Country Code Update
Denmark
IPCAA

Head of Secretariat
Rikke B. Thomassen
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  
Daiichi Sankyo  
Eisai AB  
Eli Lilly Danmark A/S  
Ferring Lægemidler A/S  
Fertin Pharma A/S  
Galderma  
GlaxoSmithKline  
H. Lundbeck A/S  
Lundbeck Pharma A/S  
M. 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 Danmark 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

As of February 1st, 2020
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
Sanctions

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

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
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.
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
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)
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 or +45 4488 9595
International congresses in Denmark
– how to get help
Guide - international congresses in Denmark
Questions/Perspectives/Challenges?