



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

Version 3.0 – June 2022

Unauthorised translation in case of doubt the Danish version is always applicable and official

## **CHAPTER 1 – INTRODUCTORY PROVISIONS**

### **Art. 1. Purpose**

*Section 1.01.* The ethical rules provide a framework for collaboration between the pharmaceutical industry and Patient Organisations, etc. There must not be doubt about that the collaboration takes place in an ethical responsible manner.

*Section 1.02.* It must be ensured that:

- a) The collaboration between the pharmaceutical industry and Patient Organisations, etc., can never bring the pharmaceutical industry in miscredit or decrease the trust in it.
- b) The ethical rules entail that opportunity for pressure and dependency between the parties is excluded.
- c) The ethical rules entail openness and transparency regarding the collaboration between the pharmaceutical industry and Patient Organisations, etc.

### **Art. 2. Definitions**

*Section 2.01.* “Patient Organisations” is defined as in Article 1, section 7 of the Advertising Order: “By Patient Organisations means organisations of patients and relatives, whose purpose is to protect the interests of patient groups, cf. Article 71 d of the Danish Medicines Act.”

*Section 2.02.* “Patient Organisations, etc.,” in relation to this code means:

- a) Patient Organisations, cf. section 2.01 and,
- b) Other organisations working for:
  1. Patient related issues,
  2. Health related issues or,
  3. Consumer interests with a focus on health issues.

*Section 2.03.* “Pharmaceutical companies” in relation to this code means:

- a) The members of the Danish Association of the Pharmaceutical Industry (Lif),
- b) The members of the Danish Generic Medicines Industry Association (IGL)
- c) The members of the Danish Association of Parallel Distributors of Medicines and,
- d) Affiliated companies and associations, i.e., companies and associations, which are not members of the above-mentioned associations, but have chosen to be subject to of this set of ethical rules and,
- e) Consulting companies etc., who are acting on behalf of the companies and associations mentioned in litra a)-d).

*Section 2.04.* “Support” is defined as any kind of financial support and non-financial support.

*Section 2.05.* “Collaboration” is defined as any kind of contact between pharmaceutical companies and one or more Patient Organisations, etc.

*Section 2.06.* “Denmark” and “Danish” does not include Greenland and Faroe Islands respectively Greenlandic and Faroese.

### **Art. 3. Scope**

*Section 3.01.* This set of rules applies to pharmaceutical companies collaboration:

- a) With Patient Organisations, etc.
- b) That takes place in Denmark with Danish or international Patient Organisations, etc.
- c) That takes place in or outside of Denmark with Danish Patient Organisations, etc.

*Section 3.02.* The ethical rules in this code exclusively apply to the pharmaceutical companies since no mutually binding collaboration agreements have been concluded with Patient Organisations, etc.

## ***Chapter 2 – Support and collaboration***

### **Art. 4. Support for healthcare services, research, and education**

*Section 4.01.* Support for Patient Organisations, etc., is allowed only if:

- a) They are provided for the purpose of supporting professional activities, in the field of 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 4.02.* Support to individuals is not allowed. However, see Article 8, regarding contracted services.

### **Art. 5. Professional activities**

*Section 5.01.* In principle, support may be granted for all activities, projects, and purposes within the sphere of the Patient Organisations, etc., work.

*Section 5.02.* Professional activities should always be the main intention of the collaboration. Services must be proportionate to any compensatory measures.

*Section 5.03.* 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.

*Section 5.04.* Hospitality may only be offered if relevant. Hospitality associated with events must be limited to expenses for transportation, meals, accommodation, and fees for participation. All kinds of hospitality must be reasonable in level and strictly limited to the purpose of the event. Generally, the hospitality provided should not exceed the amount that representatives from the Patient Organisations, etc., would normally be prepared to pay for themselves.

*Section 5.05.* 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).

*Section 5.06.* Hospitality may only be offered to persons who qualify as participants in their own right. In exceptional cases, hospitality of an accompanying person who meets health/supporting/caring needs (e.g., as helper) can be provided.

*Section 5.07.* 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 450 for lunch, DKK 850 for dinner or DKK 1,400 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 organisations in these countries apply.

*Section 5.08.* No payment must be offered to compensate merely for the time spent by representatives in attending activities referred to in Section 5.01.

*Section 5.09.* Generally, a company must not organise or sponsor an event abroad, except when:

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

## **Art. 6. Contract terms**

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, patient organisations, etc., 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.

## **Art. 7. Transparency**

*Section 7.01.* Pharmaceutical companies are obliged, in connection with support and collaborations, to publish an overview containing the information in Article 6 on their website to prevent the conception of unethical or similar connections between the pharmaceutical industry and Patient Organisations, etc. Agreements must be disclosed at the time when the agreement is concluded and must be available on the website for at least two years hereafter and for at least six months after the termination of the collaboration project.

*Section 7.02.* Copies of the agreements must be made available upon specific request from ENLI, when it is no longer available on the pharmaceutical company's website. However, this requirement does not apply if the collaboration was terminated more than 10 years ago.

*Section 7.03.* Pharmaceutical companies must once a year submit an overview to ENLI over their collaborative projects the ongoing year. The overview must contain the information listed in Article 6. The overview must be submitted after the end of each calendar year. ENLI publishes the overviews on its website.

## **Art. 8. Contracted services**

*Section 8.01.* Contracts on contracted services between a pharmaceutical company and Patient Organisations, etc., are only permitted if:

- a) such services are provided for the purpose of supporting healthcare, research, or education, and
- b) the agreement does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

*Section 8.02.* It is permitted to engage Patient Organisations, etc., 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 entering into arrangements.
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 Patient Organisations, etc., 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, contracted services must not be used as general financial support for the Patient Organisations, etc.
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 Patient Organisations, etc., companies are encouraged to incorporate provisions, which obliges the Patient Organisation, etc., 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 Patient Organisations, etc., that they have engaged to provide paid-for services in accordance with Article 7, cf. Article 6.

*Section 8.03.* Limited market research, such as one-off phone interviews or mail/email/internet questionnaires, may be conducted if the representative of the Patient Organisation, etc., 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. section 8.02, no. 4 and 7. These researches, etc. must not constitute covert promotion.

*Section 8.04.* If a representative of a Patient Organisations, etc., participates in an event (an international or other event) as a consultant or advisor to the pharmaceutical company, the relevant provisions of Article 5, shall apply.

### **Chapter 3 – General provisions**

#### **Art. 9. Information on medicinal products and advertising**

In connection with financial support for, or collaboration with, Patient Organisations, etc., 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.

#### **Art. 10. Prohibition against financial benefits and gifts**

It is not permitted to hand over, offer or promise representatives from Patient Organisations, etc., gifts or financial benefits, either in the form of cash, cash equivalents, personal services or in kind, cf., however, Article 5 regarding professional activities.

#### **Art. 11. Independence**

*Section 11.01.* Support from the pharmaceutical industry must not be conditional upon the Patient Organisations, etc., taking specific stands on professional as well as political issues. Pharmaceutical companies must ensure, that their support is always clearly acknowledged and apparent from the outset.

*Section 11.02.* The pharmaceutical industry must not, as part of an agreement, require Patient Organisations, etc., to favour specific products.

*Section 11.03.* Companies must not, in connection with support, influence the content or preparation of Patient Organisations, etc., 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 Organisations, etc., companies may contribute to the text of a material from a fair and balanced scientific perspective.

#### **Art. 12. Impartiality**

*Section 12.01.* 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.

*Section 12.02.* The pharmaceutical company must always ensure that employees or elected representatives of the Patient Organisation, etc., only performs tasks for the pharmaceutical company, if this is reported to a superior or another person responsible within the Patient Organisation, etc.

*Section 12.03.* Employees in the pharmaceutical industry must not hold positions of trust within the Patient Organisation, etc., unless it is obvious that there are no unethical conflicts of interest.

### **Art. 13. Use of the organisation's logo**

The pharmaceutical company must never use the Patient Organisation's, etc., logo, name or materials or otherwise refer to the collaboration with the Patient Organisation, etc., except by prior written agreement. When applying for such permission, the specific purpose and the use of logo, name, material, etc., must clearly be stated.

### **Art. 14. Branding**

It is generally permitted to affix the company's name to the materials that are handed out if the name appears in a non-promotional manner.

### **Art. 15. Exclusive agreements**

No exclusive agreements may be concluded. Patient Organisations, etc., are thus always free to collaborate with several pharmaceutical companies, and likewise pharmaceutical companies may collaborate with one or several Patient Organisations, etc. 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. 16. Enforcement**

This code is sanctioned as outlined in the Sanctions- and fees regulations of ENLI, please refer thereto.

### **Art. 17. Entry into force**

This code shall enter into force on the 15<sup>th</sup> of June 2022 and replaces the latest published code of 1<sup>st</sup> of January 2020.