



**The Pharmaceutical Industry's Code of Practice on
Promotion etc., of Medicinal Products
aimed at Healthcare Professionals
(Promotion Code)**

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

CHAPTER 1 – PRELIMINARY PROVISIONS

Article 1 - Scope

Section 1.1. 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 paramount, and pressure opportunities and dependency between the parties are excluded. The ethical rules state a number of minimum standards, which must be complied with, in addition to the applicable laws and regulations.

Section 1.2. Pharmaceutical companies must maintain high ethical standards at all times. Promotional measures:

- a) Must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry
- b) Should recognise the specific characteristics of medicinal products and the professional standing of the recipient(s), and
- c) Must not be likely to cause offense.

Article 2 - Field of application

Section 2.1. These ethical rules apply to the activities of pharmaceutical companies inside and outside the borders of Denmark, regarding:

- a) Promotion of and communication about medicinal products aimed at healthcare professionals.
- b) Interaction with healthcare professionals on medicinal products.
- c) The rules are only applicable in respect of activities that are partially or fully directed against Danish healthcare professionals. However, the rules, also applies to activities, which are exclusively directed against foreign healthcare professionals, provided that the activities are held in Denmark.

Section 2.2. The rules do not apply to:

- a) Activities that relate exclusively to products, which do not fall under the definition of a medicinal product, e.g., medical devices, skin care products and similar products,
- b) Activities that are not aimed at healthcare professionals, e.g.:
 - Dialogue and negotiations with decision-makers, including politicians and officials,
 - The pharmaceutical industry's cooperation with patient organisations,
 - Promotion of medicinal products aimed at the general public,
 - Press releases, etc., as well as information for investors, etc., and
 - Patients and citizens,
- c) The conditions covered by the exceptions provided for in section 2 of the Executive Order on Advertising of medicinal products,
 - 1) Medicinal products labelling and package leaflets.
 - 2) Individual correspondence, if necessary, accompanied by documents of a non-promotional nature, that serves to answer a specific query on a specific medicinal product.

- 3) Necessary and specific information or documentation that serves safety, and not advertising, purposes.
 - 4) Price lists, product catalogues, etc., containing no other information about the medicinal products than their names, pharmaceutical form, strengths, pack sizes, prices and images of the product packaging, including price lists, product catalogues, etc., published on the internet with a purpose to e-sales for medicines.
 - 5) Informative material on health and disease provided there is no direct or indirect reference to specific medicinal products.
 - 6) Patient information leaflets accompanying a prescription as part of prescribing a medicinal product, or supplied by the pharmacy when dispensing medicinal products, which only contain factual information of importance to patients and their relatives. The information in the leaflet must not conflict with product summaries.
 - 7) Press releases containing
 - a) Brief, objective information on a medicinal product,
 - b) Which has general news value,
 - c) with the press as the target group and
 - d) That are circulated to or made available to a multiplicity of journalists or the media for the purpose of journalistic review and processing prior to publishing.
 - 8) Unedited and unabridged reproduction of a package leaflet, the officially approved product summary or a publicly available evaluation report, cf. art. 72, section 1 of the Medicines Act, or an image of a medicine pack provided that the information is made available in such a way that users must actively search for the information.
- d) Cases relating to clinical research, which is reported to the scientific ethical committee system and the Danish Medicines Authority, except for Art. 13, sections 3-10, which also applies to meetings, etc., in the context of clinical research as well as Art. 15 and Art. 16, which also applies to remuneration for services offered in connection with collaboration on clinical research.

Article 3 - Definitions

Section 3.1. "Promotion" is defined as in Sec. 1, Section 1, of the Executive Order on Advertising of Medicinal Products: "*By advertising for medicines for humans is meant any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products to humans.*" The concept of advertising applies to all activity, regardless of media, which are undertaken, organised or sponsored by a pharmaceutical company or by authority of a pharmaceutical company.

Section 3.2. "Pharmaceutical companies" in relation to this code is defined on the basis of the definition in Sec. 1, subsection 4 of the Executive Order on Advertising of Medicinal Products, and means 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 Medicines 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 these ethical rules, and
- e) Consultancy service companies, etc., acting on behalf of the companies and associations mentioned in subsections a)-d).

Section 3.3. "Medicinal products" is defined as any product, which:

- a) Is presented as an appropriate means for treating or preventing disease in human beings,
- b) May be used in or administered to human beings either to restore, alter or affect physiological functions by exercising a pharmacological, immunological or metabolic effect, or to make a medical diagnosis, or
- c) Are medical devices intended to administer a medicinal product, cf. subsection a) or b) if the medical device and the medicinal product is marketed as an integrated product that exclusively is intended for use in the given combination and the medical device cannot be reused.

Section 3.4. In relation to the obligation to report in Art. 21," Events" are defined as referred to in Art. 21, section 21.2.

Section 3.5. "Healthcare professionals" is defined as in the Advertising Executive Order Section 1 (3): "Healthcare professionals means doctors, dentists, pharmacists, nurses, pharmaeconomists, midwives, bio-analysts, clinical dietitians, radiographers, social and health assistants and students in these disciplines". "Danish healthcare professionals" means healthcare professionals employed in Denmark, or healthcare professionals with independent business in Denmark, e.g., general practitioners with a clinic in Denmark.

Section 3.6. "The general public" is defined as in Sec. 1, section 2 of the Executive Order on Advertising of Medicinal Products and by this is meant anyone who is not covered by the definition of a healthcare professional, cf. section 3.5.

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

Article 4 – Marketing authorization and requirements of objectivity

Section 4.1. Promotion of the medicinal products mentioned in Sec. 3, subsections. 1-5 of the Executive Order on Advertising of Medicinal Products is not permitted. Among other things it applies that it is not possible to advertise for medicinal products which cannot legally be sold or distributed in this country, cf. Sec. 64 (1) of the Medicines Act. For products reserved to pharmacies it further applies that the price prior to a possible advertising, must be reported to medicinpriser.dk.

Section 4.2. 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 in accordance with the approved summary of product characteristics of the medicinal product.

Section 4.3. Promotion material, which appears on exhibition stands or is distributed to participants at international events outside of Denmark may, without regard to section 4.1, unless prohibited or oth-

erwise regulated by applicable national laws or other rules, including industry regulations, refer to medicinal products (or its use), which are not registered in the country where the event is taking 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 it is clear that the medicinal product or use is not registered and available locally, and
- b) Any such promotion material, which refers to the prescribing information (indications, warnings, etc.), which is authorised in one or more countries where the medicinal product is registered, should be accompanied by a explanatory statement indicating that the registration conditions vary from country to country.

CHAPTER 3 – ADVERTISEMENTS

Article 5 – Compulsory information

Section 5.1. All promotion material of medicinal products directed at healthcare professionals must include the following information:

- 1) The invented name and the generic name of the medicinal product. Promotion of combination medicinal products with no generic name must include clear information on the generic names of all active ingredients.
- 2) Name of the marketing authorisation holder as well as name and address of the pharmaceutical company or its agent responsible for the marketing the product.
- 3) Therapeutic indication as specified in the summary of product characteristics. In promotion material exclusively directed at a limited group of healthcare professionals, the indication text may be reduced to the extent relevant to the group concerned.
- 4) Contraindications.
- 5) Adverse reactions and risks.
- 6) Dosage.
- 7) Pharmaceutical forms.
- 8) Pack sizes.
- 9) Reference to the current price on medicinpriser.dk, if it is a pharmacy-only medicinal product.
- 10) Dispensing group.
- 11) Reimbursement status.
- 12) The date on which the promotion material was generated or last revised.

Section 5.2. The information referred to in section 5.1 must be so clear that the natural target group for the promotion material can read it effortlessly.

Section 5.3. If a medicinal product has been approved in several pharmaceutical forms with different fields of application, and the promotion material exclusively concerns one of these pharmaceutical forms, the promotion material may only include information on this pharmaceutical form. Furthermore, it should be included in the promotion material that the medicinal product is also available in other pharmaceutical forms.

Article 6 - Reminders

Promotion exclusively directed at healthcare professionals, may be limited solely to the invented name and generic name of the medicinal product.

Article 7 – Information material and documentation

Section 7.1. 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 qualities or properties, unless this can be substantiated. Such documentation must at reasonable requests from healthcare professionals, promptly be provided.

Section 7.2. Information material concerning medicinal products, as in promotional purposes will be sent out or distributed to healthcare professionals, must as a minimum include the information referred to in section 5.1, and the date on which the material was generated or last revised. However, see section 5.3.

Section 7.3. All information referred to in sections 7.1 and 7.2 must be adequate, objective, accurate, relevant, verifiable and sufficiently complete to enable the recipient to form his own personal opinion of the therapeutic value of the medicinal product.

Section 7.4. Quotations, tables and illustrations from medical journals, scientific literature, etc., which is used in the information material as referred to in sections 7.1 and 7.2, must be faithfully reproduced and the exact source must be provided. Particular attention must be paid to ensuring that the artwork included in promotion material is not misleading in relation to the nature of a medicinal product (for example, whether it is suitable for children) or misleading in relation to a claim or comparison (for example by using incomplete or statistically irrelevant information, or unusual scales).

Section 7.5. Substantiation of information on medicinal products must, in addition to the summary of product characteristics, only include scientifically substantiated research. The research must have been published in established and independent Danish or foreign publications, professional journals or the like. The research must prior to publication have been subject to an independent assessment (peer review).

Section 7.6. Words indicating that the medicinal product is safe may not be used to describe a medicinal product. Words that indicate that the medicinal product is new may not be used to describe a medicinal product or packaging which has been generally available, or for a therapeutic indication for which there has been widespread use of promotional measures, for more than one year. It must not be stated that a medicinal product has no adverse reactions, toxic effects, or risk of addiction.

Article 8 – Comparative advertising

Section 8.1. If a promotion material includes a comparison between several medicinal products, it must clearly appear which medicinal products the comparison includes. The comparison must only include medicinal products, which are relevant to compare from an objective point of view, i.e. medicinal products with the same field of application.

Section 8.2. Comparative advertising must be based on the information in the summaries of product characteristics of the medicinal products, which are included in the comparison.

Section 8.3. Comparisons between different medicinal products must not be misleading or disparaging.

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

Article 9 –Distribution of promotion

Section 9.1. Promotion may only be directed at those whose need for, or interest in, the particular information can reasonably be assumed.

Section 9.2. Mailing lists must be kept up to date. Requests from healthcare professionals to be removed from promotion mailing lists must be complied with.

Section 9.3. Subject to applicable national laws and other rules, including industry regulations, the use of fax, e-mails, automated calling systems, text messages and other digital communications for the purpose of promotion, is prohibited, unless prior permission has been obtained from the receiver, or upon request.

Article 10 – Transparency of sales promotional measures

Section 10.1. Promotion must not be disguised.

Section 10.2. Clinical assessments, post-marketing surveillance and experience programs and post-authorisation studies (including those of retrospective art) must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Section 10.3. If a pharmaceutical company pays for, or otherwise provide or arrange for the publication of promotion materials in journals, such material must not appear as independent editorial matter.

Section 10.4. Material relating to medicinal products and their use, whether promotional in nature or not, and which is sponsored by a company, must clearly indicate that it has been sponsored by that company.

Article 11 – Prohibition against advising on personal medical issues

In case of requests from individuals from 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 – Main rule – prohibition against financial benefits and gifts

Section 12.1. It is not allowed to supply, offer or promise healthcare professionals gifts or financial benefits, either in the form of cash, cash equivalents, personal services or benefits, except as listed in in Art. 13 - 15.

Section 12.2. 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 13.1. Pharmaceutical companies can give or offer a healthcare professional training and professional information in the form of payment of direct expenses in connection with professional relevant courses, conferences, training etc., in which the healthcare professionals participate or arrange. In these activities, pharmaceutical information or other professional relevant information, relevant for the participants, must be included. The pharmaceutical companies can act as:

- a) Organiser or co-organiser of the events referred to in section 13.1, or
- b) Sponsors of the professional events referred to in section 13.1, organised by a third party responsible for the professional content, lecturers, educational method, etc. Sponsorships must not be subject to the sponsor influencing the professional content of the program. The organisation of the event must be independent of the sponsorship given, as only events of a mere professional nature may be sponsored.

Section 13.2. The organizer and purpose of the events referred to in section 13.1 must appear from the invitation to the event, just as the invitation always 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 13.3. All promotional, scientific or professional meetings, congresses, etc., which are organised or sponsored by, or on behalf of, a pharmaceutical company must take place in an appropriate venue that is conducive to the main purpose of the event.

Section 13.4. No pharmaceutical company may organise or sponsor any of the events referred to in section 13.1, which takes place outside of the pharmaceutical company's home country, unless:

- a) Most of the invitees come from abroad and, given the countries of origin of most of the invitees, it makes significantly more logistical sense to hold the event in another country, or
- b) Given the location of the relevant resource or expertise, which is the object or subject for the event, it makes significantly more logistical sense to hold the event in another country.

Section 13.5. Hospitality extended in connection with the events referred to in section 13.1, may only be offered when relevant and must be limited to travel, meals, accommodation and genuine registration fees.

Section 13.6. Hospitality may only be extended to healthcare professionals who qualify as participants in their own right. In exceptional cases of established health needs (e.g., disability, personal injury, etc.) travel, meals, accommodation and registration fees of an accompanying person can be reimbursed within the same parameters.

Section 13.7. All forms of hospitality, cf. section 13.5, offered to healthcare professionals must be kept at a reasonable level and be strictly limited to the main purpose of the promotional or professional event. As a general rule, the hospitality provided must not exceed the amount that recipients employed in the health sector, would normally be prepared to pay for themselves. There can only be offered meals, if the professional programme, cf. section 13.1, constitutes a minimum of 2 hours.

Section 13.8. Companies must not provide or offer meals (food and beverages) to healthcare professionals, except in those cases where the value of such meal does not exceed one of the following monetary thresholds: DKK 450 for lunch, DKK 850 for dinner or DKK 1,400 covering all meals at all-day meetings/conferences, etc. The monetary thresholds apply to meals in Denmark. When providing meals in other European countries, the monetary thresholds laid down by the pharmaceutical industry associations in these countries, must be complied with.

Section 13.9. Hospitality must not include sponsorship or organisation of entertainment events, such as sporting or leisure events.

Section 13.10. Pharmaceutical companies must avoid using venues, which are known for their entertainment facilities or are extravagant and/or luxurious.

Section 13.11. Funding must not be offered merely to compensate the time spent by healthcare professionals in attending the events referred to in section 13.1.

Section 13.12. In the case of international events, as referred to in section 13.1, where a pharmaceutical company is sponsoring the participation of a healthcare professional, any funding provided to such healthcare professionals is subject to the rules of the jurisdiction where such healthcare professional carries out his or her profession, and not the rules of where the international event takes place. Danish legislation and other mandatory legislation must as a minimum always be complied with.

Section 13.13. Pharmaceutical companies must, when committing to reimburse the costs of a healthcare professional as listed in Art. 13, for his participation in professional events abroad, inform the healthcare professional of the regulations in section 27 of the Executive Order on Advertising of Medicinal Products, as well as section 202 (b) and 202 (c) in the Danish Health Act, including the healthcare professionals

obligation to notify the Danish Health and Medicines Authority, and the Authority's disclosure of the information regarding the association.

Article 14 Information and educational material and medical equipment

Section 14.1. The transmission of informational or educational materials to healthcare professionals is permitted, provided it is:

- a. inexpensive,
- b. directly relevant to the practice of medicine or pharmacy business, and
- c. directly beneficial to the care of patients. Such material or items must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Section 14.2. Furthermore, items of medical equipment aimed directly at the education of healthcare professionals and patient care, can be provided if they are inexpensive and do not offset the business practices of the recipient.

Section 14.3. The term "inexpensive", cf. sections 14.1 and 14.2, is determined on the basis of a specific assessment, which reflects what is generally considered reasonable in relation to the material/equipment type and within the scope of any regulating practice.

Section 14.4. Information and educational material as well as items of medical equipment can include the name of the pharmaceutical company but must not be branded with the trade or common name of the medicinal product unless the name of the medicinal product is essential for the correct use of the material or item.

Article 15 – The use of consultants/professional services

Section 15.1. It is permitted to contract 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, also when this participation involves remuneration and/or hospitality. A written contract or agreement must be concluded prior of the commencement of the services, specifying the nature of the services and, subject to clause (f) below, the basis of payment for these services. In addition, the following criteria, to the extent relevant, must be met:

- a) a legitimate need for the services must be clearly identified and documented prior to requesting the services and entering into arrangements;
- b) the criteria for selecting consultants must be directly related to the identified need and the persons responsible for the selection of consultants must have the expertise necessary to assess, whether the particular healthcare professionals meet the criteria;
- c) the number of healthcare professionals retained, and the extent of the service must not exceed the reasonably necessary to achieve the identified need;

- d) the contracting company must keep a record of, and make appropriate use of, the services provided by consultants;
- e) the hiring of the healthcare professional to provide the relevant service must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and
- f) the remuneration for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating healthcare professionals.
- g) Payment 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 15.2. Employment arrangements of doctors, dentists and pharmacists with a pharmaceutical company require prior notification to or permission from the Danish Health and Medicines Authority as per the Danish Health Act section 202 (a). Pharmaceutical companies must inform the healthcare professionals thereof as well as inform the Danish Health and Medicines Authority of the doctors, dentist and pharmacists who are associated with the company, as per this code's Art. 16, section 16.2.

Section 15.3. Anonymous surveys, where the study is carried out by a third party and where the anonymity between respectively the underlying company and the pharmacist, doctor or dentist will be maintained after the implementation of the study, is not covered by section 15.02. It is a requirement that the company and the pharmacist, doctor or dentist does not become aware of each other.

Section 15.4. Limited market research, such as one-off phone interviews or post/email/internet surveys is not covered by this provision, except for Art. 15, section 15.1, sub-sections c), e), f) and g) and section 15.2, 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 15.1, sub-section f). Such research must not constitute disguised promotion.

Section 15.5. If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity, the relevant provisions of Art. 13 must apply.

CHAPTER 6 – TRANSPARENCY

Article 16 - Transparency

Section 16.1. In Denmark, EFPIA's Code of Practice is implemented within the framework of Art. 23.02 on healthcare professionals' affiliation with pharmaceutical companies, according to which national variations are permitted by EFPIA in countries where so required in national legislation regarding healthcare professional's affiliation.

Section 16.2. Accordingly, companies in Denmark are obliged 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, Pharmacy Act and Danish Health Act) and the associated Executive Orders (Executive Order on Relations

between Healthcare Professionals and Pharmaceutical and Medical Technology Companies and the Executive Order on Advertising of Medicinal Products) 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 17 – Non-interventional studies of marketed medicinal products

Section 17.1. Non-interventional studies of a marketed medicinal product is defined as a study where the medicinal product(s) is 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 must be applied to the patients, and epidemiological methods must be used to analyse the collected data.

Section 17.2. Non-interventional studies, which is prospective and involves the collection of patient data from or on behalf of individuals, or groups of, who are employed in the health sector specifically for the study, must comply with all of the following criteria:

- a) The study must be conducted with a scientific purpose and must not be disguised promotion;
- b) There must be a written study plan (protocol) and written contracts between healthcare professionals and/or the institutes, at which the study will take place, on the one hand, and the pharmaceutical company, which is sponsoring the study, on the other hand, specifying the nature of the services to be provided, and the basis for payment of these services;
- c) Any remuneration provided must be reasonable and reflect 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 relating to non-interventional studies (description of non-interventional studies) must be submitted to the Danish Health and Medicines Authority for review and guidance.
- e) The General Data Protection Regulation (GDPR)(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. 20, section 20.02, subsection 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. 20, section 20.02, subsection 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 essential 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, which must also ensure adequate training of consultants. Such involvement must not be linked to the promotion of any medicinal product.

Section 17.3. To the extent applicable, companies are encouraged to comply with section 17.2, for all other types of studies covered by section 17.1, including epidemiological studies and registries and other studies of retrospective art. Such studies are in any case covered by section 17.2, subsections a), c) and f).

Article 18 - Exhibition etc.

Section 18.1. In connection with the organising 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 18.2. The promotion and marketing referred to in section 18.1 must take place only in connection with events that adhere to the professional standards in Art. 13, section 13.1.

Section 18.3. When pharmaceutical companies are given the opportunity to advertise, exhibit, display movies, inform about products, etc., it must take place on the basis of a preceding agreement on the conditions, including the financial terms and programme of the event.

Article 19 - Medical samples

Section 19.1. Samples of a medicinal product must not be supplied for more than two years after the date of introduction.

Section 19.2. The date of introduction for a new medicinal product must be the date at which it is placed on the market 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 of a marketing authorisation as a result of additional strengths/pharmaceutical forms for existing indications - or new packages - are not considered to be new medicinal products.

Section 19.3. The rules of sections 19.1-19.2 must apply to medical devices that are medicinal products pursuant to Art.3, section 3.3, subsection (c). Other medical devices are not covered by sections 19.1 and 19.2. Samples of medicinal products may be supplied together with these devices to the extent that it is 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 19.1 and 19.2.

Section 19.4. In addition to the provisions of sections 19.1 - 19.3, the Executive Order for the time being in force on the supply of samples of medicinal products must apply.

CHAPTER 8 – PERSONNEL, EDUCATION/TRAINING, ETC.

Article 20 – Personnel in pharmaceutical companies

Section 20.1. Each pharmaceutical company must ensure that its sales representatives, including personnel retained through contract with third parties, and any other company representatives who contacts 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 laws and other rules, including industry regulations, and are adequately trained and have sufficient professional knowledge to be able to provide accurate and complete information about the medicinal products they promote. Pharmaceutical sales representatives must be aware of the following conditions:

- a) Pharmaceutical sales representatives must comply with all relevant requirements of the applicable laws and other rules, including industry regulations, and the companies are responsible for ensuring their compliance.
- b) Pharmaceutical sales representatives must perform their duties responsibly and ethically.
- c) During each visit, and in accordance with applicable laws and other rules, including industry regulations, 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 the current price on medicinpriser.dk (if the medicinal product is reserved to pharmacies only) and reimbursement status.
- d) Pharmaceutical sales representatives must immediately transmit the scientific service of their companies any information they receive in relation to the use of their companies’ medicinal products, particularly reports on side-effects, cf. Sec. 20.2, subsection a).
- 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 conducted, do not cause inconvenience.
- f) Visits by pharmaceutical companies to hospitals must be agreed upon in advance with the relevant persons, and the meetings must be based on a pre-announced and agreed topic. Thus, unannounced visits must not take place.
- g) 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.
- h) The provisions of Art. 17, section 17.2, subsection i), are also applicable to the activities of pharmaceutical sales representatives.

Section 20.2. All pharmaceutical company staff, and all staff retained through contract with third parties, who are involved with the preparation or approval of promotional material or activities, must be fully

knowledgeable of the requirements of the applicable laws and other rules, including industry regulations.

- a) Each 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 20.2 (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. This person must certify that he or she has reviewed the final form of the promotional material, and that in his or her opinion it is in accordance with the requirements of the applicable laws and other rules, including industry 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 all non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by pharmaceutical sales representatives). This person must certify that he or she has reviewed the protocol for each non-interventional study and that in his or her opinion it is in accordance with the requirements of the applicable code(s).
- b) Each pharmaceutical company must appoint at least one senior employee who is responsible for ensuring that the company and its subsidiaries comply with the standards of the applicable code(s).

CHAPTER 9 – ENFORCEMENT, REPORTING REQUIREMENT AND PRE-APPROVAL

Article 21 – Reporting requirement

Section 21.1. 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 directed against Danish healthcare professionals.
- b) where a pharmaceutical company, without organising or co-organising the event, provides financial (sponsor) support to a so-called third-party event, fully or partially directed against Danish healthcare professionals or to the participation of Danish healthcare professionals.
- c) where a pharmaceutical company buys an exhibition stand at a congress in Denmark.

Section 21.2. "Event" has the meaning set forth in section 21.1 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. Excluded are visits from pharmaceutical sales representatives and events, cf. section 21.1, subsections a) and b), where the healthcare professional provides a service in return.

Section 21.3. In addition, pharmaceutical companies are obligated to report all kinds of printed promotion material aimed 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. 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 21.4. Companies are obligated to file a report online via: www.enli.dk using a standard report form. The company is obligated to ensure that the report is fully enlightened, and that all relevant documentation is submitted.

Section 21.5. Reports concerning the activities set out in section 21.1, subsection a), must be filed within 10 working days prior to the opening day of the event. Reports concerning sponsorships etc., cf. section 21.1, subsection 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 at least 10 working days prior to the opening day of the event. Reports relating to promotion material must be filed at least on the same day as the printed promotion material, cf. section 21.3, is distributed (i.e. distributed or published as advertisement).

Section 21.6. The pharmaceutical company responsible for the event must ensure that the abovementioned obligations to report are always complied with. This also applies when the planning, distribution or other practical duties of the event are fully or partially carried out by others.

Section 21.7. A pharmaceutical company, seeking a pre-publication vetting of an activity 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 21.8. 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 applicable rules, 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.

Article 22 - Enforcement

The rules are sanctioned as outlined in the Sanctions- and fees regulations of ENLI, please refer thereto.

Article 23 – Entry into force

This code enters into force on 15 June 2022 and replaces the latest published code, version 3.0, of 1st of January 2020