The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals

2011

1973-2011
38 years of self-regulation on medicinal products

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI)

Unauthorised translation
In case of doubt the Danish version
is always applicable and official
The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI)

BACKGROUND

The Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI) was established in its current form by the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic Medicines Industry Association (IGL) and the Danish Association of Parallel Distributors of Pharmaceuticals (PFL) in April 2011 and aims, among other things, to ensure the control of the Danish Ethical Rules for Promotion of medicinal products towards Healthcare Professionals.

Before ENLI was established, the promotion activities of pharmaceutical companies concerning medicinal products were controlled by the industry committee NMI (the Danish Board of Drug Advertising) and later by the Danish Legal Board of Self-Regulation Concerning Pharmaceuticals (NSL).

As early as 1973, a code of practice was adopted to ensure a proper framework for the work of the industry. Since then, the code of practice has been updated, and in 2007, it was succeeded by the so-called “Co-operative Agreement”, whose originators also included the Association of Danish Pharmacies, the Danish Medical Association, IGL and the Danish Association of Parallel Distributors, and which was controlled by NSL. The Co-operative Agreement was signed in 2007 and became effective in April 2008. The rules of the Co-operative Agreement were, however, quickly superseded to a large extent by “the Executive Order on Promotion of medicinal products” from 2007, which implements Directive 2001/83/EC of the European Parliament and of the Council, as these rules overlapped the agreement.

On the international scene, a significant development took place simultaneously. Where Denmark used to be in the lead:

- the EFPIA (European Federation of Pharmaceutical Companies and Associations):
  - in 2007 updated its code on the industry's promotion activities towards healthcare professionals, with regard to prescription-only medicines (which, like the Executive Order on Promotion, is based on the EU rules in force).
  - in 2006 updated its code on the industry's collaboration with patient groups.
- the IFPMA (the International Federation of Pharmaceutical Manufacturers & Associations):

Lif has, through its membership of the above-mentioned associations, decided to follow these international codes, which supplement the law and in many ways place higher demands on the industry than the law and the Co-operative Agreement did. It was not possible to incorporate the above-mentioned rules in the Co-operative Agreement and subject them to the control of NSL. At the same time, Lif had adopted several ethical rules such as “Lif’s Ethical Rules for Dialogue and Negotiations with Decision-Makers” (Lif’s code on lobbying activities), which also needed to be controlled, but could not be subjected to the control of NSL either.

On these grounds, Lif decided to terminate the collaboration, and together with IGL and PFL the industry established a new committee instead as of April 1, 2011, “The Ethical Committee for the Pharmaceutical Industry in Denmark” (ENLI), in order to bring the rules that follow from law and voluntary agreements etc. together in a more manageable system, in which all rules could be controlled by one regulatory body instead of having it spread out over several regulatory bodies, rules, agreements, etc. The hope is to create a better overview of the rules and practice in the field. It has also been wished to provide more guidance.

UNDERLYING RULES

ENLI ensures the control of the following rules:

- The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals
- Ethical Rules for Collaboration between Patient Groups, etc. and the Pharmaceutical Industry
- Ethical Rules for Dialogue and Negotiations with Decision-Makers (code on lobbying activities)
- Parts of the Executive Order on Promotion concerning promotion of medicinal products towards healthcare professionals (ultimately controlled by the Danish Medicines Agency) and relevant parts of Chapter 7 of the Danish Medicines Act.
- Ethical Rules for Pharmaceutical Companies’ Relations with the Danish Hospital Sector
- Ethical Rules for the Pharmaceutical Industry’s Donations and Grants to Hospitals

COMPLAINTS

Complaints concerning the Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals can be filed to ENLI via www.ENLI.dk, as can complaints concerning the other codes of practice. Eligible to complain are the pharmaceutical companies subjected to the competency of ENLI.
All complaints are assessed by a legal and medical panel of investigators in the first instance, and appeals are handled by “the Board of Appeal” (ENLI).

Reports and cases are made public to the extent legally permitted, with regard to the Danish Act on Processing of Personal Data and other applicable laws and regulations, on the ENLI website: www.ENLI.dk.

All first instance and second instance decisions are forwarded to the Danish Medicines Agency for their information.

**ORGANIZATION**

LiF’s Self-Regulating Instance (ENLI) consists of 2 instances:

- The first instance: the Legal and Medical Panel of Investigators (GP), comprising legal and medical investigators respectively, and
- The second instance: The Board of Appeal (ENLI), comprising:
  - Two lawyers (one is chairperson)
  - A medical doctor
  - A former employee of the pharmaceutical industry

The Legal and Medical Panel of Investigators is responsible for the handling of appeals in the first instance and for the control of filed cases. The panel is also responsible for providing guidance on and training in, i.a., “the Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals”.

The Board of Appeal handles cases, which are appealed from the first instance.

**THE RELATIONS BETWEEN ENLI AND LIF, IGL AND PFL**

ENLI works independently of LiF, IGL and PFL.

The relations between LiF, IGL, PFL and ENLI are regulated in the statutes of ENLI, which can be found on the ENLI website. Financial information on ENLI is published in ENLI’s annual report.
Introduction to the Danish Ethical Rules for Promotion of Medicinal Products
towards Healthcare Professionals

Access to the best medical treatment

Lif, IGL and PFL work to provide the pharmaceutical industry with the best possible conditions to research, develop, market, distribute and inform about medicinal products thus ensuring broad and fast access for patients to the best medical treatment.

For this purpose, it is firstly required that relevant information about medicinal products is available to healthcare professionals etc., and secondly that the information is exchanged in an ethically responsible and transparent way. These ethical rules aim to ensure this.

Since 1973, the promotion activities of pharmaceutical companies have been regulated and controlled on a voluntary basis. These ethical rules complement and supplement Danish and international law in the field, and place further and/or stricter demands on the activities of the pharmaceutical companies in a number of fields, than what follows from law and the previous co-operative agreement.

The ethical rules are updated on a regular basis and regulate the members of the three associations (including affiliated companies) and their:

- Promotion of medicinal products towards healthcare professionals, also including printed promotion and information material
- Interaction with healthcare professionals

In general, companies must ensure that their promotion material (including websites etc.) contains appropriate, factual, balanced and verifiable information, and that all other activities are appropriate and fair.

Ensure high ethical standards

The very detailed rules ensure that pharmaceutical companies act in an ethically responsible and professional way. The pharmaceutical industry has a legitimate and statutory right to market medicine towards healthcare professionals, and the rules aim to balance the interests of patients, healthcare professionals and the general public in such information.

The rules are very much endorsed by the pharmaceutical industry, where substantial resources are allocated to ensure compliance with the rules. Any complaint of non-compliance is considered a serious matter. Sanctions are imposed for non-compliance, and the companies are obligated to ensure that relevant employees have received training in the rules.

These ethical rules incorporate the principles from:

- The European Federation of Pharmaceutical Companies and Associations’ (EFPIA) Code on the Promotion of Prescription-only Medicines to, and interactions with, Healthcare Professionals.
- Relevant parts of “the Executive Order on Promotion of Medicinal Products no. 272 of 21 March 2007” and appurtenant guideline 2007-05-24 no. 29 on promotion of medicinal products and relevant parts of Chapter 7 of the Danish Medicines Act.
- The World Health Organizations’ Ethical criteria for medicinal drug promotion.

Who is subject to the rules?

The ethical rules only regulate the companies that are members of Lif, IGL and PFL, and the companies and associations that are not members of these associations, but have agreed to the ethical rules. A list of these companies and associations can be found on: www.ENLI.dk. Similarly, only these companies are subject to the control of ENLI.

Regardless of the above-mentioned, the healthcare professionals, who interact with the pharmaceutical industry, and the pharmaceutical companies, that are not yet affiliated with ENLI, are of course obligated to comply with the law in this field (e.g. the Executive Order on Promotion of Medicinal Products), which falls within the control of the Danish Medicines Agency.
It is noted that the ethical rules do not apply to the promotion of medical devices/medico, which is subject to other regulatory rules than medicinal products. The reason why these ethical rules only apply to the promotion of medicinal products is that Lif, IGL and PFL only represent the pharmaceutical industry – not the medico industry.

Supplementing rules

Apart from these ethical rules, ENLI controls a number of other rules concerning i.a. lobbying and collaboration with patient groups. Cf. the statutes for ENLI. See also the description in the introductory chapter on “the Ethical Committee for the Pharmaceutical Industry in Denmark” above.

Transparency

Lif, IGL, PFL and the affiliated companies and associations recognize transparency as an important means to ensure compliance with the rules and in that way maintain credibility and dispel any myths. These ethical rules, the right of appeal, and the obligation to report the companies’ promotion material and involvement in various activities, and the publication of decisions, reports etc. on: www.ENLI.dk all serve this purpose.

Sanctions

In cases, where ENLI finds, that the rules have not been complied with, the company concerned is ordered to issue a statement to ENLI that:

1) the illegal conduct is discontinued and
2) that the company guarantees, that the company has taken the necessary precautions to ensure that recurrence is prevented.

At the conclusion of the case and in case of non-compliance, the decision will be partially or fully published to the extent possible, subject to i.a. the Danish Act on Processing of Personal Data and rules laid down in another relevant statute, such as the Danish Competition Act. All decisions are also forwarded to the Danish Medicines Agency for their information.

In cases of serious non-compliance, sanctions may be imposed in addition to the above-mentioned. These sanctions include:

- Fines
- Withdrawal of illegal material
- Issuing of a corrected statement from the company
- Public reprimand
- Insertion of an advertisement in professional journals in cases, where a corrected statement or public reprimand is imposed, e.g. in the Journal of the Danish Medical Association (UfL), stating the characteristics of the case and specifying the name of the company and the nature of non-compliance.

Surveillance of activities and guidance and training

ENLI controls filed cases and also handle appeals. In addition to that, ENLI provides guidance on and training in the rules.

The associations behind ENLI

Lif – the Danish Association of the Pharmaceutical Industry is an industry association for the researching pharmaceutical industry in Denmark. The association was established in its current form in August 1997. Lif’s mission is to provide the pharmaceutical industry with the best possible conditions to research, develop, market, distribute and inform about medicinal products, thus ensuring broad and fast access for patients to the best medical treatment.

Lif has in a number of fields decided to follow stricter ethical rules, than what follows from law, as Lif finds it crucial, that we as a pharmaceutical industry act in a credible and ethically responsible way. For similar reasons, Lif has decided to lead the way in a number of fields – e.g. Lif adopted a code on lobbying activities as early as January 2010 and was the first industry in Denmark to do so.

See: www.lif.dk for further information on Lif, including information on the members of Lif.
IGL - The Danish Generic Medicines Industry Association (IGL) is an industry association established in 2002. Today, the association includes 13 member companies, which are all engaged in selling and promoting generic medicines to the Danish market. Some of these companies also manufacture generic medicines. IGL works to promote the sales of generic medicines in Denmark, thus limiting the medicine costs for consumers and society.

See: www.igldk.dk for further information on IGL, including information on the members of IGL.

PFL – The Danish Association of Parallel Distributors of Pharmaceuticals (PFL) works to ensure free access to import medicinal products on a parallel basis within the EU. Medicine imported on a parallel basis is original medicine, which has been imported from another EU country, in which it is less expensive than it is in Denmark. In the Danish system, the medicine with the lowest price of similar kind will receive grants from the Government. Medicine imported on a parallel basis thus accounts for 15% of the total use of medicine. Parallel import means that the importers monitor supply and prices on medicine in other countries, thus enabling them to offer Danish pharmacies and hospitals the medicine they demand at the lowest possible price.

The importer ensures that all information in the medicine packaging is written in Danish as laid down by the authorities, and medicine imported on a parallel basis is, similarly to any other legal medicine, distributed through wholesalers. I.e. through a pharmacy or a hospital.

See: www.pfldk.dk for further information on PFL.

Control of the Danish Ethical Rules

The Danish Ethical Rules (for Promotion of Medicinal Products towards Healthcare Professionals) are controlled by the Ethical Committee for the Pharmaceutical Industry in Denmark (ENLI), which is also responsible for guidance on the rules, training in the rules and the complaint authority.

For further information, please see the paragraph on Lil's Self-Regulating Instance above or visit: www.ENLI.dk.
The Danish Ethical Rules
for Promotion of
Medicinal Products towards Healthcare Professionals

CHAPTER 1 – PRELIMINARY PROVISIONS

Article 1 - Scope
Section 1.01. The scope of these ethical rules is to create a framework for the necessary and professionally responsible collaboration between the pharmaceutical industry and healthcare professionals, in such a manner that professional standards and ethics are given pride of place, and pressure opportunities and dependency between the parties are prevented. The ethical rules state a number of minimum standards, which must be complied with, in addition to the applicable laws and regulations.

Section 1.02. Pharmaceutical companies must maintain high ethical standards at all times. Promotion must:

a) Never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry
b) Be of a nature which recognises the special nature of medicinal products and the professional standing of the recipient(s) and
c) Not be likely to cause offence.

Article 2 - Field of application

Section 2.01. These ethical rules are applicable to the activities of pharmaceutical companies inside and outside the borders of Denmark, concerning:

a) Promotion of and communication about medicinal products towards healthcare professionals.
b) Interaction with healthcare professionals concerning medicinal products.
c) The rules are however only applicable in so far as to activities, which are partially or fully targeted at Danish healthcare professionals. The rules are however also applicable to activities, which are solely targeted at non-Danish healthcare professionals, provided that the activities are held in Denmark.

Section 2.02. The rules are not applicable to:

a) Activities solely concerning products, which do not fall under the definition of a medicinal products, e.g. medical devices, skin care products and similar products,
b) Activities not targeted at healthcare professionals, e.g.:

- Dialogue and negotiations with decision-makers, including politicians and officials,
- Collaboration between patient groups and the pharmaceutical industry,
- Promotion of medicinal products towards the general public,
- Press releases etc. and information to investors etc., and
- Patients and citizens,

c) Particulars of the exceptions to Art. 2 of the Executive Order on Promotion (i.e. particulars not included in the rules of Chapter 7 in the Executive Order on Promotion),

d) Cases concerning clinical research filed to the scientific ethical committee system and/or the Danish Medicines Agency, except for Art. 13, sections 3-9, which also apply to meetings etc. in connection with clinical research.

Section 2.03. Promotion of the medicinal products mentioned in Art. 3, nos. 1-5 of the Executive Order on Promotion is not permitted.

Article 3 - Definitions

Section 3.01. “Promotion, “the general public” and “healthcare professionals” have the meaning set forth in Art. 1 of the Executive Order on Promotion. This applies to all activities, regardless of media, covered by the concept of promotion, which are undertaken, organized or sponsored by a pharmaceutical company or by authority of a pharmaceutical company.

Section 3.02. “Pharmaceutical companies“ mean members of:

- The Danish Association of the Pharmaceutical Industry (Lif),
- The Danish Generic Medicines Industry Association (IGL)
- The Danish Association of Parallel Distributors of Pharmaceuticals (PFL) and
- “affiliated companies and associations”, i.e. companies and associations, which are not members of the above-mentioned associations, but have decided to be bound by to these ethical rules, and
- Consultancy service companies etc., acting on behalf of the companies and associations mentioned in sub-sections a)-d).

Section 3.03. “medicinal products” means any product, which is:

- presented as having properties for treating or preventing disease in human beings, or
- may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis, or
- a medical device intended for administration of a medicinal product cf. litra a) or b) if the medical device and the medicinal product are marketed as an integrated product that solely is intended for use in the given combination and the medical device cannot be reused.

Section 3.04. With reference to the obligation to report in Art. 21,“Events” have the meaning set forth in section 21.02.
Section 3.05. “Danish healthcare professionals” means healthcare professionals employed in Denmark, or self-employed healthcare professionals in Denmark, i.e. general practitioners with a clinic in Denmark.

CHAPTER 2 – MARKETING AUTHORIZATION, REQUIREMENTS OF OBJECTIVITY, ETC.

Article 4 – Marketing authorization and requirements of objectivity

Section 4.01. It is prohibited to promote medicinal products:

a) which cannot be legally sold or distributed in this country (Denmark)

b) magistral medicinal products

c) and the special medicinal products listed in Art. 3 of the Executive Order on Promotion.

Section 4.02. Promotion of a medicinal product must be sufficiently complete and objective, and it must not mislead or exaggerate the properties of the medicinal product. Information in promotion material must be consistent with the approved summary of product characteristics of the relevant medicinal product.

Section 4.03. Promotion material, which appears on exhibition stands or is distributed to participants at international events outside of Denmark may, without regard to section 4.01, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or uses), which are not registered in the country where the event takes place, or which are registered under different conditions, so long as:

a) Any such promotion material (except for promotional aids) is accompanied by a suitable statement indicating countries in which the medicinal products is registered and makes clear that the medicinal product or use is not registered locally, and

b) Any such promotion material, which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries where the medicinal product is registered should be accompanied by an explanatory statement indicating that registration conditions differ internationally.

CHAPTER 3 – PROMOTION

Article 5 – Obligatory information

Section 5.01. All promotion material of medicinal products towards healthcare professionals must include the following information:

1) The trademark and the common name of the medicinal product or the international non-proprietary name, where this exists. The common name, or the non-proprietary name, must be indicated using the same font and same appearance as the proprietary name of the medicinal product. Promotion of combination medicinal products with no common name must include clear information on the common names of all active ingredients.
2) Name and permanent address of the marketing authorization holder.

3) Therapeutic indication area, consistent with the indication area listed in the summary of product characteristics. In promotion material solely targeted at a limited group of healthcare professionals, the indication area may be reduced to the extent relevant to the group concerned.

4) Contraindications.

5) Side-effects and risks.

6) Dosage.

7) Pharmaceutical forms.

8) Packaging sizes.

9) Dated price (registered price) incl. VAT as well as a reference to a current price on www.medicinpriser.dk, if the medicinal product is reserved to pharmacies only. The price may however be excluded from promotion material that is sent out for an extended period of time, if the promotion material is accompanied by a price list referring to the promotion material, or if the promotion material is solely targeted at students.

10) Dispensing group.

11) Reimbursement status.

12) The date on which the promotion material was generated or last revised.

Section 5.02. The information listed in section 5.01 must be clear and legible, thus enabling the natural target group of the promotion material to read it with minimal effort.

Section 5.03. If a medicinal product has been approved in several forms with different fields of application, and the promotion material solely concerns one of these forms, the promotion material must only include information on this pharmaceutical form. The promotion material must further state that the medicinal product is also available in other forms.

**Article 6 - Reminders**

Promotion solely targeted at healthcare professionals may not need to comply with Article 5 above, provided that the promotional material includes no more than the trademark and common name of the medicinal product.

**Article 7 - Information material and substantiation**

Section 7.01. Promotion of medicinal products must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated. Substantiation must be promptly provided in response to reasonable requests from healthcare professionals.

Section 7.02. Information material concerning medicinal products, which is sent out or distributed to healthcare professionals with a view to promote sales, must at least include the information listed in section 5.01, however see section 5.03, and the date on which the material was generated or last revised.
Section 7.03. All information in the information material listed in sections 7.01 and 7.02 must be adequate, objective, accurate, relevant, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned.

Section 7.04. Quotations, tables and illustrations from medical and scientific literature, which is used in the information material listed in sections 7.01 and 7.02, must be faithfully reproduced and the precise sources identified. Particular care must be taken to ensure that artwork included in promotion material does not mislead about the nature of a medicinal product (for example whether it is appropriate for use in children) or mislead about a claim or comparison (for example by using incomplete or statistically irrelevant information or unusual scales).

Section 7.05. Substantiation of information on medicinal products must, apart from the summary of product characteristics, only include scientifically substantiated research. The research must have been published in established and independent Danish or non-Danish publications, professional journals or the like. The research must prior to publication have been subjected to an independent assessment (peer review).

Section 7.06. The word “safe” must never be used to describe a medicinal product. The word “new” must not be used to describe any medicinal product or packaging which has been generally available or any therapeutic indication which has been generally promoted, for more than one year. It must not be stated that a medicinal product has no side-effects, toxic hazards or risk of addiction or dependency.

Article 8 – Comparative promotion

Section 8.01. If a promotion material includes a comparison of several medicinal products, including a price comparison, all medicinal products included in the comparison and their strengths, packaging sizes etc. must be clearly stated. The comparison must only include medicinal products, including their strengths and packaging sizes, which are relevant to compare from an objective point of view, i.e. medicinal products with the same field of application.

Section 8.02. Comparative promotion must be based on the information in the summaries of product characteristics of the medicinal products concerned.

Section 8.03. Comparison of various medicinal products must not be misleading or disparaging.

CHAPTER 4 - DISTRIBUTION OF PROMOTION, TRANSPARENCY AND PERSONAL ADVICES.

Article 9 – Distribution of promotion

Section 9.01. Promotion must only be directed at those, who’s need for, or interest in, the particular information can reasonably be assumed.

Section 9.02. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotion mailing lists must be complied with.
Section 9.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

**Article 10 – Transparency**

Section 10.01. Promotion must not be disguised.

Section 10.02. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Section 10.03. Where a pharmaceutical company pays for or otherwise secures or arranges the publication of promotion material in journals, such material must not resemble independent editorial matter.

Section 10.04. Material relating to medicinal products and their uses, whether promotional in nature or not, which is sponsored by a company must clearly indicate that it has been sponsored by that company.

**Article 11 – No advice on personal medical matters**

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

**CHAPTER 5 – FINANCIAL BENEFITS**

**Article 12 – General rule – prohibition against financial benefits and gifts**

Section 12.01. Financial benefits must generally not be given or offered to healthcare professionals as part of marketing or otherwise with the intention of promoting the sales of a medicinal product, except as provided for in section 12.02, and section 13-15.

Section 12.02. The prohibition in section 12.01 does not extend to gifts of insignificant value, when such gifts are relevant to the practice of the recipient.

Section 12.03. Obligatory information need not to appear from the gift, if the gift is accompanied by the following information on the medicinal product:

   a) name and logo of the pharmaceutical company, identifying the sender,

   b) its common name or the international non-proprietary name, where this exists, and the trade mark.

Section 12.04. Gifts for the personal benefit of healthcare professionals (such as tickets to entertainment events), must not be offered or provided.
Section 12.05. Competitions must not be arranged and prizes must not be offered to healthcare professionals as part of marketing or otherwise with the intention of promoting the sales of a medicinal product.

**Article 13 – Professional events, sponsorships and hospitality**

Section 13.01. Pharmaceutical companies may give or offer a healthcare professional training and professional information related to medicinal products in the form of payment of direct expenses in connection with courses and other professional and scientific events, in which the healthcare professionals participate or arrange, including:

a) As organizers or co-organizers of the events listed in section 13.01. Invitations for such events must only be targeted at healthcare professionals,

b) As sponsors of the professional events listed in section 13.01, prepared by a third party responsible for the professional content, lecturers, educational method etc. Sponsorships must not be subject to the sponsor influencing on the professional content of the program. The preparation of the events must therefore be independent of the sponsorship given, as only events of a mere professional nature may be sponsored.

Section 13.02. It is a condition that the organizer and purpose of the events listed in section 13.01 appear from the invitation to the event, just as the invitation must state whether the event has been sponsored by one or more pharmaceutical companies. The pharmaceutical company is obligated to ensure this in the contract with any third party.

Section 13.03. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) (each, an “event”) organized or sponsored by or on behalf of a pharmaceutical company must be held in an “appropriate” venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate.

Section 13.04. No pharmaceutical company may organize or sponsor any of the events listed in section 13.01 that take place outside its home country, unless:

a) Most of the invitees are from abroad and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or

b) Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Section 13.05. Hospitality extended in connection with the events listed in section 13.01 must be limited to travel, meals, accommodation and genuine registration fees.

Section 13.06. Hospitality must only be extended to persons who qualify as participants in their own right.
Section 13.07. All forms of hospitality offered to healthcare professionals must be “reasonable” in level and strictly limited to the main purpose of the event, and also, in terms of time, be a minor consideration to the promotional and professional event. As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves.

Section 13.08. Hospitality must not include sponsoring or organizing entertainment (e.g. sporting or leisure) events.

Section 13.09. Pharmaceutical companies must avoid using venues that are “renowned” for their entertainment facilities or are extravagant and/or luxurious.

Section 13.10. Funding must not be offered to compensate merely for the time spent by healthcare professionals in attending the events listed in section 13.01.

Section 13.11. In the case of international events, as listed in section 13.01, for which a company sponsors the participation of a healthcare professional, if any funding is provided to such healthcare professional, such funding is subject to the rules of the jurisdiction where such healthcare professional carries out his or her profession, as opposed to those in which the international event takes place. Danish law and any other mandatory statute must, at a minimum, always be complied with.

**Article 14 - Donations and grants that support healthcare or research**

Section 14.01. Donations, grants and benefits in kind to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare or conduct research (that are not otherwise covered by the EFPIA HCP Code or Lif’s Ethical Rules for Collaboration between Patient Groups and the Pharmaceutical Industry) are only allowed if: (i) they are made for the purpose of supporting healthcare or research; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 14.02. Donations and grants to individual healthcare professionals are not permitted under this section, excluding company sponsorship of healthcare professionals to attend professional events, which is covered by section 13.01, or professional gifts of insignificant value, cf. section 12.02.

Section 14.03. Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them covered in this section 14.01.

Section 14.04. Contracts between pharmaceutical companies and institutions, organizations or associations of healthcare professionals under which such institutions, organizations or associations provide any type of services to companies (or any other type of funding from pharmaceutical companies not covered under these ethical rules) are only allowed if such services (or other funding):

a) Are provided for the purpose of supporting healthcare or research; and

b) Do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.
Article 15 – The use of consultants/professional services

Section 15.01. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a) a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
c) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need;
e) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;
f) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and
g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.
h) Remuneration must only be offered in the form of actual payment, and not as a set-off, benefit in kind or by other indirect means.

Section 15.02. Employment arrangements of general practitioners and pharmacists with a pharmaceutical company require preceding permission from the Danish Medicines Agency, cf. Art. 3, sections 2-3, of the Danish Pharmacy Act.

Section 15.03. In their written contracts with consultants, pharmaceutical companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he or she is a consultant to the company whenever he or she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, a pharmaceutical company that employs, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his or her employment arrangement with the company whenever he or she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that pharmaceutical company. The provisions of this section 15.03 apply even though these ethical rules do not otherwise cover non-promotional, general information.

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires is excluded from the scope of this Art. 15, except for section 15.01, sub-sections d), f), g)
and h), provided that the healthcare professionals are not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal and in proportion to the service, cf. section 15.01, sub-section g). Such research must not be disguised promotion.

Section 15.05. If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Art. 13 apply.

**CHAPTER 6 – NON-INTERVENTIONAL STUDIES AND EXHIBITION**

**Article 16 – Non-interventional studies of marketed medicinal products**

Section 16.01. A non-interventional study of a marketed medicinal product is defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicinal product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data.

Section 16.02. Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

a) The study is conducted with a scientific purpose
b) There is a written study plan (protocol) and there are written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the pharmaceutical company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause c) immediately below, the basis for payment of those services;

c) Any remuneration provided is reasonable and reflects the fair market value of the work performed; and the pharmaceutical company must, upon request, make information about how the remuneration was assessed available to ENLI.
d) Study protocols concerning non-interventional studies (description of non-interventional studies) must be submitted to the Danish Medicines Agency for review and guidance.
e) The Danish Act on Processing Personal Data (including the collection and use of personal data) must be complied with,
f) The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
g) The study protocol must be approved by the pharmaceutical company’s scientific service as described in section 19.02, sub-section a).
h) The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company’s scientific
service (as described in section 19.02, sub-section a)). The scientific service must maintain records of such reports for a reasonable period of time. The pharmaceutical company must forward the summary report to all healthcare professionals that participated in the study and must make the summary report available to ENLI upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority; and

i) Pharmaceutical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company’s scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

j) Pharmaceutical companies may only be involved in an administrative capacity and such involvement must be under the supervision of the company’s scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

Section 16.03. To the extent applicable, companies are encouraged to comply with section 16.02 for all other types of studies covered by section 16.01, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to section 16.02, sub-sections a), c) and f).

**Article 17 – Exhibition etc.**

Section 17.01. In connection with the holding of professional events, where pharmaceutical companies are given access to promotion and marketing of medicinal products, such promotion and marketing must be conducted separate from the rest of the event’s professional content.

Section 17.02. The promotion and marketing set out in section 17.01 must only take place in connection with events that adhere to the professional standards in Art. 13.

Section 17.03. When pharmaceutical companies are given the opportunity to advertise, exhibit, display movies, inform about products etc., it must be conducted on the basis of a preceding agreement on the conditions, including the financial terms and program of the event.

**Article 18 – Medical samples**

Section 18.01. Samples of a medicinal product shall at most be supplied for two years after the date of introduction.

Section 18.02. The date of introduction for a new medicinal product shall be the date at which it is marketed for the first time, i.e. listed in Medicine Prices for the first time after grant of a marketing authorization. In the event of a new/amended marketing authorisation being granted for a change in indication or changes in strength/pharmaceutical form as a result of a new indication, the date of introduction should be the first date of marketing after the new/amended marketing authorisation has
been granted. Extensions to marketing authorizations as a result of additional strengths / pharmaceutical forms for existing indications - or new pack sizes - are not regarded as new medicinal products.

Section 18.03. The rules of s.1-2 shall apply to medical devices that are medicinal products pursuant to Art.3.03 (c). Other medical devices that are not covered by s.1 – 2. Samples of medicinal products may be supplied together with these devices insofar as required to test new or changed devices, and no more than two years after the introduction of the new /changed device, but otherwise not covered by s.1 - 2.

Section 18.04. In addition to the provisions of s 1-3, the executive order for the time being in force on the supply of samples of medicinal products shall apply, currently Executive Order No.1244 of 12 December 2005.

Section 18.05. (1–4) shall take effect from 1 January 2012 and shall cover all medicinal products introduced after 1 January 2012 on the basis of a new or amended marketing authorization, cf.(1 - 2). Samples of medicinal products introduced before 1 January 2012 may be supplied until 31 December 2013 in accordance with the rules applying hitherto.

CHAPTER 7 – STAFF, TRAINING, ETC.

Article 19 – Pharmaceutical company staff

Section 19.01. Each pharmaceutical company must ensure that its sales representatives, including staff retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a “pharmaceutical sales representative”) are familiar with the relevant requirements of the applicable code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote. Pharmaceutical sales representatives must for each medicinal product presented make the summary of product characteristics available to the person visited. The summary of product characteristics must be accompanied by information about prices (if the medicinal product is reserved to pharmacies) and reimbursement status.

a) Pharmaceutical sales representatives must comply with all relevant requirements of the applicable code(s), and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

b) Pharmaceutical sales representatives must approach their duties responsibly and ethically.

c) During each visit, pharmaceutical sales representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they present. The summary of product characteristics must be accompanied by information about prices (if the medicinal product is reserved to pharmacies) and reimbursement status.

d) Pharmaceutical sales representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their companies’ medicinal products, particularly reports of side-effects.
e) Pharmaceutical sales representatives must ensure that the frequency, time and duration of visits to healthcare professionals, pharmacies, hospitals and other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.

f) Pharmaceutical sales representatives must not use unethical methods to gain an interview. In an interview, or when seeking an appointment for an interview, pharmaceutical sales representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

g) The provisions of section 16.02, sub-section (i) are also applicable to the activities of pharmaceutical sales representatives.

Section 19.02. All pharmaceutical company staff, and any staff retained by way of contract with third parties, who are concerned with the preparation or approval of promotional material or activities, must be fully conversant with the requirements of the applicable code(s) and relevant laws and regulations.

a) Every pharmaceutical company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. The pharmaceutical companies are free to decide how best to establish such service(s) in accordance with section 19.02 (i.e., whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organization. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the applicable code(s) and any applicable information laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the medicinal product. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by pharmaceutical sales representatives). Such person must certify that he or she has examined the protocol relating to the non-interventional study and that in his or her belief it is in accordance with the requirements of the applicable code(s).

b) Each pharmaceutical company must appoint at least one senior employee to be responsible for supervising the company and its subsidiaries to ensure that the standards of the applicable code(s) are met.
CHAPTER 8 – ENFORCEMENT, OBLIGATION TO REPORT AND PRE-APPROVAL

Article 20 - Enforcement

The rules are sanctioned as described in the statutes of ENLI, please refer thereto.

Article 21 – Obligation to report

Section 21.01. Pharmaceutical companies are obligated to report to ENLI activities:

a) which are organized or co-organized by a pharmaceutical company, and the event is fully or partially targeted at Danish healthcare professionals.

b) where a pharmaceutical company, not organizing or co-organizing the event, provides financial (sponsor) support to (i) a so-called third party event fully or partially targeted at Danish healthcare professionals or to (ii) the participation of Danish healthcare professionals.

c) where a pharmaceutical company buys an exhibition stand at a congress in Denmark.

Section 21.02. “Event” has the meaning set forth in section 21.01, and includes all kinds of continuing training in the form of meetings, congresses, conferences, symposia, courses, end-of-day meetings or similar events with the participation of healthcare professionals. Not included are visits from pharmaceutical sales representatives and events, cf. section 21.01, sub-sections a) and b), where the healthcare professional provides a service in return.

Section 21.03. In addition, pharmaceutical companies are obligated to report all kinds of printed promotion material targeted at healthcare professionals on the Danish market, whether in printed advertisements, leaflets, handouts or the like. Electronic texts are comparable with printed texts. Texts on websites are thus comparable with printed promotion and must be reported, if access to the promotion is restricted in a way that makes it inaccessible to the general public (as described in Annex A) and the promotion is written in Danish. If access to the website text is not restricted, it is promotion to the general public and therefore not covered by these ethical rules.

Section 21.04. Companies are obligated to file a report online via: www.ENLI.dk and fill out the standard report form. The company is obligated to ensure that the report is fully cleared up and that all relevant documentation is submitted.

Section 21.05. Reports concerning the activities set out in section 21.01, sub-section a), must be filed no later than 10 working days prior to the opening day of the event. Reports concerning sponsorships etc., cf. section 21.01, sub-section b), must be filed no later than 10 working days after a binding promise to provide financial support has been made, or in the case of exhibition no later than 10 working days prior to the opening day of the event. Reports concerning promotion material must be filed no later than the same day as the printed promotion material, cf. section 21.03, is distributed (i.e. distributed or published as advertisement).

Section 21.06. The pharmaceutical company responsible for the event must ensure that the above-mentioned obligations to report are always complied with, even when the planning, distribution or other practical duties of the event are fully or partially managed by others.
Section 21.07. A pharmaceutical company, who wants a pre-publication vetting of an activity covered by these ethical rules and its compliance with the rules, may, subject to a fee, apply for a pre-approval. Applications are submitted online via: www.ENLI.dk.

Section 21.08. Pharmaceutical companies are in their event invitations to healthcare professionals obligated to write:

a) that the event has been/will be reported to ENLI prior to the event and
b) that the event in the organizers’ opinion complies with the rules of the field, even if the event has not been pre-approved by ENLI or
c) that the event in its current form and content has been pre-approved by ENLI.
ANNEX A (to ”the Danish Ethical Rules for Promotion of medicinal products towards Healthcare Professionals”):

NB: ANNEX A IS NOT BINDING! UNDER REVIEW- PLEASE REFER TO APPLICABLE DANISH LAWS AND REGULATIONS!

[This is only a draft – and a translation of EFPIA’s corresponding annexes – must be carefully reviewed – to ensure that it follows Danish laws and regulations.]

GUIDELINES FOR INTERNET WEBSITES AVAILABLE TO HEALTHCARE PROFESSIONALS, PATIENTS AND THE PUBLIC IN THE EU

The guidelines for internet websites available to healthcare professionals, patients and the public in the EU set forth herein are intended as a supplement to the provisions of the European Federation of Pharmaceutical Industries and Associations Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals (the “EFPIA HCP Code”) and the Danish Ethical Rules (for Promotion of Medicinal Products). Member associations and companies may find it necessary to adapt these guidelines to meet their particular requirements or needs and are encouraged to adopt additional measures which extend further than the provisions included in these guidelines.

In pursuance of Art. 9, section 1, of the Executive Order on Promotion, promotion on the internet must comply with the same rules as any other promotion of medicinal products. However, the rules must as required, cf. the guideline to section 8.1 of the Executive Order on Promotion, be read and interpreted with due consideration to the special nature of the internet. In accordance with the guideline to the Executive Order on Promotion, the rules apply to banner advertisements etc., clearly taking the form of promotion, and to information about medicinal products, e.g. on the websites of pharmaceutical companies, when such information must be assumed to fall under the definition of promotion.

Art. 9, sections 2 and 3, of the Executive Order on Promotion also state that promotion of medicinal products on the internet is considered promotion towards the general public, as the information is available to any and all. This is however not the case, if the access to such information is securely restricted to healthcare professionals through a personal password or by other effective means. The website stating that the material is targeted at healthcare professionals, or users merely having to type in a password to gain access to the website, is not sufficient. The minimum requirement is user identification in the form of a unique user name, license number or the like, combined with an associated personal password. This could be ensured by using the relevant website’s own special system or a general system, e.g. the user’s digital signature, cf. section 8.1 of the guideline to the Executive Order on Promotion.

Article 1. Transparency of website origin, content and purpose. Each website must clearly identify:

(a) the identity and physical and electronic addresses of the sponsor(s) of the website;
(b) the source(s) of all information included on the website, the date of publication of the source(s) and the identity and credentials (including the date credentials were received) of all individual/institutional providers of information included on the website;

(c) the procedure followed in selecting the content included on the website;

(d) the target audience of the website (e.g. healthcare professionals, patients and the general public, or a combination thereof) and

(e) the purpose or objective of the website.

Article 2. Content of websites.

(a) Information included on the website must be regularly updated and must clearly display, for each page and/or item, as applicable, the most recent date as of which such information was updated.

(b) Examples of the information that may be included in a single website or in multiple websites are: (i) general information on the company; (ii) health education information; (iii) information intended for healthcare professionals (as defined in the EFPIA HCP Code), including any promotion; and (iv) non-promotional information intended for patients and the general public about specific medicinal products marketed by the company.

(iv) General information on the company. Websites may contain information that would be of interest to investors, the news media and the general public, including financial data, descriptions of research and development programs, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law. (v) Health education information. Websites may contain non-promotional health education information about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to medicinal products, provided that the discussion is balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Websites containing health education information must always advise persons to consult a healthcare professional for further information. (vi) Information for healthcare professionals. Any information on websites directed to healthcare professionals that constitutes promotion (as defined in the EFPIA HCP Code) must comply with applicable codes (as defined in the EFPIA HCP Code) and any other industry codes of practice governing the content and format of advertisement and promotion of medicinal products. Such information must be clearly identified as information for healthcare professionals, but need not be encrypted or otherwise restricted.
(vii) Non-promotional information for patients and the general public. Subject to any applicable laws and regulations, websites may include non-promotional information for patients and the general public on products distributed by the company (including information on their indications, side-effects, interactions with other medicinal products, proper use, reports of clinical research, etc.), provided that such information is balanced, accurate and consistent with the approved summary of product characteristics. For each product that is discussed, the website must contain full, unedited copies of the current summary of product characteristics and patient leaflet. These documents should be posted in conjunction with other information about the products or be connected with that discussion by a prominent link advising the reader to consult them. In addition, the website may provide a link to the full, unedited copy of any public assessment report issued by the Committee for Medicinal Products for Human Use or a relevant national competent authority. Brand names should be accompanied by international generic names. The website may include links to other websites containing reliable information on medicinal products, including websites maintained by government authorities, medical research bodies, patient organizations, etc. The website must always advise people to consult a healthcare professional for further information.

Article 3. E-mail enquiries. A website may invite electronic mail communications from healthcare professionals and patients or the general public seeking further information regarding the company’s products or other matters (e.g. feedback regarding the website). The company may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other media. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a healthcare professional is consulted for further information.

Article 4. Links from other websites. Links may be established to a company-sponsored website from websites sponsored by other persons, but companies should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the company or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

Article 5. Website addresses in packaging. Subject to any applicable national laws and regulations, uniform resource locators (URLs) of company-sponsored websites that comply with these guidelines may be included in packaging of medicinal products.
Article 6. Scientific review. Companies should ensure that scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable code(s). The scientific service established within the company pursuant to those provisions of the applicable code that adopt section 17.02 of the EFPIA Code may perform this function, or it may be entrusted to other appropriately qualified persons.

Article 7. Privacy. The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.