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

Art. 1. Purpose

The ethical rules provides a framework for collaboration between the pharmaceutical industry and patient organisations, etc. in order to ensure that such collaboration always takes place in an open and credible manner. The purpose of the ethical rules is to ensure that the parties appear to be independent of each other. Collaboration between the parties should always be conducted in such a way as to exclude any possibility of pressure or dependency.

Art. 2. Scope of the ethical rules

a) The ethical rules constitute a set of minimum rules, which oblige the companies that are subject to ENLI's (The Ethical Committee for the Pharmaceutical Industry) jurisdiction. 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 patient organisations, as defined in the Executive Order on Advertising of Medicinal Products section 1, subsection 7[1]. In addition, the ethical rules also applies for collaboration with other organisations working for patient related issues (patient organisations) and health-related issues (e.g. the Danish Mental Health Fund), or other organisations working to promote consumer interests (e.g. the Dane Age Association and the Danish Consumer Council). In the ethical rules, such bodies are collectively referred to as "organisations".

c) If the headquarters of a pharmaceutical company holds 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 on an event located abroad, the company is still obliged to comply with the Danish ethical rules.

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

[1] Executive Order on Advertising of Medicinal Products, cf. ex. Order no. 1153 of 22 October 2014

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

Art. 3 Support for Patient Associations' healthcare services or research

Section 3.01 Support in the form of donations, grants and benefits in kind for patient associations is allowed only if:

(a) they are provided for the purpose of supporting professional activities, including healthcare, research and education;
(b) they are documented and kept on record by the pharmaceutical company; and
(c) they do not constitute an inducive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 3.02. Support in the form of donations, grants and benefits in kind to individuals is not allowed. However, see art. 5 regarding contracted services.

Art. 4. Contract terms and transparency

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. Name of the parties who have entered into the agreement (pharmaceutical companies, organisations and any third parties),
3. Types of projects
4. Purpose of the agreement,
5. Roles of the parties in the project,
6. Timeframe of the project,
7. Size of the financial support given and what it is used for,
8. Scope and content of non-financial support.

b) Agreements – containing the above information must as a minimum always be published on the websites of the pharmaceutical companies in order to prevent notions of unethical links between the pharmaceutical industry and organisations. Agreements must be disclosed at the time when the agreement is concluded and must be available for at least six months after the termination of the collaboration project.

c) Copies of the agreements must be made available upon specific request. This also applies to agreements on previous and terminated collaboration projects, which is no longer available on

the pharmaceutical company's website. However, this requirement shall not apply to collaboration that expired more than 10 years ago. This requirement applies to agreements concluded after 1 April, 2007.

Pharmaceutical companies must once a year submit an overview to ENLI over their collaborative projects, containing the information listed under section 3 (a). The overview must be submitted by the end of each calendar year. ENLI publishes the overviews on its website.

Art 5. Contracted services

a) Contracts between companies and organisations, under which the organisations provide any type of services to companies, are only permitted 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, by involvement in medical/scientific studies, clinical trials or training services, participation in meetings, advisory bodies and in market research, where such participation involve remuneration and/or hospitality. Agreements on this must meet the following criteria:

1. A written contract must be agreed on in advance, which specifies the nature of the services to be provided as well as the basis for payment of those services. In addition, the criteria listed below (sections 2-10), to the extent relevant, must be met:

2. A legitimate need for the services must be clearly identified and documented in advance of the company requesting the services and conclusion of the arrangement.

3. The company's criteria for selecting services must be directly related to the identified needs of the company. The person in the company who is responsible for selecting a specific service must have the expertise necessary to evaluate, whether the particular experts or advisors from the desired organisation meets these criteria.

4. The extent of the service and the retained number of representatives must not exceed what is necessary to achieve the identified needs.

5. The company must maintain records, and make appropriate use, of the service.

6. The arrangement with the organisation must not include any obligation or inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

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

8. Remuneration may only be made in the form of direct payment, and thus not by set-off, transfer of fees or other indirect means.

9. In their written contracts with organisations, companies are encouraged to incorporate provisions, which obliges the organisation to openly declare that they have provided paid services to the company whenever they communicate in public on any matter that is related to the service or other issues related to the company.

10. Companies must annually publish a list of the organisations that they have engaged to provide paid-for services. The list must include a description of the provided service. In this connection, the company must publish the total amount that the company has paid each organisation during the year.

c) Limited market research, such as one-off phone interviews or mail/email/internet questionnaires, may be conducted if the organization/hospital representative is not consulted repeatedly (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal and commensurate with performance, cf. litra b), no. 4 and 7. These researches, etc. must not constitute covert advertising.

d) If a representative of a patient association participates in an event (an international or other event) as a consultant or advisor to the pharmaceutical company, the relevant provisions of Art. 8 shall apply.

Art. 6. Independence

a) Financial contributions from the pharmaceutical industry must not be conditional upon the organisation taking specific stands on professional and political issues. Pharmaceutical companies must ensure that their financial contributions are always clearly acknowledged and apparent from the outset.

b) The pharmaceutical industry must 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 the collaboration with the organisation, except by prior written agreement.

Art. 7 Prohibition against financial benefits and gifts

It is not permitted to hand over, offer or promise representatives from patient associations gifts or financial benefits, either in the form of cash, cash equivalents, personal services or in kind, cf., however, Art. 8.

Art. 8. Professional activities

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 the main intention of the collaboration. Services must be proportionate to the compensatory measures.

c) Events organised or sponsored by or on behalf of pharmaceutical companies must be held at a suitable location that contribute to the main purpose of event, and which is not renowned for their entertainment facilities or is too extravagant.

d) Catering and hospitality associated with events must be limited to expenses for transportation, meals, accommodation and fees for participation. All kinds of catering and hospitality must be reasonable in level and strictly limited to the purpose of the event. As a general rule, the hospitality provided should not exceed the amount that representatives from patient associations would normally be prepared to pay for themselves.

e) In connection with events, the company's hospitality must not include sponsoring or organising entertainment of any kind (e.g. sporting, culture, music or leisure events).

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

g) Pharmaceutical companies may not provide or offer meals (food and beverages) to representatives from patient associations, except in cases where the value of such meals does not exceed one of the following amounts: DKK 400 for lunch, DKK 700 for dinner or DKK 1,200 for dining at all-day meetings/conferences, etc. The meal caps apply to meals in Denmark. For meals in other European countries, the meal caps set by the pharmaceutical industry organizations in these countries apply.

h) No payment must be offered to compensate merely for the time spent by representatives in attending activities referred to in point (a).

i) As a general rule, a company must not organise or sponsor an event abroad, except when:

1. The majority of attendees are from abroad and in the light thereof allows for greater logistical sense to hold the event in another country, or

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

Art. 9. Information on medicinal products and advertising

Section 9.01. In connection with financial support for, or collaboration with, organisations, pharmaceutical companies must always ensure that the activity do not contravene statutory regulations of information on medicinal products and advertising as stated in the EU Advertising Directive, the advertising provisions of the Danish Medicines Act, and the Executive Order on Advertising, etc. of medicinal products– as well as internal industry regulations.

Section 9.02. Companies must not, in the context of a co-sponsorship agreement, influence the content or preparation of patient associations' material in a way that is favourable to their own commercial interests. However, pharmaceutical companies are not prevented from correcting factual inaccuracies. In addition, at the request of patient associations, companies may contribute to the text of a material from a fair and balanced scientific perspective.

Art. 10. Exclusive agreements

No exclusive agreements may be concluded. 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 or therapeutic areas. However, the parties may have a primary collaboration partner.

Art. 11. Impartiality

a) In order to avoid suspicion of unethical, etc., dependency, agreements may not be concluded, if issues of impartiality or independence of the parties is open to challenge.

b) The pharmaceutical company must always ensure that employees or elected representatives of the organisation only performs tasks for the pharmaceutical company, if this is reported to a superior or another person responsible within the organisation.

c) Employees in the pharmaceutical industry must not hold positions of trust within organisations, unless it is evident that there are no unethical conflicts of interest.

Art. 12. Enforcement

The rules are sanctioned as outlined in the Sanctions- and fees regulations of ENLI, please refer thereto.

Art. 13. Entry into force

This code shall enter into force on 1 January 2020 and replaces the latest published code of 1 January 2017.