



GUIDANCE

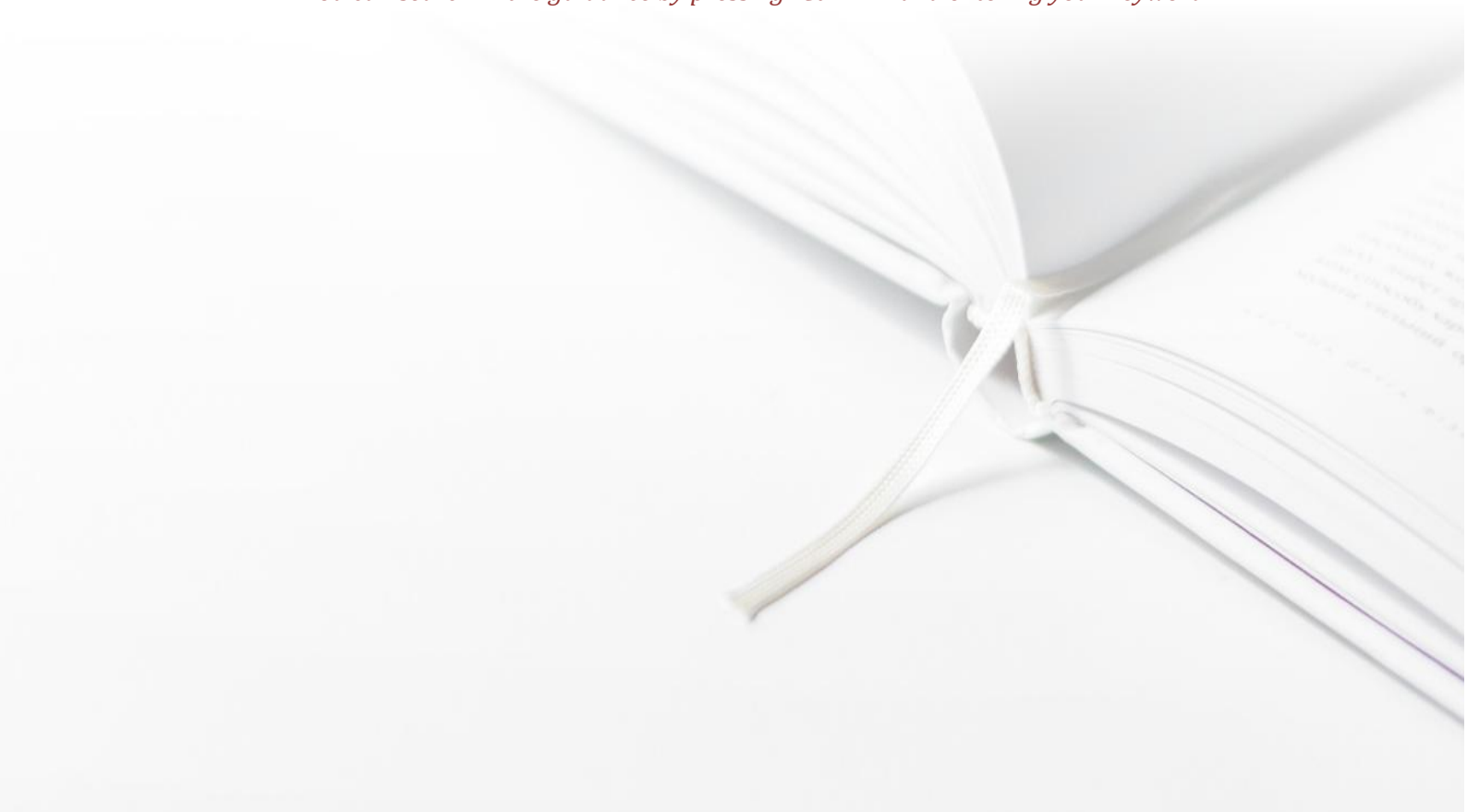
TO

The ethical rules for the pharmaceutical industry's donations

(Donation Code)

The Code of the ethical rules for the pharmaceutical industry's donations (Donation Code) will continuously be updated as practices develop or change. The guidance will therefore be dated and have a version number. All abbreviations used are explained at the back of the guidance.

NB! You can search in the guidance by pressing "Ctrl + F" and entering your keyword.



COMMENTS ON CHAPTER 1 - INTRODUCTORY PROVISIONS

Purpose

Art. 1.

Sec. 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.

Sec. 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 miscredit 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.*

Re: Article 1

The purpose of the Donation Code coincides with EFPIA's Code of Practice, Sec. 12.01.

The provisions of the Donation Code supplement the EFPIA Code of Practice.

The purpose of the Donation Code is, in addition to transparency, among other things, that the pharmaceutical companies must ensure that donations are used for the intended professional purpose, and that it is the hospital / hospital department that manages the donation.

Definitions

Art 2.

Sec. 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.

Sec. 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)*

Sec. 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.

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

Re: Article 2: Donations

The definition of grants and donations is interpreted broadly and can include financial support as well as services to hospitals/hospital departments in the form of payments in kind. This could for example be, databases, research projects, patient information leaflets, patient training programs, medical equipment, PhD projects or the like that the hospital/hospital department has applied for funding for. It is not the terminology that determines whether the benefit is covered by the Donation Code, but instead the content of the agreement that is decisive, i.e. it is subordinate whether the company calls it a donation, grant, sponsorship, etc.

Applicable to all benefits is that the donations must be transparent and well documented. Furthermore, donations must not directly nor indirectly finance social activities or other internal activities that does not relate to specific professional purposes.

It is noted that donations to hospitals/hospital departments must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Re: Article 2, section 2.2, a) to d): Pharmaceutical companies

On the frontpage of ENLI's website www.enli.dk you can find an updated list on companies affiliated with ENLI.

Re: Article 2, section 2.3: Healthcare professionals

Only professional groups which are mentioned in the Donation Code article 2, section 2.3 are covered by the definition "healthcare professional".

Scope of the ethical rules

Art 3.

Sec. 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.*

Sec. 3.2. The rules does not apply to donations which are not 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 covered by The Lobbying Code*
- c) Support covered by The Promotion Code, including*
 - 1. pharmaceutical companies' sponsorship of healthcare professionals to attend national or international events*
 - 2. Pharmaceutical companies' sponsorships to a hospital educational event that are completely or partially targeted healthcare professionals*
 - 3. Offers to attend information meetings/continuity training events arranged by pharmaceutical companies*
 - 4. Hand over 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*
 - 6. Support for individual healthcare professionals and associations of individual healthcare professionals, including medical societies*
 - 7. Donations to private hospitals/clinics in Denmark, owned by one or multiple healthcare professionals.*

Re: Article 3

The Donation Code regulates the donations of pharmaceutical companies to hospitals and hospital wards. All services for individual healthcare professionals are regulated by the Promotion Code, to which reference is made. The Donation Code thus does not regulate the financial support / sponsorships of pharmaceutical companies or the provision of benefits in kind to, for example, general practitioners or other individual doctors who, for example, are employed in a hospital.

Re: Article 3, section 3.1, c)

The Donation Code includes donations, etc., to institutions or organizations that consist of healthcare professionals and / or provide healthcare or conduct research (which is not otherwise governed by the rules subject to ENLI's control). This could be a corporate donation to a university that conducts clinical research (such as the Panum Institute, University of Copenhagen) or health services in municipalities.

Re: Article 3, section 3.1, d)**Clinical research covered by the Donation Code**

Research-initiated clinical trial projects in hospitals are covered by the Donation Code in cases where the support is given only as a donation/grant, where the company does not influence the design or implementation of the clinical trial, the hospital's specific operations, business procedures, tasks or actual use of the aid, and where it is the hospital/hospital department, which oversee the grants or the donation, that the pharmaceutical company provides. It also follows that in these cases, the company must not condition any kind of service in return for their payment/support (such as rights, data, results, etc.).

Re: Article 3, section 3.2, c)

The Donation Code applies to donations for hospitals, etc., and thus does not apply to donations for individual healthcare professionals' participation in professional events, which are regulated by Article 13 in the Promotion Code, while distribution of information and training materials as well as medical equipment is regulated by Article 14 in the Promotion Code. Donations for individual healthcare professionals or associations of healthcare professionals are thus not allowed by this code but is regulated by the Promotion Code.

Re: Article 3, section 3.2, c), no. 4

Lif has in their FAQ (Q9) to the prohibition of gifts in Article 12 of the Promotion Code emphasized that the rules in Article 14 of the Promotion Code applies to hand-outs to healthcare professionals and not to hospitals. This means, among other things that cooler bags for medicine that is delivered as a donation

or grant to a hospital can be handed out if they comply with the requirements specified in the Donation Code, including the requirements in Art. 4.

Re: Article 3, section 3.2, c), no. 5 – Clinical research not covered by the Donation Code

Clarification of the Donation Code regarding Clinical Research:

- Company-initiated collaboration on clinical trials with hospitals is basically always exempted from the Donation Code.
- Research-initiated clinical trials with hospitals are exempted from the Donation Code in cases where the initiative results in a collaboration between the parties, where the company is given the opportunity to influence the project, and/or where it is agreed that the company should receive a service in exchange (e.g., research results) for the funds.

Re: Article 3, section 3.02, c), no. 6

The prohibition of providing donations, etc. to individuals follows from EFPIA's Code of Practice but also the practice established by the Danish Medicines Agency. The Danish Medicines Agency's statements are in detail discussed in the NMI Annual Report for 2007. It follows that:

- Support for individuals and associations of individuals (healthcare professionals) are not legal. According to the Danish Medicines Agency's practice, this also covers support for medical societies (a group of individuals), regardless of whether the support is for a professional purpose (e.g., creation of a website, distribution of material or preparation of treatment databases or similar.).

It is therefore not possible under the Donation Code that companies make donations to medical societies, as these are considered an association of individuals, who are thus covered by the rules in the Promotion Code. Sponsorships for these will thus not be regulated by the Donation Code, but rather by the Promotion Code. For further information, please see the guidelines for the Promotion Code, section 13, subsection. 1.

Re: Article 3, section 3.02, c), no. 7

The prohibition of providing donations, etc. to individuals follows from EFPIA's Code of Practice but also the practice established by the Danish Medicines Agency. The Danish Medicines Agency's statements are in detail discussed in the NMI Annual Report for 2007. It follows that:

- Support for hospitals, associations of hospitals and specific hospital departments (opposite the individual healthcare professionals in hospitals) will not be in violation of the rules. The Danish Medicines Agency stated at a meeting on 27th of June 2008 that this also applies to certain types of private hospitals depending on the composition of the company's circle of owners.

In order to determine whether a pharmaceutical company's support for private clinics / private hospitals is covered by the Donation Code or the Promotion Code, it is crucial to look at the real owners. If there is a predominance of healthcare professionals in a small circle of owners, this suggests that a collaboration with the clinic is not covered by the Donation Code, but instead is covered by the Promotion Code (i.e., an association of individual healthcare professionals).

The Donation code vs. The Promotion Code – assessment of the circle of owners of the private hospital

If a private clinic / hospital is owned by the public (i.e., owned by persons who are not healthcare professionals) or owned by a company where the owners are not healthcare professionals:

- The pharmaceutical company's support is covered by the Donation Code.

If a private clinic / hospital is owned by a company where the owners are composed of both healthcare professionals and other professional groups:

- The support of the pharmaceutical company is likely to be covered by the Donation Code. It is recommended that the company discuss the issue with ENLI prior to entering into an agreement.

CHAPTER 2 – DONATIONS

The ethical rules for pharmaceutical companies' donations to hospitals in Chapter 2 supplement and tighten in selected areas EFPIA's Code of Practice, art. 12, which is implemented in Chapter 2 of this Code. It is always the strictest rules that must be complied with.

This chapter deals exclusively with donations to hospitals and hospital departments in Denmark.

Donations for healthcare of research

Art 4.

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

- a) They are provided with the purpose of supporting professional activities within healthcare, research 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.*

Sec. 4.2. Support for individuals is not allowed.

Re: Section 4.1, a)

This provision implements EFPIA's Code of Practice cf. to Art. 12

It is a requirement that the support is given for professional purposes. The Investigator Panel understands the concept of healthcare as the healthcare business that a healthcare professional is authorized to perform. Therefore, the Investigating Panel finds that donations and grants must be made in connection with an activity that is an integral part of either prevention, examination, diagnosis, treatment or subsequent monitoring of the patient. Grants and donations may only be provided for healthcare or research, or other professional measures that benefit the patient care or hospitals. Thus, the granted benefit must be specific to health care.

This means that pharmaceutical companies cannot provide support for the general operation of the hospital unless the support is for a professional activity as mentioned above, i.e. activities / projects that are an integral part of patient treatment, for example in connection with prevention, examination, diagnosis, treatment or the subsequent monitoring of the patient. Thus, companies cannot provide support for practical or administrative purposes, such as office supplies (paper, writing utensils, desks, chairs, etc.) subscriptions to telephone, internet, magazines, etc., insurance, salaries for hospital staff, rent, construction and renovation work, etc., as ENLI considers these examples to be support for the general operation of the hospital that do not meet the requirement of having a direct health professional purpose.

The Danish Medicines Agency has stated that in its assessment of the legality, it emphasizes whether the money goes to the running of professional activities, whether the support is given to the hospital, a

hospital department or the organisation that can dispose of the money, and that the pharmaceutical company does not otherwise has no influence on how the support is used or what tasks are performed.

Specific examples

Lending of tablet devices

In a specific pre-approval, the Investigator Panel found that lending tablet devices to hospital departments was in accordance with the Donation Code within specific terms. In this specific case, tablet devices were lent for an agreed period and contained a custom-designed web application with patient information concerning a disease area and a further web application aimed at healthcare professionals with two modules with respectively e-learning and product information. The information targeted to healthcare professionals was effectively access-proof, and the tablet devices were equipped with a technical device that prevented the iPad from being used for anything other than the intended purpose. Thus, it was not possible for the user to install their own programs or games, download music and movies or check e-mails, etc., because it was blocked for any Internet access for the users. The purpose of lending these tablet devices was to optimize healthcare professionals' communication with particularly young patients with the specific disease. The patient group was characterized as having poor disease understanding and poor recognition of their life situation. It was therefore particularly important for this patient group to use a communication device that the patient was familiar with, and which was not perceived as intimidating.

If tablet devices are handed out in connection with a donation, it must not be possible to use the iPad for personal use, for example if information of a non-professional nature is available.

Handing out books

The Investigator Panel has also had inquiries regarding handing out of subject-specific books to hospitals. Handing out books may in particular cases be considered compliant with the Donation Code if these books only deal with general information on specific disease areas where no medicinal names are laudatory mentioned.

Handing out office supplies, games etc.

The fact that donations/grants must have a specific professional purpose means that practical office materials in the form of paper, writing utensils, office furniture, etc. cannot be granted as a donation to hospitals/hospital departments. Such services are basically characterized as general operational support that does not meet the requirement to have a scientific purpose. For further information, please refer to Lif's FAQ (Q10) and Article 12 of the Promotion Code.

Donations in the form of computer games, board games, etc. for use in waiting rooms, etc. is viewed as being beyond the general understanding of what is considered to be activities that support healthcare or research. Therefore, such donations are not accepted.

Re: Section 4.1, b)

All the company's donations to hospitals, etc., must meet the requirements in art. 5 of The Donation code and has to be published and reported to ENLI, cf. art. 6 of The Donation code.

Re: Section 4.1, c)

The Donation Code clarifies that a donation may not be considered an advertising for a medicinal product, cf. also the definition of advertising in section 1 (1) of the Executive Order on Advertising. 1.

Re: Section 4.2

The provision implements EFPIA's Code of Practice Sec. 12.02.

Contract terms

Art 5.

Sec. 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 doantionen is given to.*
- 8) Timeframe (if possible).*
- 9) Size of financial donation.*
- 10) Extent, content and estimated value of the benefit in kind.*

Re: Article 5

There is currently no guidance to this provision.

Transparency

Art 6.

Sec. 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.

Sec. 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.

Sec. 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 6.01. The summary must be submitted immediately after the end of each calendar year and will be published on ENLI's website.

Re: Article 6, sec. 1 and 2:

Pharmaceutical companies are obliged to disclose their donations to hospitals etc. on the company's own website, i.e. the website to which the company is linked.

If the company is part of a group that only has a global website, or if the company only wants a Nordic website so that there are no national websites, these global or Nordic websites are to be considered the closest website for the affiliated company.

If there are country divisions on such pages, for example a subpage for the Danish part of the group on the global or Nordic website, the publication must be made on such subpages.

In short: Pharmaceutical companies must disclose the donation on the website to which the company is considered to be linked, and which represents the affiliated company.

Disclosure must be made from the conclusion of the agreement, meaning the date on which both parties have signed the agreement.

It is not a requirement that the agreement itself can be retrieved on the company's website. Thus, a summary can be made that contains at least the conditions outlined in Art. 5. It is also accepted to use the list that companies affiliated with ENL must submit to ENLI once a year, cf. Section 6.03 in this code.

Re: Art 6, sec. 3

This provision only obliges those companies that are affiliated to ENLI. See also the section on good advice in connection with the annual report to ENLI.

Triviality limit

Art 7.

Sec. 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.

Sec. 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.).

Re: Article 7

It is noted that for donations with a value of no more than DKK 5,000 and DKK 20,000 per calendar year, the hospital in question must be understood as a single unit and not as each hospital department.

If a company makes a donation that does not exceed a value of DKK 5,000, then Art. 5, 6 and 12, does not apply.

If a company makes a donation to the same hospital, which together does not exceed a value of DKK 20,000, Art. 5, 6 and 12, does not apply.

Example: A company provides 4 x medical equipment of DKK 4,000 per unit to four different departments at Hvidovre Hospital. As the unit price is less than DKK 5,000 and the total donation to the hospital does not exceed DKK 20,000 (4 medical equipment x DKK 4,000 = DKK 16,000), Art. 5, 6 and 12, does not apply to the four donations.

Example: A company provides 8 x medical equipment of DKK 3,000 per unit to two different departments at Rigshospitalet. Although the unit price is less than DKK 5,000 and the two departments have not received a donation in excess of DKK 20,000, the total donation to the hospital is DKK 24,000 (8 medical equipment x DKK 3,000 = DKK 24,000). The 8 donations are considered as one total donation to Rigshospitalet, and Art. 5, 6 and 12, therefore applies.

COMMENTS ON CHAPTER 3 – GENERAL PROVISIONS

Studies initiated by the company

Art 8.

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.

Re: Article 8

The provision was previously found in the now repealed "Ethical rules for pharmaceutical companies' contact with the Danish hospital system" (Hospital Code).

Contracted services

Art 9.

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.

Re: Article 9

The provision implements EFPIA's Code of Practice Sec. 15.01 and 15.04.

The provision only applies in situations where a pharmaceutical company enters into a consulting agreement with a hospital where the consultant is *not* a healthcare professional. In this case, there are no requirements for the consulting contract or requirements for publication of consulting agreements (just as is the case in the Promotion Code Art. 15 and the Patient Association Code Art. 8).

If a pharmaceutical company enters into a consulting agreement with a healthcare professional employed at a hospital, section 15 of the Promotion Code applies. For further information, please see the guidelines for section 15 of the Promotion Code.

Prohibition on financial benefits and gifts

Art 10.

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

Re: Article 10

Please refer to the guidance for Article 3 regarding the distinction between donations to hospitals and sponsorships for the professional training of individual healthcare professionals.

The article is interpreted in accordance with the principles in Article 12 of the Promotion Code.

Independence

Art 11.

The pharmaceutical companies must ensure that donations are used only for the intended professional purpose. Assuming that the desired professional purpose has 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.

Re: Article 11

In connection with a pharmaceutical company's donation to a hospital or hospital department, the company must ensure that the donation in question is used for professional purposes only. For further information, please refer to the guidance for Article 1 and 5.

A medicinal company providing a donation to a hospital, or a hospital department must not, in its contract with the hospital or otherwise, condition the support on the fact that the donation in question must be used for particular activities or in connection with specific medicines.

It is only for the hospital/hospital department to dispose of the donation provided by the pharmaceutical company so that the external party/pharmaceutical company has no influence on the operations, the tasks or the way in which the support granted is to be managed.

Approval

Art. 12

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.

Re: Article 12

The donation and transfer must be approved by a person at the hospital with competence for this and in each case, there must be a written and signed documentation of the terms.

Use of logo

Art. 13

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.

Re: Article 13

The provision implements EFPIA's Code of Practice Sec. 13.02.

Branding

Art. 14

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.

Re: Article 14

There is currently no guidance to this provision.

Exclusive agreements

Art. 15

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.

Re: Article 15

The provision implements EFPIA's Code of Practice Sec. 14.

Enforcement

Art. 16

This code is sanctioned as described in the Penalties and fees regulations for ENLI, to which reference is made.

Re: Article 16

Reference is made to the Sanctions and Fees Regulations at www.enli.dk

Entry into force

Art. 17

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

Re: Article 17

There is currently no guidance to this provision.

Guidance on the annual reporting to ENLI:

In December, ENLI submits a reporting form, in a word document, where ENLI's affiliated companies must enter all donations and grants given to Danish hospitals for that year. It is important that only this specific word document is used and that columns are not deleted, added or changed in the format (e.g., PDF, Excel, etc.).

Please remember:

- No personal names or identification numbers (CPR-nr.) in the reporting form
- All amounts in DKK (not euros, etc.)
- The amount must be stated including VAT
- Inspiration for completing the reporting form can be found by looking at the published forms from previous years located on ENLI's website.

As ENLI use the same template for reporting, companies can advantageously fill out a reporting form throughout the year, so the work is easier at the end of the year when the report is to be submitted.

ENLI has a contact list of the employees of the affiliated companies who will receive the reporting form in December. Please inform ENLI if a new employee is to receive the annual reporting form.

Q&A

General:

In short, a pharmaceutical company must only make a donation to a hospital if the donation is used for a health professional purpose that benefits the patient or the hospital. This means, activities that are an integral part of either prevention, examination diagnosis, treatment or subsequent control treatment.

- Donations are allowed for, e.g.: databases, research projects, patient information leaflets, patient training programs, medical devices and Ph.D. projects.
- Donations are *not* allowed for the general operation of the hospital, e.g., practical office material (paper, pencil, office furniture) and salaries for hospital staff.

Scope of the ethical rules - art. 3

1. A pharmaceutical company wishes to provide financial support to a hospital in connection with the hospital's organisation of a professional symposium on updates on the etiology, pathogenesis and treatment of MS, and networking among researchers. Is this covered by the Donation Code?

ANSWER: *No, any financial support is not covered by the Donation Code, cf. Section 3 of the Donation Code, even if the money is given to a hospital. ENLI considers that this is a continuing education event, which is why support should be considered as a sponsorship to an organizer (the hospital). The company must therefore assess whether the meeting complies with art. 13 of the Promotion Code before the company can grant a sponsorship. All sponsorships must be reported to ENLI via ENLI's reporting site. Only support covered by the Donation Code should be noted in the annual reporting form to ENLI.*

2. Can a pharmaceutical company provide financial support to a hospital to cover the costs of teaching and inviting foreign teachers for medical students?

ANSWER: *No, any financial support is not covered by the Donation Code, cf. Art. 3. Please see more detailed answer above.*

3. Can a pharmaceutical company provide financial support to a hospital where the hospital uses the support on a simulation-based colonoscopy education for healthcare professionals employed at the hospital?

ANSWER: *No, any financial support is not covered by the Donation Code, cf. Art. 3. Please see more detailed answer above.*

4. A pharmaceutical company wants to provide financial support to a hospital where the support is intended to cover expenses related to a study trip to Paris for a healthcare professional employed at a hospital. Is this covered by the Donation Code?

ANSWER: *No, any financial support is not covered by the Donation Code, cf. Art. 3 of the Donation Code. This will instead be a sponsorship for continuing education, why the support is regulated by the Promotion Code Art. 13.*

5. A pharmaceutical company has a medicinal product that is administered subcutaneously using a special disposable pen. The treatment typically has to be administered every 14 days, and the patients are trained and instructed by healthcare professionals at the hospital to administer the treatment themselves. For this purpose, the company offers a demonstration pen to the hospital wards with the aim of ensuring that patients are trained in administering the medicine correctly. The pen is without a company logo and product name. Is the distribution of a demonstration pen to a hospital covered by the Donation Code or the Promotion Code?

ANSWER: *Distribution of a demonstration pen to a hospital or hospital ward is covered by the Donation Code.*

6. Can a pharmaceutical company make a donation to a hospital for the purchase of infusion chairs?

ANSWER: *Yes, in the case of specialized chairs that will not be able to be used for other purposes, e.g., as chairs in a waiting room or similar.*

7. A dietitian employed at a hospital wants to do a project regarding study of quality of life among those patients who receive a given medicine and would, on behalf of the hospital, like to apply for funding for the project at a pharma company. This project will be carried out as a follow-up to and further development of many years of treatment of the disease and data collection in Denmark. Is this a donation covered by the Donation Code?

ANSWER: *Yes, this is a donation covered by the Donation Code, as the company has no influence on the project or has conditioned consideration (e.g., rights, data, results, etc.), cf. the guidance to Art. 3 of the Donation Code.*

8. Is a pharmaceutical company's purchase of quarterly reports from Dermbio, under an annual agreement with Dermbio, Rigshospitalet/Glostrup, to be considered a donation to a Danish hospital - i.e. that the rules of the Donation Code apply, including disclosure?

ANSWER: *No, the purchase is not covered by the Donation Code or the Patient Organisation Code - as it is a purchase and not a support or donation. The purchase is thus considered "quid pro quo".*

9. A hospital department has approached a pharmaceutical company regarding collaboration on the development of a dialogue tool to be used by doctors and patients when discussing potential participation in clinical studies. Is this collaboration covered by the Donation Code?

ANSWER: *Yes, it is covered by the Donation Code as the dialogue tool is considered part of the research and therefore falls within the scope of section 4(1)(a) of the Donation Code. The collaboration must therefore comply with all applicable provisions of the Donation Code.*

- 10.** A pharmaceutical company wants to support the organisation 'UngeLiv', which provides counselling on sex, body and gender to young people between the ages of 12 and 25 living or attending school in a specific municipality. Is the support to the organisation covered by the Donation Code because the municipality is behind the organisation, or is the support covered by the Patient Organisation Code because UngeLiv is considered an 'other organisation' working on patient-related issues?

ANSWER: *Support to the organisation "UngeLiv" is covered by the provisions of the Donation Code (cf. section 3(1)(c) of the Donation Code), as it is support for a healthcare service in a municipality.*

- 11.** Once a year, a pharmaceutical company gives its employees time off to do social work, such as cleaning up parks or helping with physical labour in institutions, such as painting. Is work in a nursing home covered by the Donation Code, and if so, would it be possible for employees to perform such 'social work' in a nursing home?

ANSWER: *Pharmaceutical companies' support for healthcare services in municipalities is covered by the Donation Code, cf. section 3(1)(c) and the associated guidelines. As nursing homes provide healthcare services and belong to the municipality, support to a nursing home will generally be covered by the Donation Code.*

However, it is ENLI's assessment that the described support cannot be granted under the Donation Code, as the support is considered to be support for (the nursing home's) operation. It is assessed that the aid is not granted for an activity that is an integral part of prevention, examination, diagnosis, treatment or subsequent follow-up treatment.

- 12.** As a result of its professional expertise in the field, a pharmaceutical company has been invited by a Danish hospital to participate in a global network on the use of AI for cancer detection. The hospital has applied to the EU - via the Ministry of Education and Research (UFM) - for funding to establish and run the network, including organising meetings, conferences and possible travel. Participation will therefore be free of charge for participants. Will it conflict with the Donation Code if the pharmaceutical company participates in the network?

ANSWER: *On the present basis, ENLI does not find that the participation is covered by the Donation Code (or any other of ENLI's ethical rules).*

Donations for healthcare or research – Article 4

- 13.** A pharmaceutical company wants to provide financial support for a hospital to hold an information meeting for patients and their relatives regarding anxiety and depression. Is the support covered by the Donation Code?

ANSWER: *Yes, the donation is covered by the Donation Code, as the donation has a health professional purpose that benefits the patient care, since it is an activity that is an integral part of prevention and treatment, cf. Art. 4 of the Donation Code.*

- 14.** Can a pharmaceutical company make a donation to a hospital to pay a Ph.D. student in connection with a nationwide scientific project?

ANSWER: *Yes, cf. Art. 4 of the Donation Code and the guidance for Art. 4 of the Donation Code. Remuneration in connection with a Ph.D. project is not considered as remuneration of hospital staff, but as an integral part of a research project.*

- 15.** Can a pharmaceutical company make a donation to a hospital, where the donation covers the salary of an employee, who has to enter data into a database? The purpose of the donation is to support the implementation, maintenance and entry of data in a national register of rare diseases.

ANSWER: *Yes, cf. Art. 4 of the Donation Code.*

- 16.** A pharmaceutical company wants to provide financial support to a hospital where the support is intended to cover the expenses incurred during a stay in Paris in connection with a Ph.D. project. Is this covered by the Donation Code?

ANSWER: *Yes, cf. Art. 4 of the Donation Code.*

- 17.** A hospital applies for financial support from a pharmaceutical company in connection with the hospital's project in a specific area of illness. It is stated that the hospital, as a prelude to the project, will send two healthcare professionals to attend a congress regarding the disease to which the project relates. In addition to covering expenses for healthcare professionals' participation in the congress, financial support must also cover expenses for data registration, payroll and the purchase of necessary equipment in connection with the research project. Can the company provide support to the hospital?

ANSWER: *Yes, it is possible for the company to provide support to the hospital, but the company must divide the support into a sponsorship (Art. 13 of the Promotion Code) and a donation (Art. 4 of the Donation Code, respectively). The participation of the healthcare professionals in the congress is considered training of healthcare professionals, and therefore is a sponsorship covered by art. 13 of the Promotion Code. In addition, the company can make a donation to the hospital for the project, to cover the costs of data registration, salary in connection with the project and purchase of necessary equipment, which is covered by the Donation Code, cf. Art. 4 of the Donation Code.*

- 18.** A doctor employed at a hospital is applying to a pharmaceutical company for a travel grant in connection with a research stay abroad as part of his PhD project. The application includes a project plan and a budget in which the doctor is seeking financial support for air travel and accommodation. Should this support be considered a sponsorship to a healthcare professional under the rules of the Promotion Code, or a donation to the hospital under the Donation Code?

ANSWER: *The pharmaceutical company's support will be covered by the Donation Code as the travel grant is part of the PhD project (contrary to the answer above to question 12, where the travel was not an integral part of the project).*

- 19.** A pharmaceutical company reports that some hospital-employed healthcare professionals prefer that their fee – for example, for giving a presentation at a professional event organised by the pharmaceutical company – be paid into a research account at the hospital instead of receiving the fee themselves. The pharmaceutical company asks whether this is permissible.

ANSWER: *Yes, it is possible for a fee to be paid into a research account owned by the hospital, provided that the rules of the Donation Code are observed. Pharmaceutical companies can make donations to Danish hospitals, provided that the donation is used for a research project, cf. section 4(1)(a) of the Donation Code. The pharmaceutical company must therefore ensure that payment to the research account is allocated to a specific research project. Furthermore, the donation must be published and reported to ENLI in accordance with Article 6 and 7 of the Donation Code.*

- 20.** Can a pharmaceutical company make a donation to a hospital where the donation covers the hospital's release of the book: "Young and suffering with Depression"? The hospital will deliver the book to young people with depression as well as their relatives.

ANSWER: *Yes, cf. Art. 4 of the Donation Code.*

- 21.** Can a pharmaceutical company make a donation to a hospital where the donation covers the expenses for a nurse to keep free from normal work for three months in order to complete a project; preparation of figures, tables and manuscripts for publication?

ANSWER: *Yes, cf. Art. 4 of the Donation Code, as this is a project that has a professional purpose and is of benefit to the hospital and patient care.*

- 22.** Can a pharmaceutical company make a donation to a hospital where the donation covers the salary of an additional employee for one year to reduce waiting lists for treatment more quickly?

ANSWER: *No, cf. Art. 4 of the Donation Code, the company's donation must not cover the operation of the hospital itself.*

- 23.** On behalf of a hospital, a doctor contacts a pharmaceutical company with the desire for financial support to publish his studies. The doctor is doing research on behalf of the hospital. Can the pharmaceutical company provide financial support to a hospital in connection with a doctor's publication of a study mentioning the pharmaceutical company's product?

ANSWER: *Yes, cf. Art. 4 of the Donation Code. Since a donation may be granted for hospital research, it is considered that a donation may also be used for the publication of studies, as research and publication of research results are closely related.*

- 24.** Can a pharmaceutical company make a donation to a hospital, regarding a retrospective project where the hospital will review 500 patient records? The project is not part of the daily clinical practice. A nurse must be hired for data processing in the project, and the project must end with an article to be published.

ANSWER: *Yes, cf. Art. 4 of the Donation Code.*

- 25.** Can a pharmaceutical company donate pedometers to hospitals for re-delivery to patients? The patient will not have to return the pedometer.

ANSWER: *No, it is only possible to hand out a pedometer to a patient, if this is only on loan for a specified period and that the pedometer is part of the patient's treatment, cf. section 4 of the Donation Code.*

- 26.** Can a pharmaceutical company make an extra donation to an already ongoing study sponsored by the company? The extra donation is lending of IT equipment due to the healthcare professional's need for homework and patients' inability to physically attend the hospital.

ANSWER: *Yes, the extra donation will be possible in the above situation, as the company has already given money to the project, and this extra donation can therefore be considered as an integral part of the study. As an independent donation (and thus not as part of a study / research) it will not be possible to provide financial support to regular computer equipment, as this will be support for general operations that are not directly health related.*

- 27.** Is it permissible for a pharmaceutical company to donate a special freezer to a hospital if the pharmaceutical company has a medicine that needs to be frozen to minus 50 degrees.

ANSWER: *Yes, such a donation will comply with the Donation Code.*

- 28.** Do the provisions set out in the Donation Code relating clinical trials apply to all categories of research projects – including, for instance, preclinical in vitro studies – or are they limited in scope to clinical trials only?

ANSWER: *Yes, it is ENLI's assessment that it is not decisive whether it is a clinical study or a preclinical in vitro research study - both are considered research, and ENLI applies the same distinction regardless of where you are in the research process*

- 29.** Can a pharmaceutical company make a donation to a hospital in the form of drinking bottles with the intention that these bottles are distributed by the hospital to parents of children who have been prescribed a medicine to be dissolved in water? The drinking bottles are clearly labelled with a measuring mark indicating the exact amount of water required to dissolve a packet containing the medicine. The purpose of dispensing is to ensure correct dosage and administration of the medicine.

ANSWER: *Provided that the water bottles are not branded in any way (company name, logo, or product name) and that it is the hospital that independently decides whether a water bottle should be given to the parents, the donation is considered to be in accordance with section 4(1) of the Donation Code, as the distribution of the water bottles is considered an integral part of the treatment.*

Independence – Article 11

- 30.** Can a pharmaceutical company donate needles for a device to a hospital with the condition that the needles may only be used in the company's marketed devices?

ANSWER: *No, cf. section 11 of the Donation Code. As a starting point, the company must not have an influence on the hospital's specific use of the support. Therefore, it is not possible to stipulate or mention to the hospital department that the donated needles may only be used in the company's own devices.*

Branding – Article 14

- 31.** A pharmaceutical company has received a pre-approval from ENLI for a pocket guide for doctors and a patient information leaflet. The materials are already in use in several hospitals. Other hospitals want to use the materials, but internal guidelines prevent this as the pharmaceutical company's name or logo appears in small print on the back of the materials. Is it in accordance with the Donation Code to remove the company name and logo so that the materials can be used without any visible reference to the pharmaceutical company?

ANSWER: *Yes, branding of materials under section 14 of the Donations Code is considered optional rather than compulsory. Therefore, materials can be distributed to hospitals without a company logo or company name, cf. section 14 of the Donation Code, to the contrary.*

- 32.** A pharmaceutical company wants to donate a kit to a hospital consisting of a cooler bag with a cooling element for storing medicines that need to be kept cold and a small needle container. The kit is intended for patients who have been prescribed a medicine to be injected at home and where the medicine needs to be transported in cool conditions. The pharmaceutical company wants the cooler bag to be labelled with the company name and the name of the medicine. Does the support comply with the rules of the Donation Code?

ANSWER: *Yes, such a donation (cooler and small needle container) would, in principle, comply with section 4(1) of the Donation Code, as the donation is considered an integral part of the treatment.*

According to section 66(1)(1) of the Danish Medicines Act, prescription medicines may not be advertised to the public. Therefore, donations dispensed to patients must not be branded unless it has been specifically assessed that such branding serves a patient safety purpose.

It is therefore essential that the starter kit does not bear the name, logo, product name or generic name of the company or medicine. The cooler bag must therefore not be branded.

Branding of the cooler bag will generally not be considered to serve a patient safety purpose, as only the medicine itself needs to be kept refrigerated. However, if several medicines are dispensed - e.g. from different companies - and there is uncertainty as to which medicine requires refrigerated storage, a visible indication may serve a legitimate patient safety purpose.

Abbreviations

Donation Code	Ethical rules on the pharmaceutical industry's donations and grants to hospitals.
EFPIA	The European Federation of Pharmaceutical Industries and Associations
ENLI	Ethical Committee for the Pharmaceutical Industry in Denmark
Lif	The Danish Association of the Pharmaceutical Industry
NMI	Danish Board of Medicines Advertising (Nævnet for Medicinsk Informationsmateriale)
Advertising Order	Order on Advertising, etc., for Medicinal Products (Bekendtgørelse nr. 849 af 29/04/2021 om reklame mv. for lægemidler, som ændret ved BEK nr. 227 af 27/02/2025)
The Promotion Code	The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals