



# **Ethical rules for the pharmaceutical industry's donations and grants**

## **(Donation Code)**

Version 3.0 – June 2022

## CHAPTER 1 – Introductory provisions

### Art. 1. Purpose

*Section 1.1.* The purpose of this set of rules is to determine the framework of the donations of the pharmaceutical industry to hospitals etc. There must be no doubt that the interactions between the parties takes place on an ethical level.

*Section 1.2.* It must be ensured that:

- a) The donations of the pharmaceutical companies must never be of such a nature that they bring the pharmaceutical industry in discredit or reduce the trust in it.
- b) The ethical set of rules entails that opportunities for pressure and dependencies between the parties are excluded.
- c) The ethical set of rules entails openness and transparency about the donations of the pharmaceutical industry.

### Art. 2. Definitions

*Section 2.1.* “Donations” is defined as any kind of support given to projects, activities, equipment, units or similar. Donations can be given as financial support or in kind contributions.

*Section 2.2.* “Pharmaceutical companies” in relation to this set of rules is based on the definition in the Sec. 3, subsection 1, of the Promotion Code, cf. the Advertising Executive Order, Sec. 1, subsection 4 the members of:

- a) the pharmaceutical industry association (Lif)
- b) the Industrial Association for Generic Medicines (IGL)
- c) the Association of Parallel Importers of Medicine and,
- d) Affiliated companies and associations, meaning companies and associations who are not members of the above-mentioned associations, but who has chosen to be subject 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 2.3.* “Healthcare professionals” is defined as in Sec. 1, subsection 1 of the Executive Order on Advertising of Medicinal Products as “doctors, dentists, pharmacists, nurses, pharmacoconomists, midwives, bioanalytics, clinical dietitians, radiographers, social and health assistants and students in these disciplines.

*Section 2.4.* By “hospitals” in relation to this set of rules is understood all in Sec. 3, subsection 1, mentioned units.

### Art. 3. Scope of the ethical rules

*Section 3.1.* This set of rules applies to pharmaceutical companies’ donations to:

- a) Public hospitals, associations of hospitals and specific hospital wards in Denmark,
- b) Private hospitals/clinics in Denmark if the owners are not primarily individual healthcare professionals,

- c) Institutions and organisations in Denmark that provide healthcare or conduct research performed by healthcare professionals (that are not otherwise covered by ENLI-Codes), and
- d) Researcher-initiated clinical trials, where the company does not influence the trial or conditions compensation.

*Section 3.2.* The rules does not apply to donations which are otherwise covered by ENLI-Codes or regulated in Danish legislation. Therefore the rules does not apply to, for example:

- a) Support covered by The Patient Organisations Code
- b) Support coveret by The Lobbying Code
- c) Support covered by The Promotion Code, including
  1. pharmaceutical companies' sponsorships of healthcare professionals to attend national or international events
  2. Pharmaceutical companies' sponsorships to a hospital educational events that are completely or partially targeted healthcare professionals
  3. Offers to attend information meetings/continuity training events arranged by pharmaceutical companies
  4. Distribution of information and educational material as well as medical equipment to healthcare professionals
  5. Collaboration on clinical research that are reported to the scientific committee-system and the Danish Medicines Agency (with the exception of researcher-initiated clinical trials covered by subsection 1, litra d)), however, see Art. 8 regarding company-initiated studies,
  6. Support for individual healthcare professionals and associations of individual healthcare professioals, including medical societies,
  7. Donations to private hospitals/clinics in Denmark, owned by one or mulitple healthcare professionals.

## **CHAPTER 2 - Donations**

### **Art. 4. Donations for healthcare or reseach**

*Section 4.1.* A pharmaceutical company is only allowed to give donations to hospitals, if

- a) They are provided with the purpose of supporting professional acitivites wihtin healthcare, reseach and education,
- b) They are documented and registered by the donor/the grantor, and
- c) They do not constitute an incentive to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

*Section 4.2.* Support for individuals is not allowed.

### **Art. 5. Contract terms**

*Section 5.1.* The company, which donates, shall ensure in each case that a written and signed documentation will be prepared that, at a minimum, specify:

- 1) Name of the activity, project, equipment or unit, which the donation supports.
- 2) Name(s) of the hospital/department etc., which handles the activity, project, equipment or unit.
- 3) Name(s) of person(s) at the hospital, which is responsible for the activity, project, equipment or unit.

- 4) Name(s) of person(s) responsible for the account (money) or unit (benefit in kind), which the donation is transferred to.
- 5) Name of the Manager, Director or similar person with competence at the hospital, which has approved that the hospital/department could receive the donation
- 6) Type of activity, project, equipment, unit, which the donation is granted for.
- 7) The purpose of the activity, project, equipment/unit, which the donation is given to.
- 8) Timeframe (if possible).
- 9) Size of financial donation.
- 10) Extent, content and estimated value of the benefit in kind.

## **Art. 6. Transparency**

*Section 6.1.* Pharmaceutical companies are obliged to, in connection with any donation, to publish an overview, which contains the in Art. 5, no. 1, 2, and no. 6-10 mentioned information, on their website, to prevent notions regarding unethical, etc., connections between the pharmaceutical industry and hospitals. The overview must be published when the donation is granted, and shall be available on the website for at least two years thereafter or longer if it is relevant in relation to the given donation.

*Section 6.2.* A copy of the list must be made available to ENLI upon request, when it is no longer available on the pharmaceutical company's website. This requirement does not apply to donations which were granted more than 10 years ago.

*Section 6.3.* Pharmaceutical companies must annually submit an overview to ENLI containing all the company's donations in the past year. The summary shall contain the information referred to in subsection 6.1. The summary must be submitted immediately after the end of each calendar year and will be published on ENLI's website

## **Art. 7. Triviality limit**

*Section 7.1.* Art. 5, 6 and 12 shall not apply to donations, which have a total value of maximum 5,000 DKK per calendar year for a specific purpose or a specific activity. The value is calculated as the company's costs of the donation, e.g. the amount of a financial contribution or the company's costs for in kind contributions.

*Section 7.2.* Art. 5, 6 and 12, shall not apply to donations, which have a value of maximum 20,000 DKK within a calendar year, provided that the donations are constituted by a plurality of identical donations that singly constitutes a smaller value (for example, medication cooler bags for a specific medicinal product, patient information leaflets for a specific medicinal product, injection needles for patient directed injection equipment, etc.).

## **CHAPTER 3 - General provisions**

### **Art. 8. Studies initiated by the company**

When collaborating on company-initiated studies in hospitals (e.g., clinical trials and non-intervention trials), the pharmaceutical company must in advance ensure that hospital management is informed in advance of the studies.

**Art. 9. Contracted services**

*Section 9.1.* It is only permissible for a pharmaceutical company to enter into an agreement with a hospital for a consultancy service if

- a) the service provided by the hospital is intended to support healthcare, research or education (which is not otherwise subject to the rules subject to the control of ENLI), and
- b) the agreement does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

*Section 9.2.* Limited market research, such as one-off phone interviews or mail/email/internet questionnaires, may be conducted if the 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. These researches, etc., must not constitute covert advertising.

**Art. 10. Prohibition on financial benefits and gifts**

It is not permitted to provide, offer or promise gifts or financial benefits, neither in the form of cash, personal favours nor in kind.

**Art. 11. Independence**

The pharmaceutical companies must ensure that donations are used only for the intended professional purpose. Assuming that the desired professional purpose have been complied with, the company must not affect the hospital's concrete operations, business processes, tasks, or actual use of the support. It is a prerequisite that it is the hospital/hospital department, which oversee the donation, that the pharmaceutical company provides. However, pharmaceutical companies are not prevented from correcting factual inaccuracies in connection with the contract between the parties.

**Art. 12. Approval**

Donations must be approved by a person employed at the hospital, which has the power to do so. Before the donation can be transferred to a hospital account (money) or hospital unit (benefit in kind), the actual transfer must also be approved by a person employed at the hospital, which has the power to do so.

**Art. 13. Use of logo**

The pharmaceutical company may not use the hospital's logo, name or proprietary material at any time, or otherwise use the collaboration with the hospital, without prior written agreement with the hospital. When applying for such a permission, the specific purpose and the way the logo, name, proprietary material, etc., will be used must be clearly stated.

**Art. 14. Branding**

It is allowed to use the company's name on donations that are given, when the name appears in a non-promotional manner. Application of names of products on benefits in kind, which are provided in accordance with this set of rules, can only be accepted if there are safety reasons for this.

**Art. 15. Exclusive agreements**

No exclusive agreements may be concluded. Hospitals are thus always free to collaborate with several pharmaceutical companies, and likewise pharmaceutical companies may collaborate with one or several hospitals. 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 described in the Penalties and fees regulations for ENLI, to which reference is made.

**Art. 17. Entry into force**

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