Version 3.0

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# GUIDANCE

## to

## ”Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry” (Patient Organisation Code)

The guidance on the Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry (Patient Organisation Code) will continuously be updated as practices develop or change. The guidance is therefore 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*

## Introductory comments

At first the Patient Organisation Code was decided on by the Pharmaceutical Industry, but since EFPIA adopted their PO Code on 14th June 2011, the Patient Organisation Code has subsequently been adjusted to comply with the obligations of EFPIA's PO Code (now part of EFPIA Code of Practice).

The term "Patient Organisation, etc." will be used throughout this guidance, covering Patient Organisations and other organisations working for patient-related issues, health-related issues (e.g., the Danish Mental Health Fund), or other organisations promoting consumer interests who have focus on health issues (e.g., the Dane Age Association and the Danish Consumer Council).

Please note that the rules in this guide only apply to the pharmaceutical companies affiliated with ENLI's rules. If you would like to see which companies have joined ENLI, an updated list can be found on the front page of www.enli.dk.

At the end of this guide your will find a Q&A, where answers to questions that ENLI has received can be found.

# COMMENTS ON CHAPTER 1 – INTRODUCTORY PROVISIONS

## Purpose

*Art. 1.*

*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.*

## Re Article 1

The purpose of the Patient Organisation Code is consistent with EFPIA's Code of Practice, Section 21.01.

In addition, the provision has been rewritten in relation to the previous provision in article 1, so that it is more aligned with the purpose provision in the Promotion Code in structure and wording.

## Definitions

*Art. 2.*

*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 set of ethical rules:*

*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 Importers 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 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.*

## Re Article 2

It follows from the introduction to the EFPIA Code of Practice that it covers collaborations between EFPIA members, including their subsidiaries and contractual third parties (e.g., agencies), and patient organisations operating in Europe.

It is ENLI's opinion that a company affiliated with ENLI can only be regarded as co-responsible for the activities of corporate companies if the ENLI-affiliated company is considered a co-organiser thereof. Thus, the ENLI-affiliated company must be sufficiently involved in the activity in question. This means, in ENLI's assessment, that the ENLI-affiliated company must have shown clear and direct actions in the development and / or execution of the specific activity. A company may assist the group-affiliated companies with knowledge of the understanding of the Danish rules, so that compliance with the rules is ensured. On the other hand, if more active steps are taken in the development and/or the execution of the activity, the ENLI-affiliated company in question will move in the direction of a responsibility that must be reported to ENLI.

### *Re Article 2, section 2.01*

The Patient Organisation Code applies to cooperation with patient organisations, as defined in Article 1, section 7 of the Advertising Order, meaning organisations of patients and relatives, whose purpose is to protect the interests of patient groups, cf. Article 71 d of the Danish Medicines Act. The comments on Article 71d of the Danish Medicines Act state that the Article covers organisations for patients with certain diseases, such as cancer or arthritis, as well as umbrella organisations for Patient Organisations. An example of an umbrella organisation for Patient Organisations is Danish Patients. If the organisation is not a union of patients and relatives, it is not considered a Patient Organisation.

In this relation, it should be noted that EFPIA, in their Code of Practice, defines Patient Organisations as *"not-for-profit legal person/entity (including the umbrella organizations to which it belongs), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Europe."* According to ENLI, EFPIA's definition is similar to the definition used in the Patient Organisation Code.

### *Re Article 2, section 2.02*

In addition to Patient Organisations, the Patient Organisation Code also applies to collaboration with other organisations working for patient-related issues, health-related issues (e.g., the Danish Mental Health Fund) or other organisations promoting consumer interests that have focus on health issues (e.g., the Dane Age Association and the Danish Consumer Council).

| | Definition | Example |
|---|---|---|
| **Patient organisation** | • Organisations of patients and/or relatives whose purpose is to work for the interests of a particular group of patients | • The Danish Multiple Sclerosis Society<br>• Danish Psoriasis Association<br>• Danish Patients |
| **Other organisations** | • Organisations working for *patient-related* issues *and*/or *health-related* issues<br>• Organisations working for promoting *consumer interests* that have *focus on health issues* | • The Danish Mental Health Fund<br>• The Dane Age Association<br>• The Danish Consumer Council |

ENLI does not find that collaboration with the organisations listed below is covered by the Patient Organisation Code, as these organisations are not; 1) organisations of patients and relatives or 2) organisations working for a specific disease, patient group or organisations working for promoting consumer interest with a health policy focus:

- Danish Hospital Clowns
- Youth Red Cross/Red Cross
- SMIL Fonden (Smile Foundation)
- Julemærkefonden (The Christmas Seal Foundation)

*Re Article 2, section 2.03, litra a) to d)*

On the front page of ENLI's website www.enli.dk, an updated list of the companies that have joined ENLI can be found.

*Re Article 2, section 2.03, litra e)*

This code also applies to third-party events that are targeted at Patient Organisations, etc., and where the funding (in whole or in part) comes from the pharmaceutical industry.

It should be noted that a similar provision applies to Patient Organisations in accordance to the Advertising Order, and Section 5.4 of the guidance to the Advertising Order states that: *"The provision* [Article 21 of the Advertising Order, ed.] *applies when a Patient Organisation has received a financial benefit directly from a pharmaceutical company, but also applies when a Patient Organisation has received a financial benefit, provided through a third party, from a pharmaceutical company. A financial benefit that is substantially financed by a pharmaceutical company will in principle also be covered by Article 21 of the Advertising Order, even if it is provided by a third party, if it must be clear to the Patient Organisation that the company's participation is a crucial and necessary condition for the transfer of the financial benefit to the organisation."*

*Re Article 2, section 2.04*

"Benefits" are also covered by article 2, section 4, re. "Support". For example, it would be considered a benefit for a Patient Organisation if the Patient Organisation receives information about illness and / or health from a pharmaceutical company.

*Re Article 2, section 2.05*

Any contact from a pharmaceutical company that entails a value for a Patient Organisation, etc., is covered by the Patient Organisation Code.

*Re Article 2, section 2.06*

Currently there is no guidance for this provision.

## Scope

*Art. 3.*

*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.*

## Re Article 3

- ENLI affiliated companies' collaboration with Patient Organisations:

| | **Activity in Denmark** | **Activity outside Denmark, but within Europe** | **Activity outside Europe** |
|---|---|---|---|
| **Collaboration with a Danish Patient Organisation** | The Patient Organisations Code | The Patient Organisations Code | The Patient Organisations Code |
| **Collaboration with a European Patient Organisation** | The Patient Organisations Code | EFPIA Code and national regulations | National regulations and industry association regulations |
| **Collaboration with a non-European Patient Organisation** | The Patient Organisations Code | EFPIA Code and national regulations | National regulations and industry association regulations |

The Patient Organisation Code does not apply to pharmaceutical companies' cooperation with international Patient Organisations, etc., if the cooperation takes place outside of Denmark.

# COMMENTS ON CHAPTER 2 – SUPPORT AND COLLABORATION

## Support for healthcare services, research, and education

*Art. 4.*

*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*

## Re Article 4

The provision implements EFPIA's Code of Practice Sec. 12.01 and 12.02.

Re professional activities, please refer to re Article 5 below.

*Art. 5.*

*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.*

## Re Article 5

*Re Article 5, section 5.01*

Please refer to re Article 6, no. 3.

Pharmaceutical companies can provide support for all the activities, projects, and purposes for which the Patient Organisation, etc., is working. This means that the pharmaceutical companies cannot provide general operating support to the Patient Organisation, etc., but can only provide support in connection with specific projects and purposes within the Patient Organisation's, etc., scope. ENLI finds that it is in accordance with the Patient Organisation Code to educate the Patient Organisations, etc., within the given field of disease, for example through professional meetings or congresses, as long as the other rules of the Code are respected. Should the company itself host the meeting, the general rules for promoting to the public must be respected. This means, among other things, that no prescription medicine must be promoted.

A pharmaceutical company can also provide support in kind. This could be a presentation by the pharmaceutical company at one of the Patient Organisation's events. However, the company must ensure compliance with the rules regarding promotion of medicines to the public. Another form of support in kind could be to provide facilities. However, please be aware of the appearance of independence of the company and the Patient Organisations, etc., cf. re Article 11, regarding independence.

*Re Article 5, section 5.02*

Currently there is no guidance for this provision.

*Re Article 5, section 5.03*

This provision corresponds to EFPIA's Code of Practice Section 10.01.

The provision must be interpreted in accordance with Section 13.03 and 13.10 of the Promotion Code, regarding venues.

*Re Article 5, section 5.04*

This provision corresponds to EFPIA's Code of Practice Section 10.04 and 10.07.

The provision covers both events organised by the Patient Organisations, etc., and by the pharmaceutical company.

The provision must be interpreted in accordance with Section 13.07 of the Promotion Code.

*Re Article 5, section 5.05*

This provision corresponds to EFPIA's Code of Practice Section 10.08.

To determine whether an event should be considered entertainment or professional depends on what the purpose of the event is. Is it information about the disease or is it entertainment? It is necessary to assess why participants may wish to participate in the event.

It is ENLI's opinion that Patient Organisations work to raise awareness of a specific disease, including through awareness campaigns, which is why there is some leeway for activities that Patient Organisations want to carry out. However, what matters is the purpose of the activity, information or entertainment.

In addition, the provision is interpreted based on the principle in Section 13.09 of the Promotion Code.

*Re Article 5, section 5.06*

This provision corresponds to EFPIA's Code of Practice Section 10.06.

Currently there is no guidance for this provision.

*Re Article 5, section 5.07*

This provision corresponds to EFPIA's Code of Practice Section 10.05.

The provision is interpreted based on the principle in section 13.07 and 13.08 of the Promotion Code.

*Re Article 5, section 5.08*

This provision corresponds to EFPIA's Code of Practice Section 13.01.

Currently there is no guidance for this provision.

*Re Article 5, section 5.09*

This provision corresponds to EFPIA's Code of Practice Section 10.02.

The provision is interpreted based on the principle in section 13.04 of the Promotion Code.

## Contract terms

*Art. 6.*

*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.*

## Re Article 6

*Re Article 6, no. 1*

Cooperation agreements between pharmaceutical companies and Patient Organisations, etc., must be in writing, and number 1-8 must at minimum be stated in the written agreement. The provision corresponds to EFPIA's Code of Practice Section 21.03.

*Re Article 6, no. 3*

For further information, please refer to re Section 5.01 above.

To describe the type of project it must be stated whether these are specific meetings, pamphlets, information campaigns, education programs, travel, etc.

Since it is a Patient Organisations, etc., receiving support, the Patient Organisation Code accepts that companies can provide support for the Patient Organisation’s board meetings and representative meetings, as these meetings are a natural part of a Patient Organisation. However, support for the daily operation of the organisation is not allowed.

A membership of a Patient Organisation is not considered collaboration or support if the price reflects a genuine membership. If the price is higher than a membership, the payment will be considered a support, and the rules for collaboration with a Patient Organisation must therefore be complied with. The name of the membership (e.g., business partnership, business quotas, etc.) is not the deciding factor.

What matters is the price of membership and whether this should be seen as a collaboration or simply a regular membership. Please note that the assessment above only applies to pharmaceutical companies, as Patient Organisations, in accordance with Article 21 of the Advertising Order, must report all collaborations with pharmaceutical companies that provide value to the Patient Organisation. Section 21.01 of the Advertising Order states that*: "A Patient Organisation must publish on its website all financial benefits, including financial sponsorships (money) and in kind, which the Organisation has received from pharmaceutical companies."*. The publication must take place in such a way that the amount of financial support from each individual pharmaceutical company appears on the Patient Organisation's website, cf. Section 21,02 of the Advertising Order.

*Re Article 6, no. 7 and 8*

Indication of the value of financial support:

- The factors that can be valued must state the actual value
- Other support must be clearly stated

In both cases, it must be stated what the support is used for.

For significant non-financial support that cannot be measured at meaningful financial value, such support is required to include a description that clearly explains the non-financial benefit received by the Patient Organisations, etc.

## Transparency

*Art. 7.*

*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 published 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 is concluded 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.*

## Re Article 7

This provision corresponds to EFPIA's Code of Practice Article 24.

### *Re Article 7, section 7.01*

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 eight conditions outlined in art. 6. It is also accepted to use the list that companies affiliated with ENL must submit to ENLI once a year, cf. Section 7.03 in this code.

Patient Organisations must publish all financial supports at its website, including financial sponsorships (money) and payments in kind received from pharmaceutical companies, cf. Article 21 of the Advertising Order. The publication on the website should show the amount of financial support from each company. The information must be available on the website no later than one month after the Patient Organisation has received the financial support. The information must be available on the website for at least two years, cf. Section 21.03 of the Advertising Order.

### *Re Article 7, section 7.02*

Currently there is no guidance for this provision.

### *Re Article 7, section 7.03*

This provision obliges only the companies who are affiliated ENLI. Note the section on good advice in connection with the annual report to ENLI later in this guidance.

## Contracted services

*Art. 8.*

*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.*

## Re Article 8

This provision corresponds to EFPIA's Code of Practice Section 15.01.

Currently there is no guidance for this provision.

*Art. 8.*

*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.*

*Re Article 8, section 8.02, no. 1-7*

The provision corresponds to EFPIA's Code of Practice Section 15.02, litra a-g.

*Re Article 8, section 8.02, no.7*

If the contracted service comprises the involvement of patients who are members of the Patient Organisation, payment may take place, directly from the pharmaceutical company to the patient, even if the contract is signed with the Patient Organisation. It is recommended that this is specified in the contract.

*Re Article 8, section 8.02, no.8*

The provision does not derive from EFPIA's Code of Practice but is identical to the provision in Article 15 of the Promotion Code, where the provision is implemented from Section 24.02 of the Advertising Order.

*Re Article 8, section 8.02, no.9*

Currently there is no guidance for this provision.

*Re Article 8, section 8.02, no.10*

The publication requirement corresponds to EFPIA's Code of Practice Article 24.

Companies are required to publish their agreements with the Patient Organisations, etc., within the scope of these rules. This obligation is fulfilled by disclosure on the company's websites, i.e., the website to which the company is linked.

If a company only has a global website, or only want a Nordic website, and not a national website, then the global respectively Nordic websites are to be considered the nearest website for the ENLI affiliated company.

If the global or Nordic website is subdivided into countries, such as a sub-section for the Danish part of the company, the publication must be made on the sub-pages. Thus, the company must disclose at the website that the company is linked to, and which represents the ENLI affiliated company.

*Art. 8.*

*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 promoting.*

*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.*

*Re Article 8, section 8.03*

This provision corresponds to EFPIA's Code of Practice Article 15.04.

Currently there is no guidance for this provision.

*Re Article 8, section 8.04*

This provision corresponds to EFPIA's Code of Practice Article 10 and 11 and Section 13.01.

Currently there is no guidance for this provision.

# *COMMENTS ON CHAPTER 3 – GENERAL PROVISIONS*

## Information on medicinal products and advertising

*Art. 9.*

*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.*

## Re Article 9

This provision corresponds to EFPIA's Code of Practice Section 21.02.

Currently there is no guidance for this provision.

## Prohibition against financial benefits and gifts

*Art. 10.*

*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.*

## Re Article 10

This provision corresponds to EFPIA's Code of Practice Article 11.

The provision must be interpreted in accordance with Article 12 of the Promotion Code, according to which a gift ban applies, which in this context also includes occasional gifts, etc.

## Independence

*Art. 11.*

*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.*

## Re Article 11

When a pharmaceutical company provides support to a Patient Organisation, etc., it is important that collaboration takes place between independent parties.

This means that pharmaceutical companies cannot influence the Patient Organisation material supported by the company to favour their own commercial interests.

However, a pharmaceutical company may, at the request of the Patient Organisation, etc., prepare text drafts when done in a reasonable and balanced scientific perspective. In addition, the company may correct incorrect facts.

*Re Article 11, Section 11.01 and 11.02*

These provisions correspond to EFPIA's Code of Practice Section 21.01 and 13.03.

*Re Article 11, Section 11.03*

This provision corresponds to EFPIA's Code of Practice Section 21.02. and 21.04.

## Impartiality

*Art. 12.*

*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.*

## Re: Article 12

*Re Article 12, section 12.01 and 12.02*

Currently there is no guidance for these provisions.

*Re: Article 12, section 12.03*

An example of when there is no unethical conflict of interest between the parties, would be if a Patient Organisation, etc., operates completely outside the company's business area.

## Use of the organisation's logo

*Art. 13.*

*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's, 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.*

## Re: Article 13

This provision corresponds to EFPIA's Code of Practice Section 13.02.

The written agreement with the Patient Organisation, etc., must clarify the specific purpose of the use of the logo, the name, etc., and how the use will take place.

## Branding

*Art. 14.*

*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.*

## Re: Article 14

The provision corresponds to section 14.04 of the Promotion Code and in EFPIA's Code of Practice section 17.04 regarding information and teaching materials as well as medical equipment.

The provision is interpreted based on the principle in section 14.04 of the Promotion Code.

## Exclusive agreements

*Art. 15.*

*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.*

## Re: Article 15

This provision corresponds to EFPIA's Code of Practice Art. 14.

## Enforcement

*Art. 16.*

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

## Re: Article 16

Currently there is no guidance for this provision.

## Entry into force

*Art. 17.*

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

## Re: article 17

Currently there is no guidance for this provision.

## Guidance on the annual reporting of collaborations with patient organisations to ENLI:

In December, ENLI submits a reporting form, in a word document, where ENLI's affiliated companies must enter all collaborations with patient organisations, etc., for the current 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 CPR numbers in the reporting form
- All amounts in DKK (not euros, etc.)
- It must be stated whether the amount is inclusive or exclusive 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 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 may only provide support for a Patient Organisation, etc., if the support is provided:

- With the purpose to support professional activities regarding health, research, and education

  and

- For activities, projects, and purposes for which the Patient Organisation, etc., is working.

This means that the pharmaceutical company cannot provide general operating support to a Patient Organisation, etc., but can only provide support in connection with specific projects and purposes for which the organisation is working.

## Definitions - Article 2

**1.** A pharmaceutical company provides financial support of DKK 50,000, to the Patient Academy from "Medicinske Tidsskrifter" for use in hosting an event targeted a Patient Organisation. Does the Patient Organisation Code apply?

**ANSWER**: *Yes, cf. Section 2.03, litra e) of the Patient Organisation Code. It should be noted that the Patient Organisation is also obliged to state that they have received tuition to a value of DKK 50.000 from the pharmaceutical company on the Patient Organisation's website, cf. Article 21 of Advertising Order.*

**2.** A pharmaceutical company offers a free online course on topics within a disease area targeted a Patient Organisation. The Patient Organisation does not pay to attend the meeting. Does the Patient Organisation Code apply?

**ANSWER**: *Yes, cf. Section 2.04 of the Patient Organisation Code. Support is also benefits in kind. The Patient Organisation receives education that has a value, even though the Patient Organisation in the specific case does not pay a fee for participation. However, the Patient Organisation receives a benefit that has a value, as the Patient Organisation receives new knowledge that they should have paid for under normal circumstances.*

## Scope – Article 3

**3.** A Danish pharmaceutical company has granted a Swedish patient organisation DKK 100,000 for organising an event for Nordic Patient Organisations. The event will be held in Sweden. Does the Danish Patient Organisation Code apply?

**ANSWER:** *The sponsorship is not covered by the Patient Organisation Code as the recipient is a Swedish Patient Organisation and the event is held in Sweden. However, the sponsorship must comply with the EFPIA Code and Swedish rules. Therefore, the event must be disclosed, and we recommend that Swedish Lif be contacted for further guidance.*

**4.** A German pharmaceutical company (a subsidiary that is not affiliated with ENLI) has provided a grant to a Danish Patient Organisation. The pharmaceutical company's HQ is in Denmark, but HQ has not been involved in the support for the Danish Patient Organisation. Does the Danish Patient Organisation Code apply?

**ANSWER:** *Yes. Please note that the company's headquarter is in Denmark, which is why all activities that the company (national and international group companies) carries out in Denmark must apply with ENLI's rules.*

## Support/professional activities – Article 4 and 5

**Operation:**

**5.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation for the preparation of postcards for general practitioners (illness awareness)?

**ANSWER:** *Yes. It is possible to provide operational support for a specific project aimed at raising awareness of the disease.*

**6.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation for publishing the organisation's magazine?

**ANSWER:** *Yes. It is possible to provide operational support for a specific project that is in line with the purpose of the Patient Organisation.*

**7.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation for paying a social worker and a psychologist to write an article on a disease for the Patient Organisation's magazine for members?

**ANSWER:** *Yes. It is possible to provide support for a specific project that is in line with the purpose of the Patient Organisation.*

**8.** Is it possible for a pharmaceutical company to provide financial support for the general operation of a Patient Organisation - e.g., office furniture, salary for the Patient Organisation's permanent secretary, office supplies, rent?

**ANSWER:** *No. It is not possible to provide support for the general operation of the Patient Organisation. The pharmaceutical company can only support in relation to specific activities, projects, and purposes for which the Patient Organisation works.*

**9.** A pharmaceutical company wants to offer on their website the following free online courses targeted at Patient Organisations: 1) how the Patient Organisation recruits new members, and 2) how to run a Patient Organisation in the best possible way. Can the company offer these courses?

**ANSWER:** *No, as the topics relate to the Patient Organisation's general operation, it will not be in accordance with the Patient Organisation Code. The pharmaceutical company can only provide support in connection with specific activities, projects, and purposes for which the patient organisation works, cf. Section 5.01 of the Patient Organisation Code.*

## Professional activities – Section 5.01

**10.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation by lending view books to doctors, so that the organisation does not need to charge rent from the healthcare professionals. The purpose of the view books is to provide the doctor's patients with information about the disease area, which the Patient Organisation works within.

**ANSWER:** *Yes, this financial support is regulated by the Patient Organisation Code.*

**11.** Is it possible for a company to invite the board of a Patient Organisation to visit the company, so the board can learn more about the company and how it works? No medicines are mentioned during the visit.

**ANSWER:** *Yes, provided there is no mentioning of medicines at any time, it is possible for a company to invite for such an informational meeting. The mention of prescription medicines will be considered promoting of prescription medicines to the public.*

**12.** A pharmaceutical company wants to invite a Patient Organisation to a lecture as well as a tour of the company's factory, where participants can see the process of manufacturing medicines. Is it possible for the company to invite for such an event?

**ANSWER:** *As the participants are not healthcare professionals, a pharmaceutical company is only*

*allowed to give presentations on disease and healthcare. ENLI will not recommend a guided tour of the company's factory, as the event may include promotion of medicines. Promotion to the public of prescription medicine is not allowed, cf. Section 66.01, no. 1, of the Danish Medicines Act.*

**13.** A pharmaceutical company wants to give a donation to a Patient Organisation at a TV show. The company name is mentioned on the screen. The financial support goes to courses for families with children, research into diabetes, counselling, prevention, and information. Is it possible for the pharmaceutical company to provide financial support?

**ANSWER***: Yes, cf. Section 3,01, litra a) and Section 5.01 of the Patient Organisation Code. The decisive factor is whether the support (i.e., what the company's money goes to) meets the rules of the Patient Organisation Code. As the financial support goes to courses targeted at families with children, research into diabetes, counselling, prevention and information, the support is in line with the purpose of the Patient Organisation.*

**14.** A pharmaceutical company wants to give a financial support to a Patient Organisation. The company's manager wants to provide support of DKK 20,000 from the department's budget, and the company's employees support with a total of DKK 5,000, which is the result of a private collection among the employees of the company. Is the support covered by the Patient Organisation Code?

**ANSWER***: As far as the employees' private donation is concerned, this is not covered by ENLI's rules, and the employees are therefore free to provide financial support to the Patient Organisation. The financial support that is provided by the company must comply with the rules in the Patient Organisation Code, and can therefore, for example, be given for information campaigns or the like, i.e., support in connection with specific activities, projects, and purposes for which the Patient Organisation works, cf. the Patient Organisation Code Section 5.01. It is not possible for the pharmaceutical company to provide an unrestricted grant.*

**15.** A pharmaceutical company wants to sponsor a Patient organisation's participation in an international congress, where as part of the congress fee there is access to an exhibition area (i.e., area with promotion of prescription medicine). Is it possible for the pharmaceutical company to pay for the participation of the Patient Organisation at the international congress?

**ANSWER***: A pharmaceutical company can sponsor a Patient Organisation's participation in professional activities. However, according to the Advertising Order, the public may not be allowed to access exhibition areas or other places where there may be promotion of prescription medicine.*

## Entertainment – Section 5.05

**16.** Is it possible for a pharmaceutical company to provide financial support for a Patient Organisation's hosting of a chief ball tournament where the organisation will inform and test for a given disease?

**ANSWER:** *Yes. However, it is essential what the purpose of the activity is; information or entertainment? The pharmaceutical company can only provide financial support if the purpose is information.*

**17.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation, who on Facebook wants to raise awareness of the Patient Organisation's new website?

**ANSWER:** *See the answer above.*

**18.** Is it possible for a pharmaceutical company to provide financial support to a Patient Organisation for a photo exhibition - disease awareness campaign?

**ANSWER:** *The answer depends on the content of the photo exhibition. If the photo exhibition shows photos of the disease or otherwise provides information relevant to the Patient Organisation, it will be compliant for the pharmaceutical company to provide support to the Patient Organisation in connection with the organisation's photo exhibition.*

*If the photo exhibition shows photos that are not relevant to the Patient Organisation, e.g., photos of landscapes and animals, and thus does not provide knowledge about the disease in question, the pharmaceutical company cannot provide support for the photo exhibition.*

**19**. Is it possible for a pharmaceutical company to provide financial support for a Patient Organisation to host an anniversary and theme event?

**ANSWER:** *If the event is only for the Patient Organisation's employees, the company cannot provide financial support, as the support then will not cover cost of an activity, project, or purpose for which the organisation is working, cf. Section 5.01.*

*If the event is for anyone other than the Patient Organisation staff, the company's option for support will depend on the content of the event - i.e., is information about the disease included, etc. or it is just entertainment.*

**20.** Is it possible for a pharmaceutical company to provide financial support for a Patient Organisation's hosting of a summer camp (for children, adolescents, and their parents)?

**ANSWER:** *Generally, this will not be possible, as the support is not given for an activity, project, or purpose for which the organisation is working, cf. Section 5.01. However, it depends on the content and purpose of the summer camp.*

**21.** A pharmaceutical company has purchased an exhibition stand by a Patient Organisation in connection with the organisation's educational event for healthcare professionals. Is this purchase regulated by the Patient Organisation Code?

**ANSWER:** *No, an actual purchase of an exhibition stand is not considered a financial support or collaboration with the organisation (and thus not covered by the Patient Organisation Code). The purchase is instead regulated by the rules of the Promotion Code (Article 18 of the Promotion Code). If the price for the exhibition stand exceeds the market price, the support will be covered by the Patient Organisation Code.*

**22.** A pharmaceutical company wants to purchase a seat on a bicycle team that is being offered by a Patient Organisation in connection with a campaign. The company wants to give the seats on the team to their own employees. Is this purchase regulated by the Patient Organisation Code?

**ANSWER:** *No. The Patient Organisation Code does not apply to the purchase. ENLI finds that it is an actual purchase, and thus not a collaboration.*

**23.** A Patient Organisation wants to host a music concert where the profits from ticket sales goes uncut to research in the field of disease for which the Patient Organisation works. Is it possible for the pharmaceutical company to provide support for the concert?

**ANSWER:** *No. In connection with events, the company is not allowed to sponsor or organise any type of entertainment activities, cf. Section 5.04 of the Patient Organisation Code.*

## Representation – Section 5.06

**24.** Is it possible for a pharmaceutical company to provide financial support for the Patient Organisation's transport and accommodation at the Peoples Political Festival on Bornholm (awareness campaign)?

**ANSWER:** *Yes. Keep in mind that catering and representation must be at a reasonable level and must be strictly limited to the purpose of the event. The meal-caps must be observed. For further information, please refer to the guidance to the Promotion Code regarding representation and catering.*

**25.** A network meeting is planned, where European and global Patient Organisations discuss and share strategies and will increase knowledge of the field of disease. Is it compliant for the pharmaceutical company to pay the costs associated with the meeting (catering and rent of venue)?

**ANSWER:** *Yes, a pharmaceutical company can cover Patient Organisations' expenses for catering and rent of venue in conjunction with a network meeting, where Patient Organisations discuss and share strategies to increase knowledge of the field of disease.*

**26**. A Danish pharmaceutical company has given a Danish Patient Organisation DKK 100,000 for organising an event to inform and provide knowledge about a disease. Unfortunately, the event was cancelled due to lack of participants. Is it allowed for the Patient Organisation to set off the documented expenses that the Patient Organisation has already paid in planning the event, before returning the remaining amount to the pharmaceutical company?

**ANSWER:** *Yes, but the amount the Patient Organisation receives from the company must be made public even though it may be a small amount and the event is cancelled.*

## Contract terms – art. 6

**27.** A pharmaceutical company has paid Asthma Allergy Denmark for costs associated with printing the "blue label" on products in the Nordic region. Does the Patient Organisation Code apply?

**ANSWER***: No. ENLI finds that it is a purchase of a right - the purchase of the right to use the "blue label". Therefore, the Patient Organisation Code does not apply to this purchase.*

**28.** A pharmaceutical company buys advertising space in a Patient Organisation's membership magazine. Is this purchase covered by the Patient Organisation Code?

**ANSWER***: No. Purchase of an advertisement in a membership magazine for a Patient Organisation is not to be regarded as a collaboration covered by the Patient Organisation Code if the purchase takes place on normal market terms. Thus, price and exposure options must be proportional - i.e., that there must be a reasonable ratio between the price of the ad and the number of readers of the membership magazine.*

**29.** A pharmaceutical company has acquired a business partnership from a Patient Organisation. The company gets its logo on the organisation's website, and the company may use the Patient Organisation's support logo on the company's own website. Is the collaboration covered by the Patient Organisation Code?

**ANSWER***: No. ENLI assesses that this is a purchase of advertising space - "quid pro quo". The purchase is not covered by the Patient Organisation Code.*

## Transparency – art. 7

**30.** A pharmaceutical company has paid DKK 50,000 in support to a Patient Organisation for the use of an awareness campaign. The Patient Organisation alone uses DKK 40,000 for the campaign and

therefore repays DKK 10,000 to the company. Is it the amount in the contract (DKK 50,000) or the actual amount spent (DKK 40,000) that the pharmaceutical company must report to ENLI?

**ANSWER**: *The pharmaceutical company must report to ENLI the actual amount (DKK 40,000) used by the Patient Organisation. However, the company should contact the relevant Patient Organisation to ensure that the Patient Organisation also publishes the amount spent and not the amount stated in the contract between the company and the Patient Organisation.*

**31.** In November 2021 (contract signed by the parties), a pharmaceutical company entered into an agreement to provide DKK 100,000 in support of a Patient Organisation's awareness campaign. The pharmaceutical company pays the amount to the Patient Organisation in February 2022. In which year must the amount be reported to ENLI? (i.e., must the pharmaceutical company report the collaboration in 2021, when the contract is signed or should the collaboration be reported in 2022, when the amount was paid)?

**ANSWER**: *The collaboration must be reported in 2022, as the payment is the decisive factor in relation to reporting to ENLI.*

## Contracted services – art. 8

**32.** A pharmaceutical company has arranged an Advisory Board with participation of a Patient Organisation where the company pays a fee to the invited participants. Is this collaboration regulated by the Patient Organisation Code?

**ANSWER:** *Yes, cf. Section 8.02 of the Patient Organisation Code.*

## Representative from a Patient Organisation as speaker

**33.** A pharmaceutical company wants a representative from a Patient Organisation to talk about a disease and the work of the Patient Organisation at the company's continuing education event. Is it possible for the pharmaceutical company to contact the Patient Organisation, who then selects a member of the Patient Organisation who will speak as a representative for the Patient Organisation?

**ANSWER:** *Yes.*

**34.** If a pharmaceutical company previously has used a representative from a Patient Organisation as a speaker, is the pharmaceutical company allowed to contact this speaker directly or should the contact always go through the Patient Organisation?

**ANSWER:** *This must be agreed with the specific Patient Organisation.*

**35.** Is it a requirement that the pharmaceutical company send their inquiry to the chairman of the Patient Organisation?

**ANSWER:** *It depends on the procedure in the individual Patient Organisation – does the organisation have a general mailbox to write to or a specific contact person? If not, ENLI recommends contacting the chairman.*

**36.** Does ENLI have a guide for fair market value to speakers?

**ANSWER:** *No. ENLI has no rules for fair market value of speaker-fees, but consistency between the fee and the service provided must be present.*

**37.** Is it a requirement that a pharmaceutical company sign a contract with a Patient Organisation (and pay the fee to the Patient Organisation) or should the company instead contract directly with the selected speaker (after the Patient Organisation has approved the task and the speaker)?

**ANSWER:** *It depends on the Patient Organisation's internal rules, including whether the fee belongs to the Patient Organisation or the selected speaker.*

**38**. Is it a requirement that a pharmaceutical company is paying the speaker-fee to a Patient Organisation or directly to the selected speaker?

**ANSWER:** *See the answer above.*

**39.** If a pharmaceutical company has used a representative from a Patient Organisation as a consultant (for example for a meeting) must the pharmaceutical company publish the activity (and fee) on the company's website?

**ANSWER:** *Yes, cf. Article 8 of the Patient Organisation Code.*

**40**. Is it possible for a pharmaceutical company to hire a representative from a Patient Organisation as a speaker to a meeting held abroad (pay for transport, accommodation, etc.)?

**ANSWER:** *Yes, if there is a logistical justification for the meeting being held abroad, and the specific presentation of the Patient Organisation is considered relevant for the participants.*

**41.** What can a representative from a Patient Organisation (who may also be a patient) actually talk about - can they only talk about the disease in general or may they also talk about their own experience with the disease?

**ANSWER:** *The person representing a Patient Organisation may only talk about the disease in general terms, which means that personal medical stories are not allowed.*

*Please note that if a representative attend some of the other lectures at the meeting, no prescription medicine must be mentioned as the representative is not considered a healthcare professional (unless he or she is an actual healthcare professional).*

**Abbreviations**

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| 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 |
| Patient Organisation Code (Patientforeningskodekset) | Ethical Rules for Collaboration between Patient Organisations, etc., and the Pharmaceutical Industry |
| Advertising Order | Order on Advertising, etc., of Medicinal Products (Bekendtgørelse nr. 849 af 29/04/2021 om reklame mv. for lægemidler) |
| The Promotion Code (Reklamekodekset) | The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals |