Ethical Rules for Collaboration between Patient Groups, etc. and the Pharmaceutical Industry

1. Purpose

The ethical rules create a framework for collaboration between the pharmaceutical industry and patient groups, etc. in order to ensure that such collaboration always takes place in an open and credible manner. The ethical rules should leave no doubt about the independence of the parties. Collaboration between the parties should always be conducted in such a way as to exclude any possibility of pressure or dependency.

2. Scope of the ethical rules

a. The ethical rules are a set of minimum rules that are binding on the members that are subject to ENLI's (The Ethical Committee for the Pharmaceutical Industry) control. Some pharmaceutical companies have their own ethical rules for collaboration which should be regarded as supplementing these ethical rules.

b. The ethical rules apply to collaboration with all organisations working with patient related issues (patient groups) and health-related issues (e.g. the Danish Mental Health Fund), as well as other organisations working to promote consumer interests (e.g. the DaneAge Association and the Danish Consumer Council). In these ethical rules, such bodies are collectively referred to as "organisations".

c. If the headquarters of a pharmaceutical company organises an international collaboration project in Denmark, the Danish subsidiary must ensure that the ethical rules are respected. However, if the company has its headquarters in Denmark, this obligation rests with the headquarters. If a Danish parent company or subsidiary collaborates with a Danish organisation in connection with an event taking place abroad, the company must still comply with the Danish ethical rules.

d. If an external agency (e.g. a PR or advertising agency) is used in connection with a collaboration project, it is the responsibility of the pharmaceutical company to ensure compliance with the ethical rules.

e. The ethical rules have been laid down by the pharmaceutical industry alone and are binding on the companies that are subject to ENLI's control only. No mutually binding collaboration agreements have been concluded with patient groups or other organisations.

3. Disclosure

a. All agreements concerning funding must be clear and in writing. At the very least, agreements must specify the following:

   1) Name of the collaboration project,
   2) Names of the parties to the agreement (pharmaceutical companies, organisations and any third parties),
   3) Types of project (i.e. whether the agreement relates to general operating grants, specific meetings, sponsorships, leaflets, information campaigns, training programmes, travel, etc.),
   4) Purpose,
   5) Roles of the parties in the project,
   6) Timeframe,
   7) Size of the financial support given and what it is to be used for,
   8) Scope and content of non-financial support. (Non-financial support of a significant amount that cannot be calculated as a meaningful financial value shall include a description that clearly account for the non-monetary benefit which the organisation receives).

b. Agreements containing the above information at the very least shall always be published on the websites of the pharmaceutical companies in order to prevent notions of unfortunate links between the pharmaceutical industry and organisations. Agreements must be disclosed at the time when the agreement is made and must be accessible for at least six months after the termination of the collaboration project.

c. Pharmaceutical companies should encourage organisations also to publish agreements on their websites (if any). If this is not done, the written agreement should specifically state that the organisation does not wish for this.

d. Copies of the agreements should be made available upon specific request. This also applies to agreements on previous and terminated collaboration projects that are no longer available on the pharmaceutical company's website. However, this requirement shall not apply to collaboration that expired more than 10 years previously. This requirement applies to agreements made after April 1, 2007.

e. Once a year, Lif's member companies shall furnish Lif with lists of their collaboration projects, including the information listed under item 3 a. Lists must be submitted by the end of each calendar year and will be published on Lif's website.

4. Contratced services

a. Contracts between companies and organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

b. It is permitted to engage organisations as experts and advisors for services such as participation at advisory board meetings and/or speaker services. The arrangements that cover consultancy or other services must fulfil the following criteria:

1) A written contract is agreed in advance which specifies the nature of the services to be provided and the basis for payment of those services;

2) A legitimate need for the services has been clearly identified and documented in advance of the company requesting the services and entering into the arrangement;

3) The company's criteria for selecting services are directly related to the identified need of the company. The persons in the company who is responsible for selecting a specific service must have the expertise necessary to evaluate whether the particular expert(s) or advisor(s) from the wished organisation meet(s) those criteria;

4) The extent of the service is not greater than is reasonably necessary to achieve the identified need;

5) The contracting company maintains records concerning, and makes appropriate use of, the services;

6) The engaging of the organisations shall not include any obligation or inducement to recommend a particular medicinal product;

7) The compensation for the services is reasonable and does not exceed the fair market value of the services provided. In this regard, consultancy arrangements must not be used as general financial support to the organisation;

8) In their written contracts with organisations, companies are strongly encouraged to include provisions regarding an obligation of the organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the service or any other issue relating to that company;

9) Each company must make publicly available an annual list of organisations that it has engaged to provide paid-for services. The list shall include a description of the provided service. In this connection the company shall publish the total amount that the company has paid each organisation during the year. The demand enters into force the first time at the end of the first quarter of 2013 (covering activities which are initiated after or are ongoing on January 1, 2012).

5. Independence

a. Financial contributions from the pharmaceutical industry must not be conditional upon the organisation taking specific stands on professional and political issues.

b. The pharmaceutical industry may not, as part of an agreement, require organisations to favour specific products.

c. The pharmaceutical company must never use the organisation's logo or name, or otherwise refer to collaboration with the organisation, except by prior written agreement.

6. Requirements for professional content of events

a. In principle, support may be granted for all activities, projects and purposes within the sphere of the organisation's work.

b. Professional activities should always be at the core of the collaboration. There must be a reasonable relationship between the support/services provided and received.

c. Events organised or sponsored by, or on behalf of, companies shall be held at 'suitable' locations that contribute to the main purpose of events and which are not known for their entertainment facilities or are not too extravagant.

d. Catering and hospitality associated with events shall be limited to expenses for transport, meals, overnight accommodation and fees for participation. All forms catering and hospitality shall be reasonable in level and strictly limited to the purpose of the event. In connection with events the company's hospitality shall not include sponsoring or organising entertainment (e.g. sporting, culture, music or leisure events).

e. Catering and hospitality may only be offered to persons who qualify as participant in their own right. In exceptional cases catering and hospitality of an accompanying person who meets health/supporting/caring needs (e.g. as carer) can be provided.

f. As a general rule, a company shall not organise or sponsor an event abroad except when:

- The majority of attendees are from abroad and as a result, it makes better logistical sense for the event to be held in another country or

- The location of the relevant resources or expertise involved in the event means that holding it in another country makes better logistical sense.

7. Drug information and advertising

In connection with financial support for or collaboration with organisations, pharmaceutical companies must always ensure that activities do not contravene statutory regulations on drug information and advertising as stated in the EU Advertising Directive, the advertising provisions of the Danish Medicines Act, and the Executive Order on advertising to the public – as well as internal industry guidelines.

8. Exclusive agreements

No exclusive agreements may be made. Organisations are thus always free to collaborate with several pharmaceutical companies, and likewise pharmaceutical companies may collaborate with one or several organisations. Exclusivity must not in any way be a requirement for collaboration on specific product areas or therapeutic areas, although the parties may have a primary collaboration partner.

9. Competence

a. In order to avoid suspicion of unfortunate dependency, agreements may not be made for issues where the competence or independence of the parties may be open to challenge.

b. The pharmaceutical company must always ensure that employees or elected representatives of the organisation only perform tasks for the pharmaceutical company if this has been reported to a superior or another executive within the organisation.

c. Employees of the pharmaceutical industry should not hold positions of trust within organisations unless it is evident that there is no conflict of interest.

These rules took effect on April 1, 2007 and were amended on March 26, 2008 and January 1, 2012.