GUIDANCE to
"Ethical Rules for Collaboration between Patient Organizations, etc., and the Pharmaceutical Industry" (Patient Organizations Code)

The Code of the Ethical Rules for Collaboration between Patient Organizations, etc., and the Pharmaceutical Industry (Patient Organizations Code) will continuously be updated as practices develop or change. The guidance will therefore be dated, and it has 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 Organizations Code was developed by the Pharmaceutical Industry, but since EFPIA adopted their PO Code on 14th June 2011, the Patient Organizations Code has subsequently adjusted to comply with the obligations of EFPIA’s PO Code.

The term “organization” will be used throughout this Patient Organizations Code, covering patient organizations and other organizations working for patient-related issues, health-related issues (e.g. the Danish Mental Health Fund), or other organizations promoting consumer interests (e.g. the Dane Age Association and the Danish Consumer Council).
Re Article 1 Purpose

The purpose of the Patient Organizations Code is consistent with EFPIA’s PO Code.

Re Article 2 Scope of the ethical rules

Re: Article 2, litra a)

Also re: Article 2, litra c) and d).

In the introduction to EFPIA’s PO Code it is stated that the code covers collaborations between EFPIA members including their affiliates and contractual third parties (e.g. agencies) and patient organizations operating in Europe.

In this relation ENLI has found that the Patient Organizations Code was applicable to a congress, that a pharmaceutical company had been asked for sponsorship, and for which support should go to a special three-day track for patient Organizations.

Re: Article 2, litra b)

The Patient Organizations Code applies to cooperating with patient organizations, as defined in Article 1, section 7 of the Advertising Order, meaning organizations of patients and relatives, whose purpose is to protect the interests of patient groups, cf. Article 71, litra d) of the Medicines Act.

In this connection, it should be noted that EFPIA, in their PO Code, defines patient organizations as "not-for-profit organizations (including the umbrella organizations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers." According to ENLI, EFPIA’s definition is similar to the definition used in the Patient Organizations Code.

In addition to patient organizations, the Patient Organizations Code also applies to collaborating with other organizations working for patient-related issues, health-related issues (e.g. the Danish Mental Health Fund) or other organizations promoting consumer interests (e.g. the Dane Age Association and the Danish Consumer Council) - collectively referred to as "organizations" in this guidance.

The Investigator Panel has previously received a request as to whether a treatment home was covered by the Patient Organizations Code. The specific treatment home was an independent day care institution for children and adolescents who had difficulty managing their illness. The Investigator Panel did not find that this kind of aid was covered by the Patient Organizations Code.

Re: Article 2, litra c)

Also re: Article 2, litra a) and d)
**Re: Article 2, litra d)**

Also re: Article 2, litra a) and c)

There is no guidance for this provision at present.

**Re: Article 2, litra e)**

There is no guidance for this provision at present.

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**Re Article 3 Contract terms and transparency**

**Re: Article 3, litra a)**

The provision corresponds to EFPIA’s PO Code Article 2.

Cooperation agreements between pharmaceutical companies and organizations must be in writing, and the indicated numbers 1-8 must at the minimum be stated in the written agreement.

If an organization organizes an event, such as a training program for healthcare professionals, cf. Article 13 of the Promotion Code, in which pharmaceutical companies are offered to buy exhibition stands, this is not considered financial support for or cooperation with the organization, as long as it is an actual purchase. For further information, please refer to Article 18 of the Promotion Code and the associated Guidance to the Promotion Code.

The Investigator Panel has previously stated that the purchase of an advertisement in a member magazine of a patient organization is not covered by the Patient Organizations Code, if the purchase is according to normal market conditions.

**Re Article 3, litra a), no. 3**

For further information, please refer to re Article 6, litra a) below.

In order to describe the type of project it must be stated whether these are grants, specific meetings, sponsorships, pamphlets, information campaigns, education programs, travel, etc.

Due to the fact that it is a matter of support for organizations, the Patient Organization Code accepts that subsidies may also be granted for the general operation, which includes, for example board meetings and meeting of representatives, since these are necessary for the organization to function.

Memberships of patient organizations are not perceived as cooperation if the price reflects a genuine membership. If the price is higher than for a real membership, the payment will be considered a sponsorship, and the rules for cooperation with a patient organization must therefore be respected. The name of the membership (e.g. business partnership, business quotas, etc.) is not pivotal - but the price
for the membership and whether this should be perceived as a collaboration or simply an ordinary membership is pivotal.

Re Article 3, litra a), no. 7 and 8

A pragmatic approach is used to indicate the value of the 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 aid is used for.

For non-financial support, aid of a significant extent, which cannot be determined by meaningful financial value, must contain a description clearly indicating the non-monetary benefit received by the organization.

Re Article 3, litra b) and litra c)

This provision corresponds to EFPIA's PO Code Sec. 5 (a) and (b).

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

ENLI has previously stated that it is not a requirement that the agreements themselves are on the company's website. Thus, a summary can be made that contains at least the eight conditions outlined in this provision. It is also accepted to use the list that members of ENLI must submit to ENLI once a year, cf. Article 3, litra d).

It should be emphasized that patient organizations must publish all economic benefits at its website, including financial sponsorships (money sums) and payments in kind received by the organization from pharmaceutical companies, cf. article 21 of the Advertising Order. The publication on the website should show the amount of financial benefits from each company. The information must be available on the website no later than one month after the patient organization has received the financial benefit. The information must be available on the website for at least two years.

Re Article 3, litra d)

This provision corresponds to EFPIA's PO Code Sec. 5 (a).

This provision obliges only those companies that are affiliated ENLI.
Re Article 4 Contracted services

This provision corresponds to EFPIA's PO Code Article 6.

Re Article 4, litra a)  

There is no guidance for this provision at present.

Re Article 4, litra b)  

There is no guidance for this provision at present.

Re Article 4, litra b), no. 7  

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

Re Article 4, litra b), no. 9  

The publication requirement corresponds to EFPIA’s PO Code Sec. 5 (c).

Companies are required to publish their agreements with the organizations. This obligation is fulfilled by publication at 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 Danish 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.

Therefore, you have to find the website that the company is linked to, and which represents the Danish company, which often will be a .dk domain, if any.

Re Article 5 Independence  

In case of pharmaceutical companies supporting organizations, it is important that these appear as two independent parties.
If a pharmaceutical company chooses to support an organization, and the organization chooses to use the sponsorship for an event involving healthcare professionals, it is ENLI's opinion that the pharmaceutical company is not responsible for the event unless it may be image-creating for the pharmaceutical company towards the healthcare professionals.

For the same reason, there is no requirement that the name of the pharmaceutical company should be listed in materials prepared by the organization, for example an app, when their development is due to the company's financial support. If the company is not mentioned, various drug reviews in the material will not immediately fall under the responsibility of the company. If the company chooses to have their name mentioned in the material, the appearance may lead to the company being responsible for the content of the material.

**Re Article 5, litra a) and litra b)**

This provision incorporate EFPIA's PO Code Article 4.

This means that pharmaceutical companies cannot influence the organizational material supported by the company in order to favor their own commercial interests.

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

**Re Article 5, litra c)**

This provision corresponds to EFPIA's PO Code Article 3.

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

**Re Article 6 professional activities**

This provision corresponds to EFPIA's PO Code Article 8.

**Re Article 6, litra a)**

Please refer to re Article 3, litra a), no. 3 above.

The starting point is that pharmaceutical companies can provide support for all the activities, projects and purposes for which the organization is working. ENLI finds that it is in accordance with the Patient Organization Code to educate the organization within the given area of illness, for example through professional meetings or congresses, as long as the other rules are respected. Should the company itself hold the meeting, the general rules for advertising to the public must be observed. This means, among other things, that no Rx medicines must be advertised.
A pharmaceutical company can also provide support in kind. This could be a presentation by the pharmaceutical company at one of the patient organization’s events. However, the company must ensure compliance with the rules regarding advertising 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 organization, cf. re Article 5.

The Investigator Panel has previously agreed that financial assistance could be granted to a patient organization by lending view books to doctors, so that the organization should not charge rent from these healthcare professionals. The purpose of these view books was to provide the doctor’s patients with information on the area of illness that the patient organization operated within.

The Investigator Panel has previously accepted support for publication of a patient organization’s membership magazine.

Re Article 6, litra b)

Currently there is no guidance for this provision.

Re Article 6, litra c)

Currently there is no guidance for this provision.

Re Article 6, litra d)

This provision corresponds to EFPIA's PO Code Sec 5 (a).

The provision covers both arrangements organized by the organization or by the pharmaceutical company.

Catering and representation

A concrete assessment will be made of whether catering and representation are at a reasonable level. However, inspiration may be obtained from the practice of the Promotion Code, but it is important to note that there is no direct reference to this provision.

Entertainment

Whether it is entertainment or not, it basically depends on what the purpose of the arrangement is. Is it information about the disease, or is it an entertainment event. It is necessary to assess why participants wish to participate in the event; is it because of the academic content or because of the entertainment. In ENLI's opinion patient organizations are working to raise awareness about the specific illness, through
awareness campaigns, which is why there is room for activities the patient organizations want to implement. However, what matters is the purpose of the activity; information or entertainment.

The Investigator Panel has previously accepted support granted a patient organization who conducted a bicycle race focusing on raising money to research in the concerned area. It is noted that the company's support was for research solely, and not for the cycling race itself.

In another case, the Investigator Panel accepted that a company purchased a seat on a cycling team offered by a patient organization in connection with a campaign, as the company wanted to give seats at the team to their own employees, and it was therefore a purchase and not a financial support for the patient organization.

In an earlier case, the Investigator Panel has been asked whether it is in accordance with the Donation Code that a medicinal company provides financial support for a patient organization's campaign where the patient organization forms a collaboration with a soccer team in order to make the soccer team or some of the players ambassador of a disease. In this case, the Investigator Panel stated that such cooperation would be permitted if the company's support only involves the preparation of an information campaign, project management, etc., and no entertainment element is associated with the completion of the project (e.g. holding a soccer match).

Re Article 6, litra e)

Currently there is no guidance for this provision.

Re Article 6, litra c)

There is no guidance for this provision at present.

Re Article 7 Information on medicinal products and advertising

There is no guidance for this provision at present.

Re Article 8 Exclusive agreements

This provision corresponds to EFPIA's PO Article 7.

Currently there is no guidance for this provision.
Re Article 9 Competence

Re Article 9, litra a)
There is no guidance for this provision at present.

Re Article 9, litra b)
There is no guidance for this provision at present.

Re Article 9, litra c)
An example of the apparent absence of unethical interests among the parties may be for an organization that operates outside of the company's business area.

Re Article 10 Enforcement
There is no guidance for this provision at present.

Re article 11 Entry into force
There is no guidance for this provision at present.
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>EFPIA</td>
<td>The European Federation of Pharmaceutical Industries and Associations</td>
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<td>EFPIA’s PO Code</td>
<td>EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations</td>
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<tr>
<td>ENLI</td>
<td>Ethical Committee for the Pharmaceutical Industry in Denmark</td>
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<td>Lif</td>
<td>The Danish Association of the Pharmaceutical Industry</td>
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<td>Organization</td>
<td>The term &quot;organization&quot; in this guidance is covering patient organizations and other organizations working for patient-related issues, health-related issues (e.g. the Danish Mental Health Fund) or other organizations working to promote consumer interests (e.g. the Dane Age Association and the Danish Consumer Council).</td>
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<td>Patient Organizations Code (Patientforeningskodekset)</td>
<td>Ethical Rules for Collaboration between Patient Organizations, etc., and the Pharmaceutical Industry</td>
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<tr>
<td>Advertising Order</td>
<td>Order on Advertising, etc., for Medicinal Products (Bekendtgørelse nr. 1153 af 22/10/2014 om reklame mv. for lægemidler)</td>
</tr>
<tr>
<td>The Promotion Code (Reklamekodekset)</td>
<td>The Pharmaceutical Industry’s Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals</td>
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