

Summary on pharma sales force regulation in Scandinavia

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Sources used:

Internet, regulations published by associations of pharmaceutical industry

Question:

Summary slide describing the regulation/rules on interaction of pharmaceutical sales representatives with physicians/hospitals in Denmark, Finland and Norway.

Budget needed: 2,5 hours = 250.- € / other expenses: none



Regulation

Lif's ethical rules for pharmaceutical companies' relations with the Danish hospital sector, 23/2/2010

Meetings with health professionals

- There are currently **no specific sets of ethical rules for pharmaceutical companies' employees** and their relations with the wards of and individuals in Danish hospitals.
- The **present ethical rules focus on product information and the training/ instruction process** of which the companies' products are a natural, integral part.

Ethical Code

- § 1. Visits by pharmaceutical companies to hospitals wards shall be **arranged in advance**, heads of department shall be notified if designated.
Calls and meetings shall be based on pre-advised, agreed subjects.
- § 2. Meeting shall have a scientific, informative and/or educational/ instructional purpose and interaction shall be based on a common understanding of mutual trust, recognition and respect.
- § 3. Companies' information on hospital-specific drugs shall be appropriately scientifically based and endeavours shall be made for evidence-based use in clinical practice.
- § 4. Hospital management must be informed in advance of studies by the company (for example clinical trials and non-intervention trials).

Lif: Danish Association of the Pharmaceutical Industry (Lægemedelindustriforeningen)



Monitoring Authority

Pharma Industry Finland (PIF) and Association of Finnish Local and Regional Authorities.

Regulation

PIF „Code for the Good Medical Sales Representation Practices”
Code of Ethics 2008, § 38-44, page 12-14

Ethical Code

- 38 § definition and objective of medical sales representations.
- 39 § ultimate decision on meeting is taken by the healthcare unit
- 40 § meeting must be fitted in the working day of the healthcare unit
- 41 § meetings related to Rx-medicines only at persons entitled to prescribe or dispense such medicines
- 42 §
 - a) medical sales representative must have RLE or ILE diploma
 - b) meetings must be based on advance agreements
 - c) healthcare unit compiles clear instructions regarding the booking procedure
 - d) meeting taking place in the healthcare unit premises must be arranged in the physician’s consulting room,
 - e) reasonable time must be reserved
 - f) medical sales representatives must focus primarily on the medicinal product scheduled
 - g) information about the product must correspond to the latest summary of product characteristics
 - h) hospitality offered at events must be reasonable
 - i) Free samples (smallest package size) are allowed for authorized persons

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Monitoring Authority

NMA's and LMI's Joint Committee for Information on Medicinal Products
Members of the Association of the Pharmaceutical Industry in Norway have a duty to provide the Secretariat with all information and promotional material used in marketing

Regulation

LMI „Rules for Marketing of Medicinal Products”
amendments 14/3/2011 (no changes to the amendments of 31/3/2009)

Meetings with health professionals

- As a general rule, sales representatives from the pharmaceutical industry should hold **meetings with groups of health professionals**.
This does not preclude meetings with individual health professionals for practical reasons.
- The representatives shall ensure that those meetings are provided with the SPCs of all products presented.
- Hospitality shall be **reasonable**.
- Accompanying persons and social activities are prohibited.
- Only gifts of **insignificant value** are allowed.
- A **limited** number of free samples can be given to qualified persons.

Transparency

Requests for appointments with health professionals must never be presented in such a way that the real intent is disguised.

LMI: Association of the Pharmaceutical Industry in Norway (Legemiddelindustriforeningen LMI)

NMA: Norwegian Medical Association

SPC: summary of product characteristics