correct incorrect information (cases concerning medical information material)
2) Recall illegal promotional material
3) Refrain from using unlawful promotional material
4) Issue a corrective statement, e.g. an order to place an advertisement in professional journals
5) Cancel or change a planned event (conferences, courses, etc.), including support for such an event or healthcare professionals' participation in it.

3.10. Appeal

If a company disagrees with the decision of the Investigator Panel, the specific decision can be appealed to the Appeals Board. This also applies to complaints and refusals of pre-approvals. The deadline for appeals is 21 working days after the company's receipt of the Investigator Panel's decision.

If the Appeals Board considers that a case has not been handled correctly by the Investigator Panel, or that new relevant facts have been presented for the material assessment of the case, the Appeals Board can refer the case back for reconsideration.

3.11. Publication of decisions

Decisions where companies are sanctioned are published on ENLI's website. Here the decision is published in its full form, including the name of the company. This happens regardless of the type of sanction imposed on the company. However, individuals' names are not published.

For decisions that only concern breach of the notification obligation and breach of Art. 21 (8) of the Promotion Code (regarding what information must be provided in invitations to healthcare professionals), and where only reprimands are used, the decision is published without the company name.

4. Affiliation with ENLI

Pharmaceutical companies that are already members of one of the three associations Lif, IGL or FPM are automatically affiliated with ENLI and are thus fully obliged to act in accordance with the overall set of rules.

In addition, other pharmaceutical companies have the opportunity to be affiliated with ENLI's authority, without having to be a member of a trade organisation. By joining ENLI, companies

are fully obliged to act in accordance with the overall set of rules, just as members of one of the three associations are.

4.1. Process for affiliation

If a pharmaceutical company wishes to be affiliated with ENLI, they must contact ENLI's secretariat with the following information

- Company name
- CVR number or VAT number (for foreign companies)
- Company address
- Contact details (incl. telephone and e-mail)
- The desired date for affiliation

ENLI will then send an agreement, which must be signed and returned to the secretariat.

When the pharmaceutical company is affiliated with ENLI, the company's name will appear at www.enli.dk in ENLI's overview of affiliated companies.

4.2. Process for changing or withdrawing from ENLI affiliation

An affiliated company may withdraw from the agreement on affiliation with ENLI with six months' notice to the end of a month, after which the company is no longer subject to ENLI's authority.

However, pharmaceutical companies that have cases pending before ENLI at the time of withdrawal are subject to ENLI's authority in the specific case until a final decision has been made and any fine paid.

Pharmaceutical companies that are subject to ENLI's authority as a result of membership of an affiliated organisation cannot withdraw from ENLI unless they also withdraw from the affiliated organisation.

5. Fees

ENLI's operations are primarily financed through activity-based fees (such as notification fees and pre-approval fees) and secondarily through fines.

The applicable fees for joining, notification, complaints, etc. can be seen at any time in the Sanctions and Fee Regulations for ENLI, which can be found at www.enli.dk.

Companies that are affiliated with ENLI without being a member of one of the three trade organisations that are part of ENLI's steering group pay an annual affiliation fee. In 2026, the fee is DKK 23,500 + VAT.

Other fees for notification of activities to ENLI, requests for pre-assessments, complaints and appeals apply to all affiliated companies.

6. Compliance is a mindset and is more than just rules

Compliance is not only whether something is "legal" or not. One also has to consider the signal value and the industry's reputation.

It is stated in the purpose provisions of ENLI's code that pharmaceutical companies must maintain high ethical standards at all times. Companies' activities must never be of such a nature that they bring the pharmaceutical industry into disrepute, reduce confidence in it, or cause offense.

In practice, this means that even if something is legal, you still need to consider whether it would be a good idea to carry out the activity in relation to the signal value.

The vast majority of companies have adopted compliance as a company-wide mindset, but some companies still have compliance as a function for one or two employees. Of course, it is useful for the company to have someone who knows the compliance rules and can guide the

rest of the company, but it can also be vulnerable when an experienced compliance employee leaves the company.

ENLI's secretariat is ready to provide guidance every day by phone and email and can thus see when companies change staff in the compliance functions. For some companies, a high level of compliance is directly related to the person who held the position. The secretariat therefore sees an increasing number of inquiries when an important employee leaves. And that's what the secretariat's guidance is for, among other things. Problems may arise if (new) employees are not aware of the possibility of guidance from ENLI or are not properly familiarised with the rules. This can lead to some unfortunate cases if you are not familiar with the practice and rules.

So please use the secretariat for guidance - and make sure that (new) employees are familiar with ENLI's rules and practices. You can also use checklists and guides from ENLI's website.

7. Stay informed

7.1. Newsletters and news on ENLI's website

ENLI sends out 4-6 newsletters a year, informing about any new practice, including decisions that are not published (requests for prior approvals), answers to questions received in the secretariat, information about updated or new guidelines, etc. To subscribe to newsletters, please send an email to sekretariat@enli.dk.

ENLI publishes new decisions at the beginning of each month, as well as appeals board decisions. In addition, the website is regularly updated with e.g. updated guidelines etc. If you want to stay informed about what's new on ENLI's website, you can sign up for "news on the website" by sending an email to sekretariat@enli.dk.

7.2. Courses in ENLI's rules are offered by Atrium

Atrium regularly holds courses on marketing compliance, where both lawyers and doctors from ENLIs Investigator Panel teach. 2-4 basic courses in the advertising rules are held each year, as well as a course for the more experienced in compliance. In addition, Atrium offers customised courses directly to the individual companies, where ENLI's lawyers teach the rules in the various ENLI codes. For more information about compliance training, please visit www.atriumcph.com.

8. Contact ENLI

ENLI can be contacted every weekday between 9-15 on telephone +45 3920 2575.

Inquiries can also be made at sekretariat@enli.dk