

# Country Code Update Denmark IPCAA

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# AGENDA

- Structure of ENLI
- Meeting venues – according to the Danish Code
- Interactions with HCP's and sponsorships at congresses
- International congresses in Denmark – how to get help
- Questions from participants



## *Structure of ENLI*



# Who is ENLI?

The Ethical Committee for the Pharmaceutical Industry was established 1 April 2011 as a replacement of the former self-regulation board.

Self-regulation boards (industry-inspection body) since 1973

- ENLI is established by the Pharma-industry:
  - Pharmaceutical Industry Association (Lif)
  - Industrial Association for Generic and Bioactive Medicines (IGL)
  - Parallel Importer Association
  - In addition, a number of individual companies are affiliated with ENLI without being a member of an Industry Association

# Affiliated companies

## Lifs members

Abb-Vie A/S  
ALK-Abelló A/S  
ALK-Abelló Nordic A/S  
Almirall Nordic Countries  
AMGEN AB  
Astellas Pharma  
AstraZeneca A/S  
Bayer A/S  
Biogen A/S  
Boehringer Ingelheim Danmark A/S  
Bristol Myers Squibb  
Chiesi Pharma AB  
Daiichi Sankyo  
Eisai AB  
Eli Lilly Danmark A/S  
Ferring Lægemidler A/S  
Fertin Pharma A/S  
Galderma Nordic  
GlaxoSmithKline Pharma  
GlaxoSmithKline Healthcare  
Grünenthal Danmark ApS  
IBSA Nordic ApS  
Janssen-Cilag A/S  
Kyowa Kirin AB  
LEO Pharma A/S  
Lundbeck Pharma A/S  
H. Lundbeck A/S  
Merck A/S  
(Merck Serono)  
MSD Danmark ApS  
Mundipharma A/S  
Novartis Healthcare A/S  
Novo Nordisk A/S  
Novo Nordisk Scandinavia AB  
Otsuka Pharma Scandinavia AB  
Pfizer ApS  
Pfizer PFE ApS  
Roche A/S  
Sanofi-Aventis Danmark A/S  
(herunder Genzyme, a Sanofi Company)  
Shire Denmark A/S  
SmartPractice Denmark ApS  
Takeda Pharma A/S  
UCB Nordic A/S

## IGLs members

2care4 Generics ApS  
Accord Healthcare AB  
Aristo Pharma Nordic ApS  
Bluefish Pharmaceuticals AB  
EQL Pharma AB  
Glenmark Pharmaceuticals Nordic AB  
Mylan Denmark ApS  
Orifarm Generics A/S  
Orion Pharma A/S  
Sandoz A/S  
STADA Nordic A/S  
Stragen Nordic A/S  
Teva Danmark

## Parallelimporters of medicine

2care4 ApS  
Abacus Medicine A/S  
Orifarm A/S

## Associations affiliated with ENLI

Megros

## Affiliated companies

Akcea Therapeutics UK Ltd.  
Alexion Pharma Nordics  
Alnylam Sweden AB  
Amicus Therapeutics  
Amryt Pharmaceuticals DAC

AveXis Switzerland GmbH  
Azanta Danmark A/S  
BioMarin Europe Ltd.  
Camurus AB  
CLS Behring ApS  
Covis Pharma B.V.  
FrostPharma AB  
Gedeon Richter Nordics AB  
Gilead Sciences Denmark ApS  
Indivior Nordics ApS  
Institut Produits Synthèse (IPSEN)  
Jazz Pharmaceuticals Denmark ApS  
Macure Pharma ApS  
Nordic Drugs Danmark  
Nordicinfu Care AB  
Norgine Danmark A/S  
Octapharma Nordic AB  
Pierre Fabre Pharma Norden AB  
Portola Netherlands B.V.  
Recordati AB  
Servier Danmark A/S  
Spectrum Therapeutics  
Sunovion Pharmaceuticals Europe Ltd.  
Tillots Pharma AB  
Unimedica Pharma AB  
Vifor Pharma Nordiska AB  
Zambon Sweden



## **Investigator Panel**

- Exercises control – casework/decisions/sanctioning
- Provides information and advice about the rules
  - 3 legal investigators & 3 medical investigators



## **The Board of Appeal**

- The Board of Appeal process appeals from 1. instance
- 3 members (Lawyer, Doctor and a former senior employee in the pharmaceutical industry)

# Cases

- Affiliated companies are obligated to report to ENLI:
  - 1) Promotional material
  - 2) Promotional Events
  - 3) Sponsorships
  - 4) Exhibitions=> Randomized control
- Complaints
- Pre-Approval
- ENLI initiative
- Appeal



# Complaints

- Entitled to complain:
  - 1) Pharmaceutical companies affiliated with ENLI
  - 2) Authorities
  - 3) Healthcare Professionals
  - 4) Others with a significant and commendable interest in the case
  
- Complaints often regard activities that have already taken place
  
- Usually a fee of DKK 6.000 is to be paid when filing a complaint



ENLI can impose the following sanctions (e.g.):

- Reprimands - to the company or in public
- Fine penalty
  - DKK 30.000 - 150.000 DKK
  - Double penalty for repeated violations of similar offence within 2 years
- Stop violating activity
- Correcting violating activity
  
- All decisions, in which a pharmaceutical company is found in breach of the rules, are published on ENLI's website

# All codes and guides: www.enli.dk/en

About ENLI



**Rules**



- The Promotion Code
- The Patient Organizations Code
- The Donation Code
- Ethical rules for pharmaceutical companies' relations with the Danish hospital sector
- Ethical rules for dialogue and negotiations with decision-makers
- Guide regarding use of digital media
- Guide - international congresses in Denmark
- Guide regarding pre-launch
- Guidance on Market research
- Other rules
- Guidance on reporting a case to ENLI

Thresholds for meals & drinks

## Rules



### Etiske regler for lægemiddellærere (Donations)

**Præambel**  
Lægemiddelindustriens faglige og videnskabelige den organisation støtter initiativer, som resulterer i en om, at samspillet mellem lægemiddellærere og om, at samspillet mellem lægemiddellærere og hospitaler, Institut samtidig sikrer lærebøger om lægemiddelindustrien

**KAPITEL 1 - Donationer og tilskud til sundheds**

**§ 1**  
Donationer, tilskud og forbehold i form af naturlige sundhedspersoner og/eller påvirkende aktiviteter skal afregnes underlagt ENLI's kontrol

a) de jules med det formål at støtte faglige b) de dokumenteres og registreres af donor c) de ikke udgør en betingelse til at udføre specifikke lægemidler.

### KAPITEL 2 : Donationer og tilskud til hospitaler

**§ 2**  
Kapitel 2 omfatter donationer og tilskud, som i

**§ 3**  
Nærværende regelsæt regulerer ikke lægen deltagelse i nationale eller internationale an jernbevillingskommissioner, som er en forskning eller udførelse af informationer omherald allerede er registreret andet sted af herunder Lægemiddelindustriens kodeks sundhedspersoner (Reklamekodeks).

**§ 4**  
Nærværende regelsæt definerer "tilskud" projekter, aktiviteter, udbyr, indberet til etats eller naturlige personer.

### Etiske regler for lægemiddellærere danske sygehus

**Præambel**  
Et vellykket samarbejde mellem de i for gennemførelsen af kliniske forsøg, en om nye lægemidler og deres anvendelse handling.

For at sikre et fagligt grundlag af de danske sygehuse, må der ikke komme i tvivl, der er nødvendigt for den fortsatte gen.

Således er et samarbejde mellem de i industri kan bringe nye innovative læge faglig, fordelagtige samarbejdsrelationer sikring af virkningerne af de pågæld samarbejde mellem lægemiddellærere

Lægemiddellærere har derfor adgang til information om i samarbejde med sygehuset til gavn for pa

Lægemiddellærere har derfor adgang til information om deres lægemidler og deres a

**Formål**  
Dette etiske regelsæt skal medvirke til kontakten til danske sygehuse i forbindelse

Reguleringen er udarbejdet af arbejdsgruppen regulerer samarbejde mellem de

**Eksisterende regelsæt**  
Lægemiddellærere reguleres med dag overholde en lang række nationale den danske lægemiddelindustri.

### Etiske regler for dialog og forhandlinger (Lobbykod)

**Formål**  
§ 1  
Lægemiddellærere er involveret i dialog og der med det formål at optimere patientens fald for at sikre patientens og borgers adgang til nye

De etiske regler sikrer en ramme for dialogen læge/sundhedsprofession, således at dialogen altid for måde. De etiske regler skal samtidig sikre, at den, og at samarbejde og dialogen altid fore mellem er uafbrudt.

**Definitioner**  
§ 2  
I disse etiske regler gælder følgende:

a) Ved "syndeholdsansvar" forstås personerne, der Regulerings, Kommunikationsafdeling (af af ligs).

b) Ved "syndeholdsansvar" forstås faglig myndighed, der har myndigt

1. ministerielle departementer, s råd og nævn osv., som er lovm 2. foreningerne i regulerings og lov 3. en række private foreninger te er en del af den offentlige de Regulerings og Kommission 4. EU-Kommissionen eller øvr

c) Ved "teknologiprogram" forstås b).

d) Ved "lægemiddellærere" forstås reguleringsgruppen.

ENLI's guide om brug af digitale n i reklameaktiviteter

Etisk Nævn for Lægemiddelindustrien (ENLI)

NB! Du kan søge i guiden ved at trykke "Ctrl + F" og indtaste dit søgeord

## *Meeting venues*



# Meeting venues

## ➤ Venues

- *Section 13.10. Pharmaceutical companies must avoid using venues, which are known for their entertainment facilities or are extravagant and/or luxurious.*

Basically:

- 5-star hotels, gourmet restaurants (Michelin stars)
- Castles, Mansions, Estates, Golf Hotels/Ressorts, Skiing and beach Hotels/Ressorts (in season), boats etc.

# *“General reputation”*

## ENLI:

- Independent quality ratings and other similar publicly available information, such as reviews in various newspapers, journals and other publicly available communications forums
- In principle, ENLI does not look at:
  - Subjective reviews on Tripadvisor, Facebook etc.
  - Meeting venues' marketing

# ” *General reputation* ”

## ENLI:

- On bookingsites as Trivago.com, Booking.com and on VisitDenmark’s web-page you can see how hotels are rated
  - Contribution to the overall assessment of how the venue appears in general reputation.
  - However, the overall assessment of the venue's reputation - not the rating alone - remains crucial.

# Choosing a venue

## What to do?

- Search online
- Check if the venue is luxurious in general reputation
- Visit relevant booking sites and other websites that have mentioned the venue to check for “general reputation”
- Remember, there is a difference between subjective and objective assessments
- Make sure that your collaborative partners know the Danish rules
- Remember to justify your choice of venue

*If in doubt – call/write ENLI or apply for pre-approval (note – pre-approvals only available for affiliated pharma companies)*

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# *Interactions with HCPs and sponsorships at congresses*





# Sponsorships

- The Pharmaceutical Industry in Denmark can provide sponsorships for both
  - Professional events organized by a third party, and
  - HCP participation in professional events, e.g. international congress'

# Remember

## ➤ No indirect/hidden sponsorships!

- *Pharmaceutical companies can give or offer a healthcare professional training and professional information in the form of **payment of direct expenses in connection with professional relevant courses, conferences, training etc.**, in which the healthcare professionals participate or arrange. In these activities, pharmaceutical information or other professional relevant information, relevant for the participants, must be included.*
- *Sponsorship agreements should clearly describe which activities the sponsorship may be used for*

# Remember

- Exhibition stands – commercial area
  - All activities on the exhibition stand must comply with the advertising rules (Danish legislation, ENLI code)
  - No advertising Rx-products to the public – thus no patients are allowed at exhibition stands/booths
  
- For further regarding patients at congresses, please contact the Danish Medicines Agency:
  - [dkma@dkma.dk](mailto:dkma@dkma.dk) or +45 4488 9595

*International congresses in Denmark  
– how to get help*

About ENLI +

Rules -

The Promotion Code

The Patient Organizations Code

The Donation Code

Ethical rules for pharmaceutical companies' relations with the Danish hospital sector

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Guide regarding pre-launch

Guidance on Market research

Other rules

Guidance on reporting a case to ENLI

Thresholds for meals & drinks

Case management, penalties and fees

Deadlines

Collaboration with the Danish Regions +

## Guide - international congresses in Denmark

Guide - international congresses in Denmark.



# *Questions/Perspectives/Challenges?*

