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

Self-regulation since 1973

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

Unauthorised translation

In case of doubt the Danish version

is always applicable and official

Version 1.7 February 2014

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 Health and Medicines Authority (previously the Danish Medicines Agency), except for Art. 13, sections 3-9, which also apply to meetings etc. in connection with clinical research and Art. 16 and Art. 17 which also apply to remuneration for services offered in connection with collaboration on 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, organised or sponsored by a pharmaceutical company or by authority of a pharmaceutical company.

Section 3.02. ”Pharmaceutical companies” mean members of:

a) The Danish Association of the Pharmaceutical Industry (Lif),
b) The Danish Generic Medicines Industry Association (IGL)
c) The Danish Association of Parallel Distributors of Pharmaceuticals (PFL) and
d) ”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
e) 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:

a) presented as having properties for treating or preventing disease in human beings, or
b) 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
c) a medical device intended for administration of a medicinal product cf. sub-section 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. 23,”Events” have the meaning set forth in Art. 23 in section 23.02.

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 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.) authorised 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 authorisation 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 include no more than the trade name 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-authorisation 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. No gifts or pecuniary advantages (in cash or benefit in kind) may be supplied, offered or promised to healthcare professionals, except as provided for in Art. 13 - 16.

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 organisers 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") organised 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 organise 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. Companies shall not provide or offer any meal (food and beverages) to healthcare professionals, unless, in each case, the value of such meal (food and beverages) does not exceed one of the following monetary thresholds: DKK 400 for lunch, DKK 700 for dinner or DKK 1,200 covering all meals (food and beverages) at all-day meetings /conferences etc. The monetary thresholds apply to meals taken in Denmark. When providing meals in other European countries, the monetary thresholds set by the pharmaceutical industry associations in these countries must be complied with.

Section 13.09. Hospitality must not include sponsoring or organizing entertainment (e.g. sporting or leisure) events.

Section 13.10. Pharmaceutical companies must avoid using venues that are "renowned" for their entertainment facilities or are extravagant and/or luxurious.

Section 13.11. 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 13.12. 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 Information and educational material and items of medicinal utility

Section 14.01.The transmission of informational or educational materials to healthcare professionals is permitted provided it is: (i) inexpensive, (ii) directly relevant to the practice of medicine or pharmacy, and (iii) directly beneficial to the care of patients. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 14.02. Furthermore, items of medicinal utility aimed directly at the education of healthcare professionals and patient care can be provided if they are (i) inexpensive and (ii) do not offset the business practices of the recipient.

Section 14.03. The term “Inexpensive” is determined on the basis of a specific assessment that reflects what is generally considered reasonable in relation to the material /utility type and within the scope of any authority practice.

Article 15 Donations and grants that support healthcare or research

Section 15.01. Donations, grants and benefits in kind to institutions, organisations 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 15.02. Donations and grants to individual healthcare professionals or associations of healthcare professionals are not permitted under this section, excluding company sponsorship of healthcare professionals to attend professional events, which is covered by Art. 13, section 13.01, or professional gifts of insignificant value, cf. Art. 14.

Section 15.03. Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them covered in section 15.01.

Section 15.04. Contracts between pharmaceutical companies and institutions, organizations or associations of healthcare professionals under which such institutions, organisations 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 16 – The use of consultants/professional services

Section 16.01. 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 16.02. Employment arrangements of general practitioners, dentists and pharmacists with a pharmaceutical company require preceding permission from the Danish Health and Medicines Authority (previously the Danish Medicines Agency). Pharmaceutical companies must inform the Danish Health and Medicines Authority (previously the Danish Medicines Agency) about doctors, dentist and pharmacists who are associated with the company.

Section 16.03. 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 16.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires is excluded from the scope of this Art. 16, except for Art. 16, section 16.01, 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 16.01, sub-section g). Such research must not be disguised promotion.

Section 16.05. 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 – TRANSPARENCY

Article 17 - Transparency

Section 17.01. Lif and Lif's members have signed up to “EFPIA’s CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS” (Disclosure Code). In Denmark, the Disclosure Code is embodied within the framework of Arts. 4.02 and 4.03 of the Code which state that national variations are permissible in those countries where so required in national legislation.

Section 17.02. Accordingly, companies in Denmark are required to comply with:

1) The requirements laid down within the framework of the registration /approval and Disclosure Regulation laid down in Danish legislation (Medicines Act, Pharmacies Act and National Health Act) and associated Orders (Order on Relations between Healthcare Professionals and Pharmaceutical and Medical Technology Companies and the Order on Medicinal Product Advertising) with effect from November 1, 2014.

2) The disclosure requirements arising from the pharmaceutical industry's other ethical rules on collaboration.

CHAPTER 7 – NON-INTERVENTIONAL STUDIES, EXHIBITION AND MEDICAL SAMPLES

Article 18 – Non-interventional studies of marketed medicinal products

Section 18.01. 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 18.02. 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 sub-section 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 Health and Medicines Authority (previously 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 Art. 21, section 21.02, 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 Art. 21, section 21.02, 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.

Section 18.03. To the extent applicable, companies are encouraged to comply with Art. 18, section 18.02 for all other types of studies covered by Art. 18, section 18.01, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject Art. 18, section 18.02, sub-sections a), c) and f).

Article 19 – Exhibition etc.

Section 19.01. 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 19.02. The promotion and marketing set out in section 19.01 must only take place in connection with events that adhere to the professional standards in Art. 13.

Section 19.03. 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 programme of the event.

Article 20 – Medical samples

Section 20.01. Samples of a medicinal product shall at most be supplied for two years after the date of introduction.

Section 20.02. 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 authorisation. 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 authorisations as a result of additional strengths /pharmaceutical forms for existing indications - or new packages - are not regarded as new medicinal products.

Section 20.03. The rules of sections 20.01-20.02 shall apply to medical devices that are medicinal products pursuant to Art.3, section 3.03, sub-section (c). Other medical devices that are not covered by sections 20.01 and 20.02. 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 sections 20.01 and 20.02.

Section 20.04. In addition to the provisions of sections 20.01 - 20.03, 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 20.05, (sections 20.01– 20.04) 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 authorisation, cf.(sections 20.01 and 20.02). Samples of medicinal products introduced before 1 January 2012 may be supplied until 31 December 2013 in accordance with the rules applying hitherto.

CHAPTER 8 – STAFF, TRAINING, ETC.

Article 21 – Pharmaceutical company staff

Section 21.01. 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 Art. 18, section 18.02, sub-section (i) are also applicable to the activities of pharmaceutical sales representatives.

Section 21.02. 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 Art. 21, section 21.02 (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 organisation. 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 9 – ENFORCEMENT, OBLIGATION TO REPORT AND PRE-APPROVAL

Article 22 - Enforcement

The rules are sanctioned as described in collaboration agreement of ENLI, please refer thereto.

Article 23 – Obligation to report

Section 23.01. Pharmaceutical companies are obligated to report activities to ENLI:

a) which are organised or co-organised by a pharmaceutical company, and the event is fully or partially targeted at Danish healthcare professionals.
b) where a pharmaceutical company, not organising or co-organising 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 23.02. ”Event” has the meaning set forth in section 23.01, 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 23.01, sub-sections a) and b), where the healthcare professional provides a service in return.

Section 23.03. 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 23.04. 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 23.05. Reports concerning the activities set out in Art. 23, section 23.01, 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.Art. 23, section 23.01, 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. Art. 23, section 23.03, is distributed (i.e. distributed or published as advertisement).

Section 23.06. 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 23.07. 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 23.08. 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 organisers’ 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.

Change log

Date	Version	Article/Section	Change
04.02.2011	1.1		Document established
16.09.2011	1.2	Introduction	Description of the associations IGL and PFL
01.01.2012	1.3	Article 2, section 2.01, sub-section d	Regulation of medical samples added to Article 18 and as a consequence hereof this provision is deleted.
		Article 3, section 3.01, sub-section c	Specification – medical devices that according to the legislation is defined as a medicinal product is also included in the definition of medicinal products in the code on advertising of medicinal products.
		Article 18	New rules on dispensing of medical samples.
23.04.2012	1.4	Introduction	Deleted due to similar introductory information on establishment of ENLI and the creation of the code on advertising of medicinal products in the annual report 2011.
29.06.2012	1.5	Article 2, section 2.02, Article 15, section 15.02 and Article 16, section 16.02, sub-section d	References to the Danish Medicines Agency changed to the Danish Health and Medicines Authority due to name change after the merger of the two agencies on March 1, 2012.
22.02.2013	1.6	Annex A	Guidance in annex A has been removed to guidance paper on the advertising code, now annex C.
19.12.2013	1.7	Article 2, section 2.02, sub-section d	Implementation of EFPIA's Disclosure Code.
		Article 4, section 4.03, sub-section a	Amendment as a result of prohibition against gifts in Art. 12.
		Article 12	Introduction of prohibition against gifts.
		Article 13, section 13.08	New provision – fair level for meals defined with a monetary threshold. Numbering of following provisions in Article 13 is corrected as a consequence.
		Article 14	New provision – transmission of informational and educational materials and medicinal utility. Numbering of following Articles is corrected as a consequence.
		Article 17	New provision – implementation of EFPIA's Disclosure Code. Numbering of the following chapters and articles are corrected as a consequence.
16.01.2014		Reference corrections	Corrections of references to various provisions as a consequence of the implementation of new provisions as of 19.12.2013.
25.02.2014		Article 17	IGL and PFL added