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## **Lif's ethical rules for pharmaceutical companies' relations with the Danish hospital sector**

### **Preamble**

Good relations between the Danish hospitals and the pharmaceutical companies are crucial for the conduct of clinical trials, setting up quality assurance studies, disseminating information on new drugs and their use and other activities aimed at supporting better treatment for patients.

In order to ensure a good professional basis for relations between the pharmaceutical industry and the Danish hospitals, there must be no doubts as to the exchange of knowledge and dialogue between the parties that is essential for continuing development of new drugs that improve the treatment of patients.

Collaboration on clinical research is essential for the researching pharmaceutical industry to bring new innovative drugs to the market. The use of drugs in day-to-day clinical routines, prior education and training activities for the use of certain new drugs and ongoing monitoring of the effects of the drugs concerned are situations that require close collaboration between the pharmaceutical companies and the Danish hospitals.

Communication activities by the pharmaceutical companies are aimed at ensuring that health professionals have easy, flexible access to information on drugs and their use so that drugs are used appropriately for the benefit of patients.

The pharmaceutical companies therefore have an obligation and a responsibility to produce precise information on their drugs and their use.

### **Purpose**

This set of ethical rules is aimed at ensuring high ethical standards for contacts by the pharmaceutical companies with the Danish hospitals associated with information on drugs.

These rules are aimed at activities associated with product information and training /instruction. These rules accordingly supplement the various agreements on clinical trials, non-intervention trials, etc., that currently regulate relations between the pharmaceutical companies and health professionals.

## Existing rules

Several collaboration agreements have been made between healthcare professionals and pharmaceutical companies that cover various circumstances. The aim of these agreements is to ensure high ethical standards in relations so that the use of drugs in the Danish health service is solely based on medical assessments of individual patients.

The ethical rules are therefore aimed at ensuring that relations between pharmaceutical companies and health professionals are on a transparent and credible basis so that the parties are not inappropriately interdependent.

Members of the Danish Association of the Pharmaceutical Industry have signed up to a series of sets of ethical rules and are therefore currently required to comply with a whole range of national and international rules that are stricter in certain areas than those set forth in Danish legislation.

The following national rules apply:

- The joint collaboration agreement on the terms and conditions for collaborations between doctors and pharmacists and pharmaceutical companies;
- The collaboration agreement between the Danish Medical Association and the Danish Association of the Pharmaceutical Industry on clinical trials,
- The current applicable rules and practices of the Ethical Committee for the Pharmaceutical Industry (ENLI)

The Danish Association of the Pharmaceutical Industry is required by virtue of its membership of international organisations to implement international codes with respect to its members. These include:

- EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals, ("EFPIA Code");
- IFPMA Code on Pharmaceutical Marketing Practices.

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.

Relations between the pharmaceutical companies and the Danish hospitals are on several levels that all play an important role in relations.

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 for pharmaceutical companies' contacts with Danish hospitals.

Pharmaceutical companies' contacts with hospital wards, etc., must be aimed at ensuring a better basis for using drugs in Danish hospitals and hence for the benefit of Danish



patients.

On this basis, the ethical code is specified as follows:

Art. 1. Visits by pharmaceutical companies to hospital wards or meetings with individuals and hospitals shall be arranged in advance with the relevant persons. Calls and meetings shall be based on pre-advised, agreed subjects.

Art. 2. The purpose of companies' interaction with hospital wards or individuals 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.

Art. 3. Companies' information on hospital-specific drugs shall be appropriately scientifically based and endeavours shall be made for evidence-based use in clinical practice.

Art. 4. Companies shall ensure that hospital management is informed in advance of studies being implemented at the hospital initiated by the company (for example clinical trials and non-intervention trials).