



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

1. Purpose

The ethical rules create a framework for collaboration between the pharmaceutical industry and patient associations, 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. The collaboration between the parties should always be conducted in such a way that all possibility of pressure or dependency is excluded.

2. Scope of the ethical rules

- a. The ethical rules are a set of minimum rules that are binding on Lif members. Some pharmaceutical companies have their own ethical rules for collaboration, which should be seen as a supplement to these ethical rules.
- b. The ethical rules apply to collaboration with all organisations working with patient-related issues (patient associations) 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 that the ethical rules are complied with.



- e. The ethical rules have been laid down by the pharmaceutical industry alone and are binding on Lif members only. No mutually binding collaboration agreements have been concluded with patient associations or other organisations.

3. Publication

- a. All agreements concerning support must be clear and in writing. As a minimum, the 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 projects (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.
- b. The agreements – containing the above information as a minimum – must always be published at the websites of the pharmaceutical companies in order to prevent notions of unfortunate links between the pharmaceutical industry and organisations. Publication must take place at the time when the agreement is concluded, and the agreement must be accessible for at least six months after the termination of the collaboration project.
- c. The pharmaceutical companies should encourage the organisations also to publish the agreements at their websites (if any). If this request is not met, the written agreement should specifically state that the organisation does not wish to do so.
- d. Copies of the agreements should be handed out upon specific request. This also applies to agreements concerning previous and terminated collaboration projects that are no longer available at the pharmaceutical company's website. However, this requirement does not apply to collaboration that expired more than 10 years previously. This requirement applies to agreements concluded after 1 April 2007.
- e. Once a year, the pharmaceutical companies must 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 at Lif's website.



4. Independence

- a. Financial contributions from the pharmaceutical industry must not be conditional upon the organisation taking specific stands in relation to professional and political issues.
- b. The pharmaceutical industry may not, as part of an agreement, require that the organisations favour specific products.
- c. The pharmaceutical company must never use the organisation's logo or name, or otherwise refer to the collaboration with the organisation, except by prior written agreement.

5. Content requirements

- 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.

6. Drug information and advertising

In connection with financial support for or collaboration with organisations, pharmaceutical companies must always ensure that the activities do not take place contrary to the statutory regulations on drug information and advertising, which can be found 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.

7. Exclusive agreements

No exclusive agreements may be concluded. The organisations are thus always free to collaborate with several pharmaceutical companies, and likewise the pharmaceutical companies may collaborate with one or several organisations. Exclusively must not in any way be a requirement in relation to collaboration on specific product areas or therapeutic areas. It is, nevertheless, possible for the parties to have a primary collaboration partner.

8. Competence

- a. In order to avoid suspicion of unfortunate dependency, agreements may not be concluded concerning issues where the competence or independence of the parties can be challenged.



- 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 interests.

Ethical rules effective from April 1, 2007