GUIDANCE

on

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

(Promotion Code)

Unauthorised translation – the Danish version is the official and always applicable version

This guidance on the Promotion Code will be regularly updated as practice develops or changes. The guidance is thus dated and also has a version number. All special abbreviations used in the guidance are explained at the back of the guidance, where also a change log is found for identifying amendments to the document.

COMMENTARY ON CHAPTER 1 – PRELIMINARY PROVISIONS

Re: Article 1 - Scope

New knowledge about drugs and medical treatment is a necessary precondition for healthcare professionals to be able to do their daily work. When patients go to the doctor and have medicinal products prescribed, they should be able to rely on the doctor being well informed and up-to-date with the latest information on the product that is best for the patient concerned. Further, healthcare professionals and the pharmaceutical industry each possess valuable knowledge about medicines and their use. Knowledge-sharing is therefore crucial for developing new medicines for the benefit of everyone.

This is the reason for legislation permitting these so-called "promotional" activities, etc. The field is tightly regulated to ensure that relations are on an ethically responsible footing, with patient safety and professionalism at the centre.

Parts of the pharmaceutical industry (which are subject to this code) have decided to go a step further and to supplement legislation with a series of voluntary rules. The outcome of these rules is to be found in this

set of rules on promotional activities, i.e. the Promotion Code. In a letter dated 15 January 2013 to ENLI, Lif specified that they wished the sector-specific ethical rules in Denmark to be interpreted so that:

- Insofar as possible they reflect the situation in the rest of Europe (as a result of the pan-European code.
- They reflect the intention of the rules, based on the principle that an overall assessment of an activity shows that it is not harmful to the sector's credibility and image.

Re: Section 1 (2)

Corresponds to section 5.01 EFPIA HCP Code.

This clause is an important contributor to interpretation of the other provisions of the rules since compliance with the principles and standards of the rules is first and foremost assessed by the general public. This also means that interpretation of the rules is dynamic since, to put it simply, an understanding or acceptance of how one *should* behave today may not necessarily be the same tomorrow. Since several of the provisions involve an interpretational view and hence in reality leaving a "grey zone," it may be a good idea to use a simple ethical test prior to a given decision in which one asks oneself this question: how would a given activity be assessed if it were on the front page of tomorrow's papers? If you are not afraid of public comment without knowing all the factual issues, there is a reasonable chance that the decision will be seen as good/ correct. Similarly, in the case of comparative advertising, you could ask the question: How would I react to the advert if I worked for the competing company?

Re: Article 2 – Field of application

Re: Section 2 (1)

It should be noted that the Medicines Act and the Advertising Order and associated guidance also regulate the issues noted in this section 2 (1). The Advertising Order is regulated by the Danish Health and Medicines Authority (previously the Danish Medicines Agency). ENLI's regulation thus supplements governmental controls on the area and the authorities do, however, always have the final competence with respect to interpreting the Advertising Order. It is important to bear in mind that some aspects of the present rules go further than as laid down in Danish legislation whereas Danish legislation at the very least applies to and is contained in this set of rules. In such cases, the "toughest" set of rules applies, i.e. the rule that is most restrictive on the pharmaceutical company.

In order to ensure that this code complies at the very least with Danish law, the former Danish Medicines Agency received the Promotion Code in consultation. The fact that in some places the rules are worded differently than Danish legislation is therefore not due to Danish law not applying, since Danish law must at the very least be complied with regardless of the wording of this set of rules.

About corporate responsibility:

The Promotion Code only applies to "pharmaceutical companies" as defined in section 3 (2), hereafter called “affiliated companies” as per section 3 (2)(d), i.e. not to companies or legal entities that have not individually signed up to the agreement with ENLI and are not members of Lif, IGL or PFL. This means that other companies, including companies in Denmark and abroad even if in the same group of companies as the member company, are not obligated by ENLI’s regulation and cannot be sanctioned by ENLI, naturally enough since they are not party to the agreement on ENLI. Similarly, neither can "pharmaceutical companies" noted in section 3 (2) (i.e. members of Lif, IGL, PFL, etc.) be sanctioned for activities that they are not themselves party to or have legal liability for (e.g. activities relating to Denmark by e.g. foreign companies associated with a group). ENLI finds, that a an affiliated company will assume liability for activities conducted by another company within the group only, if the affiliated company can be regarded as a co-organiser of the event. This will entail that the affiliated company must have been sufficiently involved in the event through clear and direct steps in preparing and/or conducting the event. The affiliated company may well advise another company in its group about ENLI’s regulation to ensure compliance without assuming liability for the event itself. If on the other hand, the affiliated company is actively involved in the event, e.g. by selecting Danish HCPs to participate in the event, or otherwise having contributing to the scientific programme or facilitation of the event, such affiliated company is regarded as a co-organiser.

It is important to note that companies that are not subject to ENLI’s authority are always required to comply with Danish legislation and in this respect, they are subject to regulation by the Danish Health and Medicines Authority (formerly Danish Medicines Agency).

In contrast, corporate liability does apply in the EFPIA HCP Code, cf. EFPIA HCP Code's definition of “company”. It should be noted that Lif has consulted with EFPIA and requested clarification of the legal aspects of how the 'group' corporate rule should function. So far, no clarification has been obtained.

Activities outside Denmark:

The rules apply to a pharmaceutical company's operations directed at healthcare professionals both within and outside the country's national borders, cf. also the EFPIA HCP Code, but this predicates that operations are aimed wholly or partially at "Danish healthcare professionals" or involve operations in Denmark.

Where Danish healthcare professionals are concerned, Greenland and the Faroes are NOT regarded as part of Denmark in this respect.

As noted below, the EFPIA HCP Code requires compliance with the national rules of the organiser as well as the rules of the land in which an event is held. Clearly it would be difficult for ENLI to track compliance with international legislation and other countries’ national codes (where for example a Danish subsidiary holds an event abroad) but nevertheless, it is a requirement for companies to do their best to ensure compliance and the regulatory authorities in the country concerned are responsible for ensuring that there are controls on compliance with the law of the country concerned.

Accordingly, it follows from the introductory section of the EFPIA HCP Code that sales promotional activities or interaction within Europe must comply with applicable laws and rules (Europe in this respect means the countries in which EFPIA member associations' codes apply).

Further, the EFPIA HCP code requires sales promotional activities or interaction to comply with each of the following applicable codes:

a) (i) In the case of promotion or interaction that is undertaken, sponsored or organized by or on behalf of, or with, a company located within Europe, the member association national code of the country in which such company is located must be complied with; or (ii) in the case of promotion or interaction that is undertaken, sponsored or organized by or on behalf of, or with, a company located outside of Europe, the EFPIA HCP Code must be complied with and

b) The member association national code of the country in which the promotion or interaction takes place.

In the event of a conflict between the provisions of the above-identified codes, the most restrictive of the conflicting provisions shall apply (unless otherwise stated).

Example: A Danish company plans activities outside Denmark within the EU, for example in France. The company must comply with the Danish and French codes (sets of rules). Similarly, a French company must comply with both the French and the Danish rules when the company plans activities in Denmark.

It should also be noted that the Danish rules on promotion of medicinal products in the Medicines Act, Advertising Order and the associated guidance only apply, according to the former Danish Medicines Agency, to commercial activities carried out in Denmark and to advertising on the internet originating from pharmaceutical companies established in Denmark.

Re: section 2 (2)

General comments on section 2 (2): These rules naturally do not regulate the general prohibitions set forth in Article 3 of the Advertising Order, that is situations in which promotion is totally prohibited. This applies for example to promotion of medicinal products that cannot be lawfully traded or supplied in Denmark.

Re: (a): This therefore also applies to pharmaceutical companies that sell other things than medicines, when the commercial activity concerned does not relate to promotion for a medicinal product but for the company's other products. Were the opposite to apply, such companies would be prevented from participating in and competing on equal terms with their competitors at for example medtech conferences which are subject to more lenient promotional rules in the legislation, etc., (medical devices, skin care products, etc., are subject to special rules regulating the respective product areas that are controlled by the respective regulatory authorities for the area).

Re: (b): If promotion is not directed at a healthcare professional, it would be comparable to promotion to the general public, which is regulated by the Advertising Order and controlled by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency). Additionally, Lif's other codes apply. These other codes are similarly controlled by ENLI and must at the very least comply with the requirements set forth in the current legislation on the area. See also the commentary to section 2 (2.e) below.

Re: (c): Article 2 of the Advertising Order provides that the rules of Chapter 7 Medicines Act and the Advertising Order, and hence also this set of rules, do not apply to:

1. *Labelling of the medicinal products and package leaflets, cf. Order on Labelling etc. of medicinal products.*

   This area is regulated by Order No. 869 of 21 July 2011 on labelling, etc., of medicinal products. A new Danish guidance has been issued, no. 9365 from 3 July 2013 to the order in connection with an amendment to the order, among other things due to new rules on medicinal products subject to additional monitoring.

2. *Correspondence of an individual nature, if necessary accompanied by documents not intended for advertising purposes, which serve to respond to a specific query about a specific medicinal product.*

   The exception does not apply to the company's responses to queries made on the internet, for example a blog, since such correspondence can be read by everyone.

3. *Specific, essential information or documentation that serves safety-related, non-advertising purposes.*

   According to the guidance on the Advertising Order, this might for example be information about changes to packaging, new risks of side effects (adverse effects) or production faults. 'Safety purposes' should be construed broadly so that for example information on how a medicinal product should be opened so as to prevent its being physically damaged also satisfy serves a safety purpose within the meaning of the phrase in the Advertising Order.

   The Danish Health and Medicines Authority has stated that direct healthcare professional communication (DHPC), which usually contains new safety information and is subsequently included in the product summary that is agreed with the authorities, and training materials which for example EMA requires to be circulated to a defined group of healthcare professionals as part of approval of new core products, and in the event of changes to already approved medicinal products, do serve safety purposes and not advertising purposes. A specific assessment of the material will always be required as to whether or not it in reality contains advertising for a medicinal product.

4. *Price lists, product catalogues, etc., not containing information about medicinal products apart from their names and prices. Publications shall not include information on competing medicinal products.*

5. *Information matter about health and disease, provided that there is no direct or indirect mention of specific medicinal products. This might be anything from traditional folders to extensive internet websites.*

   One example of material that would not be regarded as advertising a medicinal product is information material for adults on children and depression where there is no direct or

indirect mention of specific medicinal products. According to ENLI, specific medicinal products are construed as those referred to by a brand name or generic name. If a generic name or a brand name is mentioned, the material is covered by the rules on medicinal product advertising, including comparative advertising. ENLI does not regard a simple report on medicinal product groups in information material on healthcare and disease, where there is no emphasis on special advantages of products in one or more groups, as mentioning specific medicinal products which are subject to the rules on medicinal product advertising.

On 31 January 2012, the Appeal Board in ENLI ruled in AN-2011-2486 that stating areas of disease and/or medicinal product groups in invitations to events cannot be regarded as indirect mention of specific medicinal products, on condition however that in so doing, there is no emphasis on special product advantages for one or more groups of medicinal products, since in that case it could constitute medicinal product advertising.

6. *Patient information leaflet provided by the issuer of a prescription as part of prescription for a medicinal product or provided by the pharmacy when supplying a medicinal product, and which only contain objective information of importance to patients and their relatives. The information in the folder must not conflict with product summary (summary of product characteristics).*

Patient information leaflets supplied to healthcare professionals are regarded as a promotional activity towards a healthcare professional. This means that in this instance, the handing over of the patient information leaflets are subject to the rules of the promotion code, meaning that compulsory product information (compulsory text) must be accompanying the leaflets separately. Please note that also any accompanying letters must also be in accordance with this code. It should be noted that ENLI does not check whether a patient information leaflet contains promotional statements towards the general public. On 3 November 2011, Lif reported that the previous Danish Medicines Agency, now the Danish Health and Medicines Authority, had ruled in three specific rulings that patient information leaflets did contain promotion for specific medicines to patients in contravention of section 66 (1.1) Medicines Act. The Danish Medicines Agency subsequently specified their practice/guidance in this area to Lif.

Patient information leaflets are not required to be notified to ENLI pursuant to section 23 (3).

7. *Press releases which contain summary information about a medicinal product, have general news value, are aimed at the media as a target group and which are sent to or made available to a majority of journalists or media with a view to journalistic assessment and consideration before publication.*

Back in 2003, the former Danish Medicines Agency (now the Danish Health and Medicines Authority) further notified Lif that press releases should be taken to mean objective information sent to journals, radio and TV, news agencies, etc., cf. above. The Danish Medicines Agency stated: ”A *‘press release’ that for example as a result of non-objective content (such as grossly misleading information) or which appears as aggressive promotional information, is not regarded as a press release. A paid-for ’press release’ or one without any*

genuine journalistic input, is regarded as advertising. The Danish Medicines Agency's view is that a pharmaceutical company can post a press release on its website for about three weeks. After that, a press release is regarded as advertising."

8. *An unedited and unabbreviated reproduction of officially approved information on a medicinal product by way of a patient information leaflet, product summary or publicly available evaluation report cf. section 72 (1) Medicines Act, on condition that the information is made available in such a way that users need to actively search for the information. This means for example that a company can put a list of the names of its medicinal products on its website with links to product summaries and patient information leaflets for each individual medicinal product.*

   The guidance to the Advertising Order states that information material on medicinal products drawn up by public health medicines committees that are tasked with promoting rational use of medicines are not covered by the advertising rules. Neither is it regarded as promotion when pharmaceutical companies issue scientific articles on clinical trials on medicines to healthcare professionals, provided that these articles are sent without comment and without supplementary material. Articles must have already been published in a recognized, independent Danish or international journal, or the like. This also applies to uncommented scientific articles containing the results of comparative studies of different medicines.

Re: (d): It is important to note that in Denmark, the clinical area is controlled by the Danish Health and Medicines Authority and the Biomedical Research Ethics Committee system. Cases relating to clinical research notified to the Biomedical Research Ethics Committee system and/or the Danish Health and Medicines Authority (formerly the Danish Medicines Agency) are therefore not controlled by ENLI. This also applies to sponsorship of clinical trials, although the rules on venues, hospitality etc. as well as the rules on the use of consultants and transparency in this set of rules do also apply to clinical research. Please see Annex A for further details of the controls exercised by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency) and the Biomedical Research Ethics Committee system.

In addition to the legislation in the area, collaborations on clinical research (and non-interventions trials) are also regulated by Lif and Danish Medical Association's Collaboration Agreement on Clinical Research which supplements the legislation with respect to members of Lif and the Danish Medical Association. The agreement is available at www.lif.dk. ENLI only monitors compliance with the provisions set forth in these rules and Lif's other codes but not the above-identified agreement with the Danish Medical Association.

Re: Article 3 - Definitions

Re: Section 3 (1)

Promotion for medicinal products should be construed in accordance with Article 1 Advertising Order as "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products."

The concept of advertising or promotion comes from the European Parliament and Council Directive 2001/83 and is subject to regular interpretation by the ECJ which typically interprets the concept broadly. One example is the so-called ”Damgaard case” (C-421/07), in which the court held that information about a medicinal product communicated by *a third party,* namely about its curative or prophylactic properties, could be regarded as promotion, even though the third party was acting on his own initiative and legally and actually was completely independent of the manufacturer or seller of such a medicine.

ENLI finds that the above ruling indicates an obligation for pharmaceutical companies to ensure that when writing about a pharmaceutical company's medicinal products in the social media, such as Facebook pages set up by the company itself, third parties shall also comply with the rules on promotion. The pharmaceutical company should therefore regularly monitor such websites. Here it should be emphasized that the Promotion Code only applies if access to the social media in use is restricted so as to effectively limit access only to healthcare professionals. If not, the website would be publicly accessible and so the rules on promotion to the public in the Advertising Order would then have to be complied with. ENLI’s view is that it follows from the Promotion Code that companies cannot basically be held accountable for a third party mentioning of competitors' products on the pharmaceutical company’s website.

The fact that the concept of promotion should be construed broadly can further be seen directly from section 5.5 to the guidance to the Advertising Order. It states that Article 21 Advertising Order (prohibition against giving or offering financial benefits to healthcare professionals for promotional purposes) also covers ”image gifts” from pharmaceutical companies to healthcare professionals. *”Accordingly, it does not matter whether the gift is directly associated with marketing a specific medicinal product since the company's interest in providing such financial inducements has to be assumed to be based on the desire to market the company and its products. Image gifts are accordingly deemed to be given for advertising purposes.*”

Promotion accordingly covers all kinds of advertising and/or promotion, regardless of the medium, including but not limited to, written advertising activities, direct mail, promotion by medical representatives, use of the internet and other electronic media, films, videos, brochures and product samples, gifts and hospitality. Other types of written communication with healthcare professionals may also be regarded as promotion, including a request or confirmation of a meeting in accordance with an appointment, cf. section 9 (3), a request for participation in an advisory board or expert group or otherwise. In other words, the medium used for advertising or promotion is irrelevant, cf. also IFPMA Code, section 1 (2). When a healthcare professional is employed by a pharmaceutical company or is in some other way associated with a pharmaceutical company, with the consent of the Danish Health and Medicines Authority (formerly the Danish Medicines Agency), ENLI regards the healthcare professional concerned as an employee of the pharmaceutical company and correspondence with the healthcare professional concerned is no longer regarded as promotion.

Most recently on 25 November 2011, the former Danish Medicines Agency stated that promotion for a medicinal product is involved if a pharmaceutical company has direct links on its website to the name of its product or active ingredient and to information about, among other things, the indication, prices, package sizes and reimbursement on www.min.medicin.dk. The Danish Medicines Agency regarded a company's use of such deep links as door-to-door information aimed at promoting sales and usage of the medicinal

product. It is perfectly permissible for the company to have a link to the website of www.min.medicin.dk, since from there on, users have to navigate to the information they find relevant.

All activities regardless of the medium are covered by the concept of promotion. This means that invitations to medical events can be promotion. However on 31 January 2012, the Board of Appeal ruled in AN-2011-2486 that indicating areas of disease and groups of medicinal products in invitations to events sent to healthcare professionals could basically not be regarded as indirect mention of specific medicines and hence that the invitation could not in itself be regarded as an advertisement for a medicinal product. Promotion for a medicinal product could be involved if special product advantages have been emphasised for one or more groups of medicines. Be aware in this connection that giving a generic name (active ingredient) or brand name (product name) in the invitation means that it will be regarded as advertising medicinal products.

When conducting a professional event of a medical/pharmacy nature for healthcare professionals, the pharmaceutical company is responsible for the event as a whole. This means that the company is also responsible for all presentations made at the event, irrespective of whether a presentation originate from and are presented by an independent third party, e.g. a specialist healthcare professional contracted to present on behalf of the company. ENLI does however find that presentations from independent HCPs from the outsets should be regarded as scientific by nature and not advertising, unless the pharmaceutical company has tried to influence the content of the presentation. Due to the company's overall responsibility for the event, a company is obligated to clearly note to participants, if their medicinal products are referenced in violation of the ENLI regulation, e.g. for use outside the approved therapeutic indication area. Further, ENLI finds that there is no obligation to report presentations made by a third party unless the company has been influential in preparing them. If a pharmaceutical company subsequently decides to hand-out slides prepared and used by a third party, the material will be regarded as promotion the company, irrespective of whether such hand-out took place at the meeting, subsequently or during calls by medical representatives.

From time to time the Committee receives notice of material that does not constitute promotion matter. For example Christmas cards have been notified which only state the pharmaceutical company's name and a greeting to the recipient. Such material is basically not promotion for a pharmaceutical product and is not required to be reported In accordance with Article 23.

"Healthcare professionals" are defined in section 1 (3) Advertising Order as "*doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaceutical economists, midwives, bioanalysts, clinical dieticians, radiographers and students of these professions*." In contrast, for example psychologists, biologists, social and healthcare assistants, physiotherapists, ergotherapists and medical secretaries are not included in the definition and accordingly the latter group is equated with the "general public", which is understood to include all those not defined as healthcare professionals, cf. section 1 (2) Advertising Order. According to the Danish Health and Medicines Authority, a healthcare professional should be taken literally and formally as any person educated/in education in one of these professions. It thus makes no difference whether or not a given healthcare professional is actually working in its profession.

The rules apply to all activities aimed wholly or partially at Danish healthcare professionals, regardless of whether such activities are located in or outside Denmark. Accordingly, this also applies to international

meetings and conferences outside Danish borders, as long as such meetings and conferences are aimed wholly/partially at Danish healthcare professionals.

Re: Section 3 (2)

The three associations' websites respectively state which pharmaceutical companies are members of the associations. www.enli.dk has a schedule of "associated companies." The rules also apply to third parties acting on behalf of these companies, such as consultancies, including for example advertising and communication agencies, etc., that are assumed to be acting within the scope of this set of rules.

Re: Section 3 (3)

The definition follows the definition in Article 2 Medicines Act, except for veterinary medicines that are not subject to the rules of this code.

Re: (c): This merely codifies the Committee's practice and follows directly from section 1 (3) of the Medical Devices Order (Order No. 1263 of 15/12/2008).

COMMENTARY TO CHAPTER 2 – MARKETING AUTHORISATION, REQUIREMENTS OF OBJECTIVITY, ETC.

Re: Article 4 – Marketing Authorisation and requirements of objectivity

Re: Section 4 (1)

This clause is based on section 1.01 EFPIA HCP Code and section 64 (1) Medicines Act, cf. Article 7 Medicines Act and the guidance to section 3.3 Advertising Order which states that a medicine can only be marketed in Denmark when approved by a marketing authorisation.

- There are some further requirements for pharmacy-only medicinal products, as set forth in Article 77 Medicines Act, cf. section 3.3 in the guidance to the Advertising Order, including the fact that the price of the product must have been notified to the Health and Medicines Authority (formerly Danish Medicines Agency) at least 14 days in advance of the price becoming effective. Promotion may however take place immediately after the price has been notified. If the price has not been published on medicinpriser.dk (tariff), the notified price must be documented to ENLI when reporting promotional matters, by way of a copy of the price notification and confirmation from the Danish Health and Medicines Authority. For radioactive medicinal products, the company shall document that the price has been informed to the Health and Medicines Authority at least 14 days in advance of the price becoming effective.

It can be difficult to assess whether mentioning a specific medicine before the date of its marketing authorisation (pre-launch) constitutes promotion. ENLI has therefore decided that:

- The Committee will regard any mention of scientific studies and data relating to an impending medicine to healthcare professionals as falling outside the scope of the Promotion Code up to the

date of publication of the results from the Phase 3 study (i.e. publication date, understood as the date of publication (e-publication with DOI number or print) in a recognised peer-reviewed journal, cf. Article 7 Promotion Code). Any mention which relates directly to the medicinal product will not be regarded as mention of scientific studies and data and may be subject to the requirements of the Promotion Code.

- After the publication date of the results from the Phase 3 study, ENLI will assess whether the company's mention of a medicine that has been documented as having an effect *may* be promotion since the company will be assumed to be specifically working to obtain a marketing authorisation as from that date. This means that the company needs to assess whether mention of the medicine after publication date is being made on a scientific basis and in a scientific forum (for example at an independent international congress), which the Committee finds should not be restricted by the Promotion Code, cf. also the principle in the EFPIA HCP code on access to "non-promotional medical, scientific or factual information". If mention relates directly to the medicinal product and is regarded as advertising, it must be done in accordance with the rules of the Advertising Order, including this clause. Medicinal products that are not approved for the Danish market may therefore not be mentioned or in some other way used in promotion of medicines to Danish healthcare professionals.

Further, no promotion is allowed for magistral medicines cf. section 64 (2) Medicines Act and for certain special medicines, cf. section 3 (1-3) Advertising Order.

Re: Section 4 (2)

Also cf. Article 63 Medicines Act and EFPIA HCP Code sections 1.02 and 3.

Article 63 Medicines Act contains certain fundamental requirements for the content and format of medicinal product advertising, cf. also the guidance to the Advertising Order section 3.1, which states:

"First, advertising must be adequate. This means that it is not sufficient for an advertisement not to contain incorrect or misleading information. An advertisement must contain sufficient information to enable the recipient of the advertisement to understand and assess when and in which situations medicinal products can and should be used and when they should not be used.
For example, an advertisement is inadequate if it contains such broad statements that it is aimed at promoting use of a product which is in fact not an especially appropriate drug to use in the particular situation.
The provisions that an advertisement should contain a certain amount of so-called mandatory information, cf. secs. 4.4 and 5.1, are based on the requirement for medicinal product advertising to be adequate.
Secondly, advertising must be objective. This means that medicinal products must not be marketed in such an aggressive and consumption- stimulating way as ordinary consumer goods. Medicinal product advertising should not aim, or be suited, to stimulate unnecessary additional use of medicinal products.
Thirdly, advertising must not be misleading or exaggerate the properties of medicinal products. This means that the design and content of the advertisement must not give users of medicines or persons who prescribe or supply medicinal products, an erroneous perception of the medicinal

product, including its efficacy, side-effects, price, content, etc. The advertisement must also not place the medicinal product in a more favourable light than other comparable and possibly even more suitable medicinal products.
Fourthly, the information in the advertisement must be in accordance with the medicinal product's approved product summary. The product summary contains, inter alia, information about the composition of the medicinal product, its form, indications (applications), contra-indications, sideeffects, precautionary measures, dosage and any warnings.
This means that the actual content of the advertisement must not conflict with the content of the product summary. But it is possible, within the bounds of objectivity, to use other wording than in the product summary."

The latter is further supplemented in section 87 (2) in European Parliament and Council Directive 2001/83/EC which states: "*All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of the product's characteristics."* In a preliminary ruling on 5 May 2011, the ECJ stated that section 87 (2) should be construed as a prohibition against information that conflicts with the product summary but is not a requirement for all information to be contained in the product summary or to be inferred from it. An advertisement may include information that supplements the product summary on condition that this information confirms or clarifies, and is compatible with, the information in the product summary and is not misleading and complies with the requirements of Article 87 (3) and 92 (2) and (3) of the Directive. The latter requirement is also set forth in the Medicines Act Chapter 7, and section 13 (2 – 3) Advertising Order.

- In an overall assessment, an advertisement should appear correct, balanced, serious, precise and objective. The advertisement must contain, according to the conditions, correct, complete and well-documented information that is not misleading (by way of omission, ambiguity or the like). See also Article 5 and Article 7 of this guidance. The wording of the advertisement must not in any way signify a broader indication than the approved indication described in the product summary.

It may not always be sufficient for an advertisement to be based on the information in the approved product summary. For instance, the Board of Appeal has stated that comparative advertising that is solely based on product summaries may not always comply with the requirements of this clause. If for example further or more recent relevant data is available, the requirements for complete and well-documented information will not be satisfied solely by using the product summaries, cf. AN-2012-2713. See more on comparative advertising in the guidance on Article 8.

It follows from Directive 2001/83/EC (as changed by Directive 2010/84/EC) that for medicinal products subject to additional monitoring, it is a requirement that the summary of product characteristics includes information that "This medicinal product is subject to additional monitoring", plus a black triangle and an appropriate explanation. It appears that the Danish Health and Medicines Authority finds that Advertising Order in its current form does not require that pharmaceutical companies declare either the black triangle or any other text regarding additional monitoring in its promotional material to HCPs, and neither can such requirement be interpreted to be inherent. If the Health and Medicines Authority decides to require such information, the Advertising Order will be amended to specifically require this. Hence, ENLI has also chosen not to control companies' mention of such information, however companies are of course free to do that.

The Committee does not find that the use of patient cases is compatible with the requirements in the Promotion Code for advertisements to be serious, precise and objective. This is regardless of whether patient cases are fictional or true.

- By "patient case" is meant a direct or indirect product-individual relation which is characterized by having a promotional nature, a typical starting point being a picture or a set of pictures. This does not entail that a photographic presentation of objective symptoms relating to a specific disease is regarded as a patient case, unless such presentation is also put in relation to a medicinal product, e.g. by a corresponding text or by implicitly eluding to symptoms or the disease in general before/after using the medicinal product.
- Please note that the conclusion of whether an ad or other promotional activity is making use of a patient case will always be subject to an overall assessment of the ad or promotional activity regarded as a whole.

Re: Section 4 (3)

This clause corresponds to EFPIA HCP Code section 10.03 and is not replicated in the Advertising Order.

COMMENTARY ON CHAPTER 3 – PROMOTION

Re: Article 5 - Obligatory information

This rule is regulated by section 2.01 EFPIA HCP Code and corresponds to section 11 (3) Advertising Order, except for section 11 (3) of the Order on veterinary medicinal products that are not relevant for the present set of rules.

Re: Section 5 (1.1)

Section 5 (1.1) Advertising Order states that: *"The same typeface means that it must have the same height, width, design and line thickness. It is, however, permitted to use different distances between the character for a brand name and a generic name, for example so that the letters in the generic name are written closer together than those in the brand name. Brand and generic names shall be equally prominent. This is normally achieved by using the same colour and the same colour background for the names. If a combination product is concerned for which there is no generic name, the generic names of the active ingredients need not necessarily be given in the same typeface as the brand name."*

It used to be ENLI's practice to require that both the brand name and the generic name or the active ingredients contained must be stated the first time that the medicinal product is mentioned and where it is most prominent. However, ENLI was informed that the Health and Medicines Authority exercised a more strict interpretation than ENLI. According to the Health and Medicines Authority, there is no standard exception to the general rule, which requires that the generic name shall be in the same font size and appear just as prominently as the brand name of the medicinal product. Accordingly, ENLI will adopt a similar approach, such that for ads and other promotional activities towards healthcare professionals, it will

depend on a specific assessment whether the generic name shall be in the same font size and appear just as prominently as the brand name of the medicinal product with each mention of the medicinal product.

- The "same font size" shall be construed as having exactly the same typeface (including the use of italics, lower case) type size and colour. The term 'equally prominent way' shall be understood to mean that the generic name must be placed in the text immediately after or below the brand name and using exactly the same base colour. A brief text may however be inserted, for example a company name, between the brand name and the generic name on condition that, despite the insertion, the two names can be regarded as a single entity.

- However, a special logo may be acceptable in the brand name on condition that this does not significantly change the balance between the generic name and the brand name.

- If a medicinal product has more than one active ingredient, it is acceptable to ENLI for the generic names to be written in a smaller font size than the brand name.

Re: Section 5 (1.2)

The requirement for an address is not stated in the Advertising Order but follows from Art 5.1 IFPMA Code and is also set forth for example in section 4.2 ABPI Code, and is thus more stringent than the Danish legislation.

Re: Section 5 (1.3)

It follows from the guidance to section 5 (1.3) Advertising Order that: *"Basically, identical wording from the product summary should be used in the mandatory text. If the indications in the product summary are so extensive that it is thought inappropriate to repeat them in full, they may be rewritten and abbreviated. In so doing, information that is less relevant may be omitted.*
Indications may under no circumstances be reworded in such a way as to lead to misunderstandings, including giving the impression that the scope of indications is different or broader than that set forth in the product summary.
If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. The following wording may be used: "The indications section has been rewritten and/or abbreviated compared to the product summary approved by the Danish Medicines Agency. The product summary may be obtained free of charge from xx (the holder of the marketing authorization)". This information should be written in typeface that is larger than or in some other way clearly differs from the actual mandatory text. If information is missing, the advertisement is inadequate and thus not in conformity with Medicines Act s. 63. "

If the indication for a medicinal product is stated several times in a promotion, for example a presentation, it is sufficient to give the full indication, when the type of disease is being mentioned first in a material and where it is most prominent. ENLI accepts that the full indication is provided based on the rewritten and/or abbreviated product summary, provided that this does not omit significant information, which could be considered significant by a prescribing physician. In the rest of the material, it is acceptable to use the

shorter versions, e.g. pain relief, depression, etc.

Re: Section 5 (1.4)

It follows from section 5 (1.4) Advertising Order that: *"Basically, the contra-indications included in the product summary should be included in the mandatory text. If the contra-indications in the product summary are so extensive that it is thought inappropriate to repeat them in full, they may be rewritten and abbreviated. In so doing, information that is less relevant may be omitted.*
A view should be taken as to the precise delimitation of which contra-indications should be included and this should be done on the basis of objective criteria and take into account the requirements of Medicines Act s. 63.
If the contra-indications noted in the product summary are altered or their wording is changed, it shall be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization.
Reference is made to the wording proposed above for the indications section. "

Re: Section 5 (1.5)

It follows from the guidance to section 5 (1.5) Advertising Order that: "*Basically, side-effects and risks, that is interactions, warnings, risk of overdosing, persistence, etc. contained in the product summary should be included in the mandatory text. If the choice of wording or extent of the formulation in the product summary makes it inappropriate for identical reproduction, the information may be rewritten or abbreviated.*
Information that is regarded as less relevant in the given circumstances may be omitted.
If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. Reference is made to the wording proposed above for the indications section."

It follows from Directive 2001/83/EC (as changed by Directive 2010/84/EC) that for medicinal products subject to additional monitoring, it is a requirement that the summary of product characteristics includes information that "This medicinal product is subject to additional monitoring", plus a black triangle and an appropriate explanation. It appears that the Danish Health and Medicines Authority finds that Advertising Order in its current form does not require that pharmaceutical companies declare either the black triangle or any other text regarding additional monitoring in its promotional material to HCPs, and neither can such requirement be interpreted to be inherent. If the Health and Medicines Authority decides to require such information, the Advertising Order will be amended to specifically require this. Hence, ENLI has also chosen not to control companies' mention of such information, however companies are of course free to do that.

Re: Section 5 (1.6)

It follows from the guidance to section 5 (1.6) Advertising Order that: "*Dosage must be stated in accordance with the product summary. If the choice of wording or extent of the formulation in the product*

summary makes it inappropriate for identical reproduction, theinformation may be rewritten or abbreviated. Information that is regarded as less relevant in the given circumstances may be omitted. If the wording of the product summary is not reproduced identically, it must be clearly so stated in the advertisement. It must further be clearly stated that the product summary may be obtained in its entirety from the holder of the marketing authorization. Reference is made to the wording proposed above for the indications section.
Rewording the dosage information requires great caution since any change in wording must not be able to lead to misunderstandings. "

Re: Section 5 (1.7)

It follows from the guidance to section 5 (1.7) Advertising Order that: *"Basically, all the forms in which the medicinal product is available shall be given. If a medicinal product has been approved in several medicinal product forms with different applications and the advertisement only refers to one of the forms of the medicinal product, the advertisement shall only include information about the particularly medicinal product form. It shall further be clear from the advertisement that the medicinal product is also available in other product forms, cf. Advertising Order s. 11(2).*
Reference is made tosection 5.2 for medicinal products designed for several animal species."

Re: Section 5 (1.8)

It follows from the guidance to section 5 (1.8) Advertising Order that: *"All pack sizes in which the medicinal product is available must be given. However, in instances where only some of the indications are included in the advertisement in line with the above, packs that cannot be used for the indications concerned should be omitted."*

Re: Section 5 (1.9)

It follows from the guidance to section 5 (1.9) Advertising Order that: "*The advertisement shall at the very least contain details of the retail price for individuals, cf. s. 2 of the Order on calculating consumer prices for pharmacy-only medicinal products and non-pharmacy-only OTC medicinal products, etc.*
Insofar as it applies to the target group of the advertisement, the advertisement must give the price for supply to the institutions or persons given in s. 2(3-6) in the Order on calculating consumer prices for pharmacy-only medicinal products and non-pharmacy-only OTC medicinal products, etc.
Insofar as possible, the stated price must be current, i.e. applicable on the date on which the advertisement reaches the recipient, cf. Medicines Act s. 63.
The price may be omitted in advertisements displayed over a longer period, if a price list is appended instead and in advertisements with students as the only target group, cf. Advertising Order s. 11(4).
If the requirement for the statement of price is met by a regularly updatable price list, etc., being appended, the provisions on the statement of price are only satisfied if current prices are included or appended to the advertisement.

In some journals, advertisements have to be delivered a relatively long time before release date. It may therefore happen that it is not possible to meet the requirement for full price topicality. In such instances, some minor deviations from the prices actually applicable at publication date would be acceptable. How large such deviations could be depends on a specific assessment, but it would not be acceptable if the difference were to be such as to be significant for the user's choice of medicinal product.
If an advertisement contains price comparisons, the requirement for price topicality is normally regarded as unconditional."

- For pharmacy-only medicinal products, the Advertising Order s. 11 (9) requires that the registered price including VAT must be referenced in the promotional material. The Danish Health and Medicines Authority has informed, that an ad also can include supplementary information about the consumer price including VAT, also called the counter sales price (ESP). ENLI does not sanction if the consumer price/counter sales price (ESP) is the only price being referenced. The Danish Health and Medicines Authority has informed, that the consumer price/counter sales price (ESP) is calculated using the notified pharmacy retail price per pack excluding VAT (AIP) adding a certain specific percentage, cf. Article 2 in the Consumer Price Order. Reference should further be made to medicinpriser.dk if the product concerned is pharmacy-only.

- For non-pharmacy only medicinal products (OTC) there is no single comparable price, such as one registered price or one consumer price/counter sales price (ESP). Only guideline prices can be found at www.medicinpriser.dk (tariff), but stores may themselves opt for another price. Accordingly it is not possible to give a single updated price. ENLI is therefore continuing the Committee's practice, with a requirement to refer to www.medicinpriser.dk for the guideline price and not to one specific price.

- For medicinal products which can only be provided to hospitals, ads and other promotional activities must include the registered price. Additional information may be supplied, including e.g. lower prices, in the obligatory information sheet.

Re: Section 5 (1.11)

It follows from the guidance to section 5 (1.11) Advertising Order that: *"Advertisements must contain information about any general reimbursement for medicinal products.*
In contrast, no information needs to be given about the possibility of being granted special individual reimbursement. If exceptionally it is thought to that information about individual reimbursement options should be given, for example individual reimbursement, it must be clearly stated that individual reimbursement is only obtainable on application.
All mandatory information must be so clearly presented that the natural target group for the advertisement can read it readily, cf. Advertising Order s. 11(5)."

It is therefore not sufficient to write, for example, "reimbursable", which ENLI finds could also cover individual reimbursement following an application.

Re: Section 5 (1.12)

The requirement to date advertising matters derives from section 5.1 IFPMA Code (and also for example from section 4.9 of the ABPI Code). This rule is further set forth in section 13 (1) Advertising Order.

ENLI requires dates to be stated clearly, with the month and year, and dating should normally relate to the date of transmission. When advertising in a magazine, separate dating is unnecessary if the magazine clearly gives a month and year.

Re: Section 5(2)

The clause corresponds to section 11 (5) Advertising Order.

Compulsory text must be easily legible. Legibility depends among other things on typeface and colour, font size, background colour, line length, line separation and subdivision of text in the paragraph. A font size of less than 6 point in black on white would thus not normally be approved.

The advertisement and the accompanying product information must be related. Product information must therefore not be separated from the advertisement but must follow immediately afterwards.

- If there are practical reasons why the compulsory text cannot be placed in direct conjunction with the advertisement, e.g. due to the format:
    - For printed matter, ENLI will accept a maximum separation of three pages provided there is a clear reference in the advert to the page number where the compulsory text is given.
    - For roll-ups, posters, etc., at meetings for example, ENLI accepts compulsory text on roll-ups, posters, etc., being replaced by visible information that the compulsory text is available at a freely accessible place on the booth.
    - For electronic promotion, there must be a direct link to the compulsory text on each page of the advertisement, including the front page, i.e. a maximum of one click.

Regardless of whether an advertisement is placed on a roll-up, poster or the like, it must comply with the Promotion Code, including the requirements to an integrated objective basis for comparative advertising, cf. Article 8.

Re: Section 5 3)

The clause corresponds to section 11 (2) Advertising Order.

Re: Article 6 - Reminders

A comparable rule is to be found in section EFPIA HCP Code. 2.02.

The rule corresponds to Article 12 Advertising Order, the so-called ”reminder rule”. In the guidance on this, it states in (5.3) that: *"An advertisement solely directed at healthcare personnel may be restricted so as only to contain the name and generic name of the medicinal product, cf. Advertising Order s. 12. This also applies if a pharmaceutical company publishes a product listing with the names of all medicinal products (without any form of comparison) for a specific area of treatment. If other information is included, such as prices, the advertisement would fall outside this clause and all mandatory information would have to be included. The company name and logo identifying the publisher of the advertisement may be included, however. "*

Logos can - as a general rule - be used in reminders.

- However, a logo *cannot be used* in a reminder, if the logo in any way indicates or makes a reference to the indication or use of the medicinal product. One example could be a logo, showing a bone structure, when the logo is being used for a medicinal product against osteoporosis. In this case, the ordinary rules from the Promotion Code apply and all compulsory information must be included on the material.

Please note the ban on gifts in the revised article 12, after which pharmaceutical companies no longer can give, offer or promise to HCPs gifts, including the so-called “gimmicks” such as pens, notepads etc. Further remarks are made to article 12.

Please also note, that in contrast to the requirements for compulsory text, cf. section 5 (1.1), there is no requirement in the reminder rule in Article 12 Advertising Order for the generic and brand name to be given in the same font and to be equally prominent.

If there have been significant changes relating to awareness of indications, contraindications or adverse reactions or other significant issues since the last detailed promotion material, reminders should basically not be used before the new detailed promotion material has been implemented, unless a specific assessment finds that these significant changes would have no influence on the promotion effect of a reminder.

Re: Article 7 – Information material and substantiation

By way of introduction, attention is drawn to Article 17 Advertising Order on retaining promotion material, which states that the party promoting a medicinal product shall keep a copy of, or other documentation for, the advertisement for two years, cf. section 68 (1 & 3) Medicines Act and that the advertisement must be in a commonly accessible digital format. It is further stated that in addition to the actual advertisement, Information must be kept on 1) the target group of the advertisement, i.e. the group of people at which the advertisement is aimed, 2) the mode of distribution, 3) a schedule of the media in which the advertisement was shown, and 4) the dates on which the advertisement was used.

Re: Section 7 (1)

The provisions of (1) correspond to parts of the EFPIA HCP Code's Arts. 3.01-3.03 and are not given in this form in the Advertising Order. The clause supplements Article 63 Medicines Act and the guidance for the Advertising Order, section 3.1.

Advertisements must not exaggerate the medicinal product's properties. The advertisement must therefore, depending on the conditions, in every respect include correct, complete and well-documented information that is not misleading (by way of omission, ambiguity or the like).

The use of patient cases, including pictures illustrating an effect in an individual patient would not satisfy the requirements for documentation (for further guidance on patient cases, ref. to this guidance on section 4(2).

No documentation is required with respect to claims that are:

1) Stated in the approved product summary (although reference must be made to this), or

2) Regarded as generally known by professionals. Basically therefore, no information is required about issues that are available in standard text books or from the medicines formulary (data is available on the website Medicin.dk).

In contrast, the following information does require documentation:

a) Emphasis on special product benefits.

- If particular claims are not included in the approved product summary, or cannot be regarded as general knowledge among healthcare professionals, such claims must carry specific reference to appropriate documentation.

- If for example it is stated that a medicine is "better than" a competitor's, "unsurpassed," "unique," "an ideal choice," "the best guarantee," "good efficacy," "has fewer side effects," or in other ways has special benefits, there must be documentation for the statement.

- In the Committee's view, the term "effective" or "effectively" should only be used when referring to close to 100% cure, for which there must be documentation. For treating symptoms, investigators will accept that a medicine is effective if practically 100% of patients become symptom-free (and not just have symptoms relieved). At their meeting on 23 November, 2011, the Board of Appeal agreed on this interpretation of the term "effective/effectively".

- Use of definitive expressions such as ”stops”, ”only” and ”optimal” must be documented and must not be used in a misleading way which would contravene section 4 (2) Promotion Code, see for example AN-2012-3673.

b) Claims that a product is effective within a given timescale must be accompanied by documentation. If it is wished for example to emphasize that a product works within 1 hour, the statement must be scientifically supported and documented.

c) Claims indicating innovation must be documented. Claims for such as " a long-awaited remedy" and "new treatment that breaks with tradition" also require documentation.

Cost analyses are acceptable in medicinal product promotion provided that Danish conditions and prices are used and that these comply with the documentation requirements. ENLI only accepts references to

foreign data if an independent Danish economist has approved the calculations in accordance with Danish conditions.

Re: Section 7 (2)

This clause corresponds to section 13 (1) Advertising Order.

Re: Section 7 (3)

This clause corresponds to section 13 (2) Advertising Order.

References must be true and references must be included insofar as required to elucidate overall knowledge of the area.

References to literature must be included as required. None of these may refer to obsolete information or be misleading in some other way.

Re: Section 7 (4)

This clause derives from section 3.06 EFPIA HCP Code and corresponds in part to section 13 (3) Advertising Order.

Figures and tables from a reference must be given exactly as in the reference used, without omissions or distortions and with exact reference to the source. Reproduction should thus be photographic.

- Although depending on the circumstances, changes to colour of the figure or table are acceptable provided the colours are without emphasis and do not affect the understanding in a promotional way . Colourchanges can thus only be used to make the expression more "appealing". This means a company must not change the colour of the figure or table relating to it's own medicinal product and make itgreen and the competitors' red.

The company may only draw up figures and tables concerning results in the source material, if such graphic representations are not already in the source material.

- In that case, a new figure or table can be drawn up provided that the new figure or table is made with exact reproduction of the results from the reference without omissions or distortions. It is important, that the figure or table reflects the results from the source material in a loyal way. Furthermore, it must be clearly stated that the figure and/or table has/have been drawn up by the company and with a precise reference to the source material.

Re: Section 7 (5)

This clause corresponds to section 13 (4) Advertising Order.

- The term "recognized" is not defined in the guidance to the Advertising Order, although a recognized journal should be taken to mean a peer-reviewed journal listed in ISI Web of Science. Similarly, peer-reviewed textbooks used for teaching purposes in universities in Denmark and guidelines drawn up by, or recommended by, a Danish scientific body in the Medical Societies' organization in Denmark (LVS, formerly the Danish Medical Society) would also be regarded as recognized works.The term "independent" is to be construed in accordance with section 5 (4) of the guidance on the Advertising Order in which it is stated that: *""Independent" shall be taken to mean that the party publishing the work or journal has no interest in the sale or any other form of promotion of medicinal products. Studies must have been subject to prior independent review."* The editorial team of the journal or work concerned must accordingly have no interest in the sale or promotion of the medicinal product. The term "peer review" is not defined in the guidance to the Advertising Order, but should be construed as a review undertaken by any person (or persons) with no personal interest, cf. in this respect also the meaning of "independent" above, i.e. an independent consultant/referee.

Dispensation may be given from the requirement for the study to have been published provided that it can be demonstrated that the article has been approved for acceptance by a journal that complies with the guidelines of this clause.

It must be possible to document an emphasized product advantage from the published article used. It is not acceptable to emphasize a positive statement about the product in the article if the overall investigation does not bear out the statement. Neither is it basically acceptable to emphasize an individual study mentioning the company's own product in positive terms if this conflicts with common knowledge in the area.

It is acceptable to refer to review articles provided that these comply with the documentation requirements. Scientific studies can only be referred to in such review articles if each of these meets the requirements for documentation.

Meta-analyses, i.e. an overall statistical report on data from several drug trials can be used as documentation provided that there is full medical backing for the statements made and provided the study has been published in a peer-reviewed scientific journal, cf. (5).

The pharmaceutical company is responsible for being able to show that material complies with the documentation requirements.

The following materials are, in ENLI's view, not suitable as sources of documentation.

- Abstracts and posters: These cannot be equated with scientific articles, partly because various details of the study are often missing in abstracts and posters and partly because abstracts and posters are generally not subject to the same strict review of the scientific value of the publication as are articles in scientific journals. This applies irrespective of whether the abstract or posters have been published and peer reviewed.

- Data on file: Such data can basically not be used since they do not satisfy the requirements of this clause. Data on file that have been subject to independent review which can be equated with the

review undertaken prior to acceptance by a recognised scientific journal and which have been acknowledged as credible in peer-review could however be used as documentation until comparable information has been published, publication of the information has been rejected or new information has disproved the scientific validity of the material.

- Information about any clinical trial that has been published, for example at www.clin.gov.com, since such information does not meet the requirements of this clause. Foreign recommendations are not acceptable as references since these are individual countries' recommendations for the use of specific medicinal products and there may be reasons why these are not usable in Denmark. For example, recommendations are not accepted from FDA (Food and Drug Administration, (USA)) or NICE (National Institute for Health and Clinical Excellence (UK)). In the same way, neither are recommendations from WHO immediately acceptable since recommendations from them may be based on general societal or political considerations which could mean deviating from the product summary approved by the Danish Health and Medicines Authority.

    - If foreign guidelines have been officially agreed by a Danish scientific body that is a member of the Organisation of Medical Societies in Denmark (LVS, formerly the Danish Medical Society) and reported as such in Denmark, they may be used as references.

    - Information from EMEA (European Medicines Agency) may be used on condition that it does not conflict with the information in the approved product summary.

    - Information from RADS (the Council for the Use of Expensive Hospital medicines, in Danish: Rådet for Anvendelse af Dyr Sygehusmedin - RADS), KRIS (the Coordinating Council for the First Use of Hospital medicines, in Danish: Koordineringsrådet for ibrugtagning af sygehusmedicin - KRIS) and IRF (the Institute for Rational Pharmacotherapy, in Danish: Institut for Rationel Farmakoterapi - IRF) do as a starting point NOT live up to the requirements for documentation for promotion of a medicinal product.

Re: Section 7 (6)

This clause implements Arts. 3.07-3.09 of the EFPIA HCP Code.

The words "safe" or "safely" are unacceptable in an advertisement. Even though the words "safe" or "safely" can be used to give a different meaning than "not hazardous", the fact that this is a possible interpretation means that using the words "safe" or "safely" is unacceptable. The same applies, depending on the circumstances, to use of related words such as "safety", when this word is used or can be understood as used to signal that the use of the medicinal product is safe. Thus, other expressions should be use that cannot be interpreted as being either "safe" or "safely", cf. AN-2011-1480. The word "safety" can be used depending on the circumstances, e.g. in a neutral way, cf. AN-2013-2911, which in this circumstance did not reference or imply that the use of the medicinal product is safe.

Use of the word "new" in promotional material is only allowed 1 year from receipt of marketing authorization in Denmark or EMA and a price has been notified, as required. This is due to ENLI assuming in

general that promotional activities have been carried out as from this point in time.

Re: Article 8 - Comparative advertising

Comparative advertising may be defined as any advertising or promotion that directly or indirectly refers to another medicinal product.

In addition to the requirements of this clause, comparative advertising must also comply with the other provisions in the code. For example, a comparative advertisement solely based on product summaries would not always be complete and objective, cf. section 4 (2) of the code and the ruling from the Board of Appeals in AN-2012-2713. The Board of Appeal held here that the design with a figure gave a visual impression that could be misleading despite the fact that the advertisement correctly gave references to studies, source material, baseline values, etc.

Re: Section 8 (1)

The wording of (1) is the same as section 16 (1) Advertising Order.

Comparative advertising is lawful when an advertisement is correct, relevant and true, overall. See also the guidance to (3).

Comparisons must be objective and relate to documentable information. This normally means that:

- All material differences which could be considered significant by the prescribing physician must be included in the comparison in an informative way, eg. in a comparison table, which provides for an objective assessment of differences and similarities – see under section 8(2) for notes on the specific requirements for providing a comparison table or compulsory text, respectively. Section 4 (2) (Article 63 Medicines Act) requires advertising for a medicinal product to be adequate. Accordingly, the comparison table or compulsory text, respectively, must always clearly state that the table/text is inadequate and make reference to the full summary of product characteristics.

- The price of a medicinal product is always essential information and shall thus always be informed, e.g. in the comparison table. Prices used in comparative advertisements must be completely up-to-date and correct on the date the advertising matter is used. It should generally be noted that the use of price statistics associated with comparative advertising is not permitted, that is information only about the product name and prices.

    - There is no differentiation between the dispensing provisions to which the medicine belongs.

- Any comparative advertising must clearly state which products are being used for comparison. This also applies when the company compares products that are only sold by the company itself. Advertisements should therefore not be run containing some form of comparison with other products that are not named or otherwise made identifiable. If this is done even so, for example by way of stating that a product "does it better - and cheaper" or the product "works fastest," there must be full

documentation in relation to all relevant products on the market, in accordance with the rules for documentation in (7). Less specific statements such as with "other products" or "competing products" would not normally be acceptable.

Comparison with a group of products of a more undefined nature are not acceptable. For example, stating that a product "achieves the best treatment response compared to other selective serotonin reuptake inhibitor (SSRI) products" would not be in compliance with the code. If on the other hand the group of products being compared with is clearly defined, for example "all other inhalation steroids ", a more detailed statement of the individual products is unnecessary. However, compliance is still required with the documentation rules, cf. (7).

Re: Section 8 (2)

The wording of (2) is the same as section 16 (2) Advertising Order.

If a comparison contains one or more medicinal products, the required information about all the products must be included.

- There must be no comparison with products that are not legally sold or distributed in Denmark. Information about any such products must be removed from the comparison. When using figures, information about these products must also be removed and the figure must also comply with the rules of section 7 (4) of the code.

It is not a requirement to give the full product information for the products being compared but instead all significant properties and the issues on which competing products differ from the company's own products must be stated, and a full account must be given of these differences where it is thought such could be considered significant by the prescribing physician.

- However, it is not enough just to include compulsory texts (cf. section 5 (1.1-12) of the code) for the products compared.
    - An exception to this is advertisements solely giving the results of a study comparing two drugs. In this case, it is possible to make do by including the compulsory text for the two products but it is a requirement at the very least always to state the primary endpoints giving the main message of the study. Further, secondary endpoints may be given where thought relevant. The selected results must be true, clinically and scientific relevant and must represent the overall conclusion of the study. The study referred to must have been published and comply with the general requirements for documentation. All results should also be in the advert, however, for example by way of a table at the end of the material so that the prescribing physician has access to them.
- For analogue products (those with the same clinical effect), in addition to the full product information, information must be provided on all significant differences in efficacy, adverse reactions, dosage, dispensing forms, pack sizes, prices, etc.

- For synonymous products (those with the same active ingredient(s)), there must be a correct account of the relevant differences and similarities, for example bioaccessibility, slow release effect, dispensing forms, pack sizes, prices, etc.

- For add-on medicinal products (comparison between a basic treatment on the one side and a basic treatment combined with an add-on medicinal product on the other side), the Board of Appeal has ruled on 24 February 2014, that the requirements for the advertising material will be limited to the following: 1) identification of all medicinal products mentioned or referenced in the ad, cf. section 8 (1), and 2) compulsory text for own medicinal product, cf. section 8(2) and 5(1).

Comparative advertising in electronic formats requires a link from each individual page to the objective comparison material (e.g. in a table), i.e. a maximum of 1 click, cf. the requirement in the guidance ref. section 5 (2).

- This entails that the comparative basis (e.g. a table) as well as the compulsory information for the company's own medicinal product, cf. section 5 (1), must be accessible from the same "click", i.e. presented in a coherent way, with the comparative basis listed first.

For price comparisons, the calculation system employed and the basis for this must be precisely stated, i.e. the daily dosage used for calculations and tablet size, pack size and pack price. Generic and brand names and also information about pack sizes and prices, dosage for the products compared, etc., must be stated if such information differs from the information about the company's own product. Price comparisons in which analogue or synonymous products are included must only be based on the dosage approved by the Danish Health and Medicines Authority. Accordingly, treatment prices where there is an approved dosage range must be stated for the highest and lowest approved daily dose for a 24 hour period.

- If not all prices have been calculated, they must be based on relevant, common pack sizes which give the lowest price for the competitor.

- For parallel imports, depending on the circumstances, comparisons can be collected into a common group where the highest and the lowest prices are given for the range into which the group falls from a pricing point of view.

- For certain medicines, it may not be possible to give a predetermined daily dose, for example certain medicines used for headache attacks. In such situations, price comparisons may be based on a comparison of prices for the recommended starting dose and for the dosing interval from the smallest start dose to the highest recommended dose. A price comparison may accordingly not be based here on how frequently certain doses are used for treatment.

Re: Section 8 (3)

All significant properties, including prices and other significant issues, must be stated truly and in a similarly presented way to give the reader as complete a basis for comparison as possible. If for example a product advantage is emphasized in a large font size on the front page of an advertisement, all other significant properties for the compared products must be emphasized in a similar way.

All information must be absolutely current and correct when the advertisement reaches the market.

In making a price comparison, it is regarded as improper to calculate treatment prices on the basis of part of a pack of the company's own product and not do the same for a competitor.

(3) has been added to comply with the requirements of Art 3.05 EFPIA HCP Code (end).

COMMENTARY ON CHAPTER 4 – DISTRIBUTION OF PROMOTION, TRANSPARENCY AND PERSONAL ADVICES

Re: Article 9 - Distribution of promotion

The clause corresponds to Art. 6 EFPIA HCP Code and supplements the rules set forth in the Marketing Act, *inter alia* on SPAM mail in Article 6 and the rules on registers in the Data Protection Act to which reference is also made.

Re: Article 10 – Transparency

The clause corresponds to Art. 7 EFPIA HCP Code. Reference is further made to the provisions of the Marketing Act, including Article 4.

Re: Article 11 - No advice on personal medical matters

The clause corresponds to EFPIA HCP Code Art. 8.

COMMENTARY ON CHAPTER 5 – FINANCIAL BENEFITS

Re: Article 12 - General rule – prohibition against financial benefits and gifts

This clause corresponds to the most restrictive regulation pursuant to section 21 (1) Advertising Order (although there is no reference to exceptions for public meetings and discounts not regulated by these rules but only by the Advertising Order and controlled by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency)) and EFPIA HCP Code section 10.01 (the former Art. 9). Accordingly, pharmaceutical companies must not give or offer financial inducements to healthcare professionals, be they gifts, pecuniary benefits or benefits in kind.

Article 12 has been implemented in the Promotion Code as per 1 January 2014, but the parties behind ENLI have decided a transitional period of 6 months, which means that the new Article 12 will only be sanctioned as from 1 July 2014, cf. also EFPIA's FAQ from February 2014 (Q2).

The ban on gifts originates from EFPIA's decision on 24 June 2013 to have a new EFPIA Disclosure Code on disclosure of transfers of value to HCPs and HCO's. As a consequence of the new code EFPIA has at the same time decided on two new provisions in the EFPIA HCP Code. One of these provisions is the new ban on gifts implemented in this Article 12.

The interpretation of the new ban on gifts has its starting point in relevant authority practice and, in areas where the EFPIA regulation is more strict than Danish legislation, guidance from EFPIA (FAQ) as well as any supplementary guidance from Lif. It follows from EFPIA's FAQ (Q12) from February 2014, which can be found at www.ENLI.dk, the ban on gifts entails, that as a general rule, no gofts or items that offset routine business practoces of the recipient are allowed, unless they fall into a category of items that are otherwise permitted under the EFPIA HCP Code (which has been implemented in this Promotion Code).

The starting point for the prohibition of financial benefits has been modified by a range of express exemptions in Chapter 7 Advertising Order and Articles13 – 16 of the Promotion Code which in certain areas contain more strict prohibitions than as set forth in Danish law. Amongst other things, this code contains more stringent regulation with respect to gifts, hospitality, permitted venues and organising entertainment than as laid down in Danish law.

The exemptions all arise from the need for professional collaboration, including the exchange of information between healthcare professionals and the pharmaceutical industry. Overall, the aim is to ensure that patients have access to the best treatment, that healthcare professionals are up-to-date and have access to the latest information on medicinal products and that they have the opportunity to work with the industry, for example on developing new drugs. However, it is crucial that this collaboration is done in an ethically responsible way and within the framework that has been set out in the legislation for the same reason (Ch. 7 Advertising Order) and in the EFPIA HCP Code, included here in the Promotion Code.

The ban on gifts includes among other things the so-called "gimmicks" or "leave behinds", such as pens, notepads etc., which are office supplies of low value which previously were allowed to give pursuant the former section 12(2).

The prohibition against financial benefits and gifts does not only include traditional gifts but also e.g. lending of IT-equipment free-of-charge or other economical benefits such as an extraordinary long credit term or beneficial return on deposits at the supplier.

The more strict ban on gifts in the new Article 12 highlights the fact that also image gifts from pharmaceutical companies to healthcare professionals are covered by this clause. It thus makes no difference whether or not the gift directly relates to marketing a certain medicinal product since the company's interest in offering any such financial benefits must be assumed to rest on the wish to market the company and its products. Consequently, image gifts must also be regarded as being given for promotion purposes, cf. also guidance to section 21 (1.5.5) Advertising Order. On this basis, ENLI finds that among other things, bursaries and other more general sponsorships for healthcare professionals would basically not be permitted unless the conditions of Article 13 of these rules have been met, including the requirement for "professionalism" of a medical/pharmacy nature, documentation for specific expenses and hospitality at a reasonable level. A bursary should never appear as a competition, cf. Article 22 Advertising

Order, as referenced below. If the bursary is not given directly from the pharmaceutical company but sponsored through a third party, e.g. a medical society (the bursary is not provided in the name of the pharmaceutical company), the requirements will nevertheless be the same, and the sponsorship must be conditioned on being given in accordance with Article 13, which must be further specified in the sponsorship agreement (scientific content, hospitality on a reasonable level, venue etc.). On the other hand, ENLI does not require that the pharmaceutical company can document the specific costs, which is a requirement if the bursary is given in the name of the pharmaceutical company, cf. section 13(5) and the guidance thereto. Educational material provided to an HCP as part of a scientific event in accordance with section 13(1) will not be regarded as a gift in violation of Article 12.

Please note that the absolute prohibition against holding competitions and awarding prizes from Article 22 Advertising Order still applies, cf. also guidance to section 5.5.1 Advertising Order. The nature of the competition and the value of prizes make no difference. Nor does it make a difference whether this is part of marketing a specific medicinal product or as part of the company's "image care".

Re: Article 13 - Professional events, sponsorships and hospitality

The clause is an amalgamation of the provisions in Art. 10 EFPIA HCP Code and section 25 (1) Advertising Order.

Re: Section 13 (1)

General

The provisions of this section 1 are not in the EFPIA HCP Code, but part of section 1 corresponds to the wording of section 25 (1.2) Advertising Order and ensures that ENLI's practice follows the spirit and objective of the provisions of section 25 (1.2) Advertising Order. This part states:

”Pharmaceutical companies may give or offer a healthcare professional medical information and training on medicinal products in the form of payment of direct expenses in connection with courses and other professional and scientific events, in which healthcare professionals participate or arrange.”

Requirement for professionalism of a medical/pharmacy nature:

According to the regular practice of the Committee, the concept of "professional information and education on medicinal products" should be taken to mean that the event must have a special professional healthcare content and be intended as educational training for healthcare professionals, including medical presentations on diseases, areas of disease, products and methods of treatment. On 27 March 2012, the concept of professionalism of a medical/pharmacy nature was nuanced by the Board of Appeal. Nowadays it is construed more widely in the light of ENLI’s various sets of ethical rules to also include more overarching healthcare policy and health economic issues and areas that do not directly for example make the doctor more able to treat a patient but which address developments in a field of disease or investigate the quality

of a given treatment or in some other way have a more long-term therapeutic aim. ENLI regards these as professional in accordance with section 13 (1) Promotion Code, provided that the focus continues to be on treating an area of disease so as to provide patients with the best medical treatment. On this basis, ENLI approved sponsorship for an international conference on chronic diseases. The conference was intended for healthcare professionals as well as public decision-makers, health economists and patient associations. Most of the presentations dealt with prevention and control of chronic diseases, with the focus on health economic, political and general consequences for society and management mechanisms.

On the other hand, the Committee's regular practice means that offers of, or support for, non-healthcare related courses would not be acceptable, such as those also offered to other professional groups such as financial control, organisational development, leadership, computer and collaboration courses, coaching, practice management (accountancy assistance), comedy/entertainment, political presentations, communication, speaker training, etc. The Committee has similarly determined that events focusing on the sales and/or managerial aspects of pharmacy operations are not specific to the pharmacy profession. The critical factor is that the focus of the event should be on professional advice as pharmacist's and not on sales and/or pharmacy operations.

Already under NSL the issue of e.g. courses on health economics was discussed. Such courses were also permitted under NSL if it was felt that the focus was on specific treatment/medicine-oriented issues and not solely on more overarching political discussions of the topic, cf. NSL 2009.

Offers to assist in searches in a doctor's electronic patient records (EPJ system) as part of phasing out a medicine were found by the investigations panel to conflict with this requirement. In AN-201-2584, the Board of Appeal confirmed this view, emphasising that there was no current safety related problem involved.

The Committee regards the use of patient cases in promotion matter as not complying with the code's requirement for advertisements to be serious, precise and objective, regardless of whether the case is fictional or true, cf. section 4 (2) above. Similarly, patient cases cannot be used as documentation for claims made by the pharmaceutical company in connection with the promotional activity. However, it is perfectly permissible for patient cases to be included in professional events provided that they have not been selected by the pharmaceutical company, but has been selected by an independent HCP contracted to give a presentation, if such patient case is closely connected to the scientific content of the material presented, e.g. as an illustration of scientific information provided. However, the Committee finds that professional presentations consisting of a more general review of patient cases, such as those provided by attending healthcare professionals would not have the requisite level of detail required for the professionalism of the presentation. Such presentations would therefore be characterized more by a general exchange of experience, cf. the section on sponsorships below.

<u>Events organised by the pharmaceutical company</u>:

When running a professional event for healthcare professionals, the pharmaceutical company is responsible for the event as a whole. This also means that the company is responsible for all presentations at the event, irrespective of the fact that these may come from an independent third party. Thus, the

company must as a minimum condition its speaker agreement with a third party upon presentations being conducted in compliance with ENLI's regulation. ENLI also finds that the pharmaceutical company has an obligation to react, if a speaker e.g. makes a statement about the company's medicinal products in violation of ENLI's regulation.

ENLI finds that presentations made by third party speakers does not have to be notified to ENLI, cf. section 23 (3), unless the pharmaceutical company has influenced the content of the presentation. If the company decides to hand out the third party's presentation, such presentation will be regarded as the company's material, regardless of whether the hand-out occurs in connection with the event or afterwards, and must be notified in accordance with section 23(3).

Sponsorships:

Section 13 (1.a-b) solely serves to give more details of the activity or event and to differentiate between events arranged or co-arranged by pharmaceutical companies themselves, and events arranged by a third party, where the pharmaceutical company is solely sponsoring the event by way of sponsorship to the organiser or directly to the healthcare professional to cover the specific costs associated with attendance. Such provisions must naturally be construed as allowing pharmaceutical companies only to offer medical information and training to healthcare professionals, and regardless of whether this is for events that healthcare professionals attend or run themselves. Accordingly, providing support for a healthcare professional to run a professional event for patients and relatives for example would not be permitted since such support would not be in compliance with this clause (and Articles 12 and 14).

Further, sponsors may not in accordance with (b.2) exert influence on the event programme. If the company runs a satellite symposium as part of the event, this is not regarded as exerting influence on the event program provided that topics or guidelines have been prescribed to the company for the professional area on which the symposium is to be held or if the organiser has to approve the satellite symposium.

A professional event must comply with all the relevant requirements in Article 13, regardless of whether the pharmaceutical company only sponsors a third party event and therefore has no involvement in organizing the event. The pharmaceutical company must not agree to sponsorship before the company has verified that all the relevant provisions of the Promotion Code have been complied with, cf. also section 23 (4) and the guidance thereon. The event can accordingly not be reported to ENLI before all relevant information needed to assess the case is available, cf. section 23 (4) of these rules and within ten working days of the pharmaceutical company having given a binding promise of financial support, cf. section 23 (5).

Content requirements (e.g. program):

The Committee has previously emphasised that the fact that an activity is "serious" is not the same as saying that pharmaceutical companies can support it. The rules prevent for example pharmaceutical companies from getting involved in events that do not specifically focus on professional educational training of a medical/pharmacy nature, regardless of whether such events might otherwise up-skill healthcare professionals in other areas for the benefit of patients and in the final count, for the benefit of

society as a whole. This would for example often be the case in courses or presentations on administrative systems, organisational development, on collective agreement rules on pay and working conditions, and the role of the doctor in the media. Such events might be relevant for a group of professionals and can be held, however not with the financial support of the pharmaceutical industry unless the focus is on for example therapeutic issues so as to ensure patients get the best medical treatment, in accordance also with the Board of Appeal's recent ruling above.

Only activities of a purely professional medical/pharmacy nature can be supported, cf. (b), final point. If the agreed amount of sponsorship is very high compared to the activities supported, the sponsorship contract with the organizer must specify that the sum should only be used for activities of a purely professional medical/pharmacy nature in accordance with the rules of Article 13 of the code, including a requirement that any surplus from the sponsorship not used for activities of a professional medical/pharmacy nature in accordance with Article 13 should be refunded. Further, ENLI finds that it would be reasonable in sponsorship contracts for large amounts that sponsors request organizers to provide subsequent documentation, for example by way of accounts after the event with a statement of all associated income and expenditure. This is to ensure that the organizers, for example a group of healthcare professionals, do not receive more funding than required for professional continuity training activities which would otherwise be regarded as a financial gift in contravention of section 12 (1) of the code.

Individual pharmaceutical companies are required to ensure that an activity being supported has the necessary professional content of a medical/pharmacy nature. Financial support may therefore only be given to specific activities where the company knows about the content, meaning that the company can determine that the activity being supported complies with the rules and requirement for professionalism (bearing in mind that the company is not permitted, however, to influence the program cf. section 13 (1. b)). Accordingly, when consenting to support an activity, a sufficiently specific program or the like must be available to enable the company to assess whether supporting it would be lawful.

The Committee's practice is that reference to last year's program would generally not be sufficient to meet the professionalism criterion. However in specific cases, ENLI has ruled that international annually recurring conferences for medical specialists/specialist doctors organized by third parties on the basis of preceding year’s professional program could generally be assumed to be sufficiently professional.

The requirement for prior knowledge of the professionalism of an event also means that it would for example be unlawful to support activities relating to more unspecific issues such as 'knowledge sharing', or similar. An event with such a program would not have the necessary level of detail required for its professionalism to be assessed. Support for PhD studies or similar research-based further education would thus only be permitted if the study or research is described in sufficient detail at the time the company consents to provide support, for example by way of a project description. Giving general support to a healthcare professional, for example 'for research purposes' would not be permitted, cf. section 14 (2) which prohibits donations and grants to individual healthcare professionals. If a company wishes to invite healthcare professionals to a professional event before a program is available with sufficient information to be able to make this assessment, the rules infer that the company can only send out a provisional (non-binding) invitation which could for example make it conditional upon the professional event complying with Article 13. Use of headings such as "Save-the-date" or similar in an invitation would not be decisive for ENLI’s assessment of whether the invitation is provisional (non-binding) since this assessment would be

based on the content of the invitation, see also re: section 21 (1) for reporting deadlines. Consequently, a non-binding invitation (alert) does not therefore have to be reported to ENLI.

Activities being supported should have a program with a majority of activities being of a ” professional medical/pharmacy nature” in accordance with the above. ENLI interprets this to mean that pharmaceutical companies are allowed to support an event where part of it is not specifically professional of a medical/pharmacy nature, if the part that is specifically professional constitutes the majority of the event. This could for example be certain annual general meetings (e.g. for medical societies) or other internal discussions in a professional body of healthcare professionals involving no aspects of entertainment, cf. (9), and which comply with the stated requirements. Please note that only events of a mere professional medical/pharmacy nature may be sponsored, cf. section 13(1b).

Pharmaceutical companies should never provide support for events, parts of events or participation in events that include any form of entertainment, cf. (9) or other activities that are not of a professional medical/pharmacy nature, cf. (1.b) (end). In a memorandum dated 1 June 2011, however, ENLI (Board of Appeal) ruled that pharmaceutical companies can provide sponsorship/support for events of the types named provided that participants themselves pay for any entertainment or other activities that are not of a professional medical/pharmacy nature. At the request of ENLI, pharmaceutical companies must be able to document that any support has been given, and used, in accordance therewith. See also the guidance to section 13(9).

Support for hospitals or healthcare professionals:

In 2007, the committee (NMI) submitted a series of questions to the former Danish Medicines Agency (now the Danish Health and Medicines Authority) on interpretation of Article 21 Advertising Order on financial benefits for healthcare professionals with respect to support for public hospitals and professional associations of physicians (for example medical societies). As a direct result of the Danish Medicines Agency's ruling on Articles 21 and 23 Advertising Order, ENLI has determined the following guidelines on interpretation of the rules on sponsorships, donations, etc.:

- Support for public hospitals, including specific hospital departments, should not be considered the same as for "healthcare professionals" and is therefore not regulated by Article 21 Advertising Order or this clause. On certain conditions, support may be lawfully provided as a gift regardless of what support is used for, in accordance with the rulings of the former Danish Medicines Agency. (Reference here is made to the requirements for donations and grants in Article 15 of these rules and associated guidance, and Lif’s ethical rules for the pharmaceutical industry's donations and grants to hospitals).

- Support for individuals, named healthcare professionals or associations of healthcare professionals (such as medical societies) for society operations, including for example setting up a website, distribution of material or drawing up treatment databases and the like, are regarded as conflicting with Article 21 Advertising Order and not covered by the exemptions to Article 23 Advertising Order. This is in accordance with the provisions of section 15 (2) of these rules which precludes support for individual healthcare professionals, unless permitted in accordance with Article 13.

The Danish Medicines Agency's rulings are discussed in detail in NMI's annual report for 2007 (Annex B).

Save-the-date:

If a company wishes to invite healthcare professionals to a professional event before a program is available with sufficient information to be able to make this assessment, the rules infer that the company can only send out a provisional (non-binding) invitation which could for example make it conditional upon the professional event complying with Article 13. Use of headings such as "Save-the-date" or similar in an invitation would not be decisive for ENLI's assessment of whether the invitation is provisional (non-binding) since this assessment would be based on the content of the invitation, see also re: section 21 (1) for reporting deadlines. Consequently, a non-binding invitation (alert) does not therefore have to be reported to ENLI.

Re: Section 13 (2)

This clause requires the purpose of the event to be stated on the invitation. However, there is no requirement for this to be stated formally, for example "the purpose of the event is...." although it should be possible to see this from the invitation.

It also follows from (2) that the invitation should state whether the event is being sponsored /supported by one or more pharmaceutical companies. ENLI has specifically determined that the conditions of (2) were met by it being very clearly stated on the first, and practically all, subsequent pages of the event website that sponsorship is being provided by the pharmaceutical company concerned. In this connection, ENLI emphasizes that signing up to the event should be via the website. In another case, ENLI ruled that the conditions of (2) would be met by the sponsorship contract stating that the organizer would announce the sponsorship and publish the company's logo on all printed marketing/information matters for the event and on the website. ENLI accepted these instances by virtue of the fact that the purpose of the provisions of (2) on sponsors being stated on the invitation (namely that participants should be able to see the sponsorship(s) prior to registration), would have to be regarded as satisfied in the cases concerned, since the sponsor is especially clearly named and it is to be assumed that participants could not avoid being aware of this.

Based on the wording of this provision, ENLI finds that it would be difficult for pharmaceutical companies to give sponsorships for scientific events very close to the date of the event, and in particular after the event, without being in breach of this obligation.

Re: Section 13 (3)

In Denmark, there is no "negative" or "positive" list of "prohibited" and "permitted" meeting venues. Competition law reasons preclude such a list. See also (7).

The rule on "suitable" meeting venues corresponds to the rules on ”appropriate" meeting venues in section 10.01 EFPIA HCP Code. ENLI has ruled that a venue is not suitable for the main purpose of an event which is to communicate factual information and training on medicinal products, cf. (1), if the venue cannot provide a framework for a professional meeting, a so-called 'non-professional' venue. This could for example be a boat trip, museum or elsewhere with cultural offerings for the public on payment of an admission fee and restaurants (without separate suitable meeting facilities) since such places cannot basically be said to be a "suitable venue" compared to a conference room at a company, hospital /medical practice, university, conference facilities, etc.

In contrast to (10) that relates to meeting venues which are "reknowned" for entertainment or their extravagant and/or luxurious facilities, and so involves places that exceeds the standard of what might be regarded as ordinary standard, an assessment according to (3) thus depends on whether the venue is suitable for holding a professional event. Whether in fact there is also access to entertainment will then be a separate assessment, cf. section 13(9).

Re: Section 13 (4)

This clause corresponds to an amalgamation of section 10.02 EFPIA HCP Code and section 25 (3) Advertising Order, although (as was also the case in the former "collaboration agreement") financial issues cannot be taken into consideration as in the Advertising Order. In contrast, the requirement for 'significance' does not follow from the EFPIA HCP Code, but from section 25 (3) Advertising Order.

Logistical reasons could for example be:

- The possibilities of the target group for attending the event (many/few/foreign participants)
- The possibilities of speakers and other participants for attending
- The possibilities for running the event (suitable premises, conference facilities, access to head office/research centres)

The rule means that an event for healthcare professionals, for example, from North Jutland should be located in the local area unless significant logistical issues indicate that the event should be organized elsewhere.

The Committee finds that arranging a study tour abroad for participants to learn about the health service in the country concerned would not be permitted. Such an event would not have the necessary professional content as set forth in (1) and would, in the Committee's view, also conflict with this clause. The same applies to events involving a tour of foreign branche offices (or head offices) of a pharmaceutical company.

Re: Section 13 (5)

According to section 25 (1.1) Advertising Order, “*hospitality by way of payments for direct expenses incurred for meals, travelling, accommodation, etc., associated with promotion for and professional information about medicinal products*" can be provided. It is unclear what is meant by "etc". In contrast, the

EFPIA HCP Code has defined hospitality strictly and hence, the EFPIA HCP Code does not have an opening corresponding to the "etc.," in the Advertising Order. On the other hand, it is specified therein that hospitality should also cover "precise application fees" in accordance with section 10.04 EFPIA HCP Code. According to the guidance on Advertising Order, (5.6) this covers *"hospitality associated with participation in training courses and other activities for professional medical and pharmacy purposes"* The provisions of (5) may therefore be said to be more restrictive than Danish legislation.

The former Danish Medicines Agency ruled in a consultation dated 7 January 2011 that: "It is permitted to provide hospitality for a healthcare professional even though this is for a professional event not organised by the pharmaceutical company concerned. This could for example be a pharmaceutical company that pays travel and accommodation expenses for a healthcare professional's attendance at an international professional conference, even though the company is not the organizer of the conference." ENLI accepts on this basis that pharmaceutical companies can provide hospitality for professional events organised by a third party if the pharmaceutical company concerned has in some other way supported the professional content. This could be payment for travel or hotel to the HCP or payment for a speaker, rent of meeting facilities or similar. ENLI does not regard the provision or offering of a meal to an HCP as in accordance with the regulation, if the HCP participates in an event organised by a third party. ENLI's view is also that sponsorship to the organiser does not justify inviting Danish HCP attendees for meals at events unless the pharmaceutical company has in some other ways supported attendees' involvement in the professional content, e.g. by sponsoring the HCP's costs for travel and/or hotel, as mentioned by the former Danish Medicines Agency.

Only expenditure actually made is covered (against receipt). For example, a company cannot pay a healthcare professional for "hire of premises" for an event held in the doctor's practice. The same applies to travel and accommodation expenses which can only be paid against receipt. A company cannot therefore pay a fixed amount for transport to an event which would allow participants to find a cheap transport solution and make a profit. For use of own car, the pharmaceutical company must ensure that the stated number of kilometres has actually been driven, which could for example be done by way of a statement from the healthcare professional thereon. Accordingly, neither is it possible to pay the healthcare professional in advance for such expenses.

If as part of attending a conference, a healthcare professional sponsored by a pharmaceutical company wishes to extend his/her to stay at the conference venue for holiday purposes and thus asks the pharmaceutical company to change an out/inbound journey, this would be regarded as a financial benefit provided to a healthcare professional in contravention of the general prohibition in section 12 Promotion Code, and also section 13 (7) of the guidance below. Hotel expenses can only be paid if the nature of the event necessitates a stay in a hotel (cf. also "relevant", (3) (end)). If an event last less than six hours, it should normally be able to plan it without requiring a hotel stay. It is also basically a requirement that for a pharmaceutical company to pay hotel expenses there should be professional activities of a professional medical/pharmacy nature on both the day before and after the overnight stay. For overseas travel, the Committee does accept arrival up to 24 hours before the start of the professional meeting.

Please see also section 13 (7) and (8) for payment for hospitality, including meals, etc.

Payment for insurance for participants during their stay and transport to and from is covered, in ENLI's view, by the wording of section 13 (5) and falls within acceptable hospitality.

Re: Section 13 (6)

The clause corresponds to EFPIA HCP Code section 10.04, and no comparable provision is to be found in the Advertising Order, which merely mentions (section 25 (2) (end)) that hospitality is restricted to healthcare professionals. The rule means that hospitality must not be provided for spouses who happen to be healthcare professionals (for example a doctor married to a nurse), unless the spouses themselves have a direct professional, medical interest in attending the event. Neither may companions, in contrast to the rule in the former Collaboration Agreement, attend such events even though they pay for their own associated expenses. This would be comparable with organising social events that are prohibited in accordance with section 13 (9).

Accordingly, pharmaceutical companies cannot act as 'travel agencies' for accompanying spouses/partners. People can decide for themselves where they will travel but it is not allowed for pharmaceutical companies to book tickets for flights, etc., for accompanying spouses/partners regardless of whether or not the pharmaceutical company is bearing the cost of the actual ticket. There is no comparable prohibition in the Advertising Order, cf. guidance thereon on section 5.6.1.

However, in special cases hospitality may be offered to an accompanying person if it is documented that there are objective reasons for the healthcare professional having a companion, for example for religious reasons or for meeting the healthcare professional's healthcare /support /care requirements (e.g. handicap).

Re: Section 13 (7)

The provisions correspond to the amalgamation of (the highest common factors in) section 25 (2) Advertising Order and section 10.06 EFPIA HCP Code.

The essence is an assessment of the extent and level of hospitality with respect to the professional event. "Reasonable" level is taken to mean a general standard level that is not luxurious or in any other way extravagant. It is not possible to provide an unambiguous definition of "reasonable level." An assessment depends on a specific consideration which would include the geographic location of the event and local pricing. Choosing the most expensive restaurants and/or choosing the most expensive menus and wines would not be in accordance with the rules.

When a pharmaceutical company provides sponsorship for a third party organiser, the company can certainly make its sponsorship conditional upon only covering expenses for the professional program, for example payment for speakers, and thus avoid being subject to these provisions (this is not possible as regards section 13(9) and (10)) which are always relevant and assessed as part of the framework for the professional event and hence under the supervision of the company). In cases relating to hospitality, ENLI finds that the company is only responsible for meals for participants lying within the framework of this provision and section 13 (8) if such hospitality is paid for/supported by the company. Hence, the company

is not responsible for a gala dinner (with luxurious catering and/or entertainment), if the company's sponsorship specifically exempts hospitality and/or entertainment. In contrast, a company may not pay a reasonable amount towards or as support for luxurious meals, cf. also section 13(8), meaning e.g. partial self-payment by the HCP. Here, ENLI finds that it is the overall hospitality for which the company provides support that must be at a reasonable level and within the thresholds of section 13(8), since the company would otherwise be providing luxurious hospitality in contravention with this clause.

If an HCP is invited to a professional event, which overall would be characterized as luxurious by the standards of the Promotion Code, this would only be compliant, if a participating HCP pays for him/herself an amount which reflects the real financial value of the luxurious hospitality for the participant.

If a pharmaceutical company invites a healthcare professional to a professional event at a time when details of the event have not yet been fixed, such as the program (for more details see the guidance to (1)) and hospitality in general, for example choice of hotel, possibly restaurant, transport etc., the company will to still be required to document compliance with the rules for professionalism and hospitality at the point at which the company gives binding consent to the healthcare professional, for example when sending out an invitation with the option of signing up, cf. also (1) and section 23 (4). With respect to hospitality, such documentation could for example be a specified budget giving the standard of hospitality (e.g. hotel standard, flight class, etc.) and departure dates. Provided that hospitality is kept within the given limits and on condition that venues in question are not known for their entertainment facilities or are extravagant and/or luxurious, ENLI would regard hospitality as complying with the Promotion Code, including section 13 (7).

Hospitality may only be provided for specific professional events in accordance with the definition of professionalism in the commentary to (1), to which reference is made.

Further, the professional purposes and content must always rest on an overall financial/timing assessment. This means that companies cannot offer to postpone the homebound trip for a healthcare professional, whose attendance at a professional event has been sponsored, for holiday purposes since these provisions require that hospitality must be strictly limited to the main purpose of the meeting, see also (5). The same consideration applies to the prohibition against pharmaceutical companies facilitating accompanying trips by spouses, cf. (6). For overseas travel, the Committee does accept arrival up to 24 hours before the start of a professional meeting.

The wording: "What a healthcare professional is willing to pay", comes from the EFPIA HCP Code, section 10.07. This is naturally subjective and not too much weight should therefore be placed on the wording but it should however be regarded as a kind of guidance according to which no more should be given than what it is assumed the average healthcare professional would be willing to pay, and the requirement for reasonableness, etc., must naturally also be fulfilled. On the other hand, there is no requirement for individual healthcare professionals to be asked what they would be willing to pay themselves.

<u>Overnight stays:</u>

With respect to choice of overnight accommodation, the general remarks made in the Board of Appeal's ruling of 21 September 2011 on the choice of venue for professional events (see (10)) would also apply, cf. AN-2012-2202. Whether a hotel's standards appear extravagant and/or luxurious would depend on an

overall view of how the hotel generally appears in publicly available information and whether it is generally regarded as luxurious, cf. AN-2012-2202 and AN-2012-2203. The same assessment applies in general to hospitality, including restaurants. If an event last less than six hours, it should normally be able to plan it without requiring a hotel stay. It is also basically a requirement that for a pharmaceutical company to pay hotel expenses there should be professional activities of a professional medical/pharmacy nature on both the day before and after the overnight stay. For overseas travel, the Committee does accept arrival up to 24 hours before the start of the professional meeting.

Travel:

In a letter to ENLI on 6 February 2013, Lif submitted suggestions for interpreting the rule, as suggested in section 10.08 EFPIA HCP Code, thus supplementing ENLI's guidance on the meaning of " reasonable" with respect specifically to transport at a reasonable level which has to take into account the circumstances surrounding travel by healthcare professionals. Reasonableness should therefore be assessed on the basis of whether a healthcare professional has been invited by a pharmaceutical company to attend a professional event or whether the healthcare professionals is travelling as a result of having been hired as a consultant to provide a professional service for the company. Lif then states as follows:

1. *Rail travel is regarded as travel at a reasonable level, regardless of the choice of class (e.g. 1st and 2nd class), although on condition that the journey is not significantly expensive, reflecting luxury, extravagance or "entertainment" (e.g. Orient Express, Royal Scotsman, Palace on Wheels, Rovos Rail, etc.).*

2. *Air travel to professional events (to which the healthcare professional has been invited) in Europe should generally be in Economy class.*

3. *Air travel to professional events (to which the healthcare professional has been invited) to intercontinental destinations should generally be either in Economy or Economy Plus, such as "Economy Flex" or "Premium Economy".*

4. *Flights for consultants providing professional services to the company and who travel in Europe should mainly be either in the economy or economy plus such as "Economy Flex" or "Premium Economy". Reference is also made to the requirements of Article 16 and the guidance thereon.*

5. *Flights for consultants providing professional services to the company and who travel intercontinentally can be in Business Class. Reference is also made to the requirements of Article 16 and the guidance thereon.*

6. *If justified by special logistical issues, ENLI may derogate from the above on the basis of a specific assessment of logistics, price, class and any alternative solutions and accept flights in a higher class than stated above.*

7. *Further, the use of Business Class is acceptable at all levels if the traveller is in a wheelchair, etc.*

8. *Air travel in First Class (where First Class is at a level above Business Class) is never permitted.*

As regards travel, the pharmaceutical company can offer to pay for the travel costs only in accordance with section 13(7), as per above. The pharmaceutical company shall document this along with its notification to ENLI. If an HCP on his/hers own initiative and for its own costs and without the involvement of the pharmaceutical company subsequently changes his/her travel arrangement, e.g. by upgrading a flight ticket to business class or change the return dates, this does not change ENLI's view that the pharmaceutical company had arranged and paid for travel on a reasonable level pursuant to the Promotion Code.Meals:

The level or standard of any hospitality is always subject to an individual assessment in each case. The assessment as regards meals shall be in accordance with section 13(8). Hence, meals (sandwiches, coffee/ tea/ soft drinks, etc, excepted) can only be offered at events consisting of at least two hours of professional content of a medical/pharmacy nature. It also follows from the guidance to the Advertising Order, section 25 (2) (section 5.6.1) that *"This means for example that a professional whole-day seminar from 09-17 hours could include breakfast on arrival, lunch and possibly a light dinner to conclude the seminar."*

Re: Section 13 (8)

Upon the enactment of the EFPIA Disclosure Code on 24 June 2013 on disclosure of transfers of value to HCPs and HCO's, EFPIA also decided that each member country in its national code shall set a monetary threshold for meals (food and beverages) provided or offered to HCPs. The provision is implemented in the EFPIA HCP Code section 10.05 and in the Promotion Code in this section 13(8).

Lif has upon its implementation informed that:

- The monetary threshold is unambiguous. This means that pharmaceutical companies shall not provide or offer meals in Denmark which exceeds the threshold, whereas companies may always provide or offer meals in Denmark which does not exceed the monetary threshold (as long as the requirement for a meeting of a minimum of 2 hours professional content has been met).
- The monetary threshold is inclusive of beverages, VAT and tips, as relevant.

If a pharmaceutical company provides or offers meals outside of Denmark, as regards the other EFPIA member countries, the monetary threshold decided for these countries shall be complied with – the list from EFPIA is available at www.ENLI.dk. As regards countries outside EFPIA, ENLI finds that a reasonable level shall be established using the Danish monetary threshold as a starting point, and only where documented material differences to the Danish price level exist, the monetary threshold shall be regulated up or down, as applicable.

Please note that compliance to the monetary thresholds will be controlled by ENLI. Even though the reporting website does not require specification of hospitality on a meal-per-meal level, the pharmaceutical company must specify all meals in its notification. This can be done either in the commentary box or in a separate document.

Re: Section 13 (9)

This clause corresponds to section 10.07 EFPIA HCP Code, which contains a prohibition against hospitality

covering *sponsoring* as well as *organising* entertainment events regardless of whether these are wholly or partially professional in nature and regardless of whether entertainment is subordinate to the professional part. This means for example that a pharmaceutical company may not organize a professional activity and in so doing facilitate for example a magician, a band or the like to provide entertainment after dinner, regardless of whether the healthcare professionals themselves bear the costs of this. Following a request by Lif and ENLI, the Board of Appeal drew up a memorandum dated 1 June 2011 on "interpreting the rules on sponsorship of events with elements of entertainment." The memorandum is on ENLI's website. The issue attracted considerable interest from pharmaceutical companies which had been seeking clear criteria for the area prior to the memorandum.

Subsequently, both Lif and ENLI have had countless discussions with member companies that have had great difficulty in complying with the rules on payment for professional events organized by a third party, especially relating to international scientific congresses. In a letter to ENLI on 15 January 2013, Lif submitted a contribution to interpreting how the rule should be construed, as urged in the EFPIA HCP Code's section 10.08 and hence supplemented ENLI's guidance on how "entertainment" should be understood as follows:

1) *There is a total prohibition against organizing/ sponsoring entertainment with respect to events organised by pharmaceutical companies (both in Denmark and abroad).*
2) *With respect to sponsored third party events (where the company is not the organizer or co-organizer and therefore has no influence on the program), the different types of entertainment must be differentiated, meaning that there must be differentiation between "primary" (prohibited) and "secondary" (permitted) entertainment.*
    a. *"Primary" entertainment would for example be music or other acts forming part of a stand-alone performance during a dinner or the like – or in which participants are invited, or have access, to separate entertainment on-location, where the critical factor is that an overall view would regard this as damaging for the industry's credibility and image. This might for example be concerts, opera, theatre, sporting events, sports or entertainment activities, stand-up comedy, sightseeing, wine tasting /lectures, etc. Performances involving people generally regarded as "known" " – artistes, bands, actors, sports personalities, etc., - constitute value by virtue of their reputation and would generally be regarded as primary entertainment, even though this is not by way of a separate performance.*
    b. *"Secondary" entertainment would be activities not consisting of a special event which is limited in its extent and/or reputation and which does not have any entertainment value of significance for the attendee. This would include performances which attendees would not in normal circumstances be willing to pay for themselves and which from an overall view would not be damaging for the industry's credibility and image. Examples of this would be background music, etc., at an opening reception or in a lobby.*
3) *It should generally be noted that the Board of Appeal is maintaining its interpretation that pharmaceutical companies are permitted to provide sponsorship for professional events, if any entertainment (in accordance with the above definition regarded as primary entertainment) associated with the event is expressly funded otherwise than by the pharmaceutical company's sponsorship, for example by attendees paying for themselves or the sponsorship comes from a non-*

pharmaceutical company.

ENLI welcomes Lif's supplementary interpretation in that it is regarded as perfectly natural for a member organization that adopts very complex rules to also provide some guidance on how they intend the rule to be construed, cf. as also urged in the EFPIA HCP Code, section 10.08. ENLI would however note that in specifying its understanding, Lif has placed most emphasis on the EFPIA HCP Code and ignored the international IFPMACode, the rules of which were also implemented in the Promotion Code on its adoption in 2011. In September, 2012, the IFPMA Code introduced a prohibition against entertainment in its section 7.1.6, and this makes no differentiation between primary (stand-alone) and secondary entertainment. This is further specified in IFPMA's Q&A No. 13 which states that there are no exceptions to the prohibition against entertainment unless such background music or the like is not sponsored by the pharmaceutical company, cf. also ENLI's previous interpretation and practice.

With respect to any self-payment, the Panel of Investigators has emphasized that for healthcare professionals, getting sponsorship should be conditioned upon the company ensuring it does receive payment for the entertainment element, that the amount had been reported by the congress organizers and that the size of the amount reflected the economic value of the specific entertainment elements to attendees. The Panel has also approved sponsorship for attending a scientific congress in which the fees included activities with elements of entertainment, since participation required ticking a box when signing up. In this connection, ENLI requires documentation that sponsored healthcare professionals do not have access to the social event.

Conversely, a pharmaceutical company cannot sponsor parts of a professional event that includes "primary" entertainment just by making its sponsorship conditional on specific payment for speakers or other professionally permitted activities or hospitality unless predetermined conditions are met (entertainment is expressly paid by attendees themselves or expressly funded by sponsorship by a non-pharmaceutical company).

Pharmaceutical companies must be able to show, at the request of ENLI, that any support has been given, and used, in accordance with this rule. The rule therefore goes a step further than Article 27 Advertising Order which first only contains a prohibition against sponsors, but not a prohibition against organizing entertainment and which further does not prohibit sponsorship of entertainment provided that this does not involve "purely" social or cultural events. The prohibition in the Advertising Order should however also be interpreted broadly as fundamentally prohibiting payment for admission to theatres, museums, football matches, etc., regardless of how much it costs. The Advertising Order does however permit payment of admission when a professional event is held in conference facilities in museums or other cultural venues. This means paying admission fees so that healthcare professionals can get to a professional event, and is thus not payment for attending a purely a cultural event (cf. guidance section 5.7). This is as a starting point not permitted in the Promotion Code, since payment for admission would represent a financial benefit, namely access to "entertainment" in contravention with this section of the Promotion Code or could reputationally give this impression, cf. below section 13(10).

Re: Section 13 (10)

In Denmark, there is no "negative" or ”positive” list of "prohibited” and ”permitted” meeting venues. Competition law reasons preclude such a list.

In contrast, venues are required to be at a "reasonable level" as also set forth in section 25 (2) Advertising Order, and pursuant to these rules, venues must not be extravagant (meaning they must be ordinary standard and not luxurious). ENLI interprets "reasonable level" and "ordinary standard" with respect to each specific event. The requirement for pharmaceutical companies to avoid places that are known for their entertainment facilities is more restrictive than the Advertising Order and the previous Collaboration Agreement that permitted such venues on certain conditions.

In considering two cases of principle on 21 September 2011, the Board of Appeal ruled as follows on the general interpretation of these provisions:

”*Financial benefits must not be given or offered to healthcare professionals for promotion purposes or otherwise to promote the sale of a medicinal product, cf. Article 12 Promotion Code [today, this section is more strict: “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 Articles 13-16.]. When as in section 13 (9)[today: section 13(10) Promotion Code exceptions are made for the choice of venue from the prohibition against financial benefits, this should be interpreted in the light of section 1 (2.a) Promotion Code. According to this clause, pharmaceutical companies must always maintain high ethical standards and measures to promote sales must never be such as to bring the pharmaceutical industry into discredit or to reduce confidence in it. This means that exceptions from the prohibition against financial inducements should be interpreted restrictively.*

Meeting venues, including among other things their general reputation, design and location, must not in themselves significantly influence attendees in deciding to attend a professional event. Considerable caution should therefore be observed in the choice of venue so that no justified doubts can be raised as to whether the venue lives up to the professional purposes. Fundamentally, holding professional events at for example five star hotels, gourmet restaurants (understood as restaurants awarded one or more stars in the Michelin Guide or similar acknowledgement in comparable independent quality assessment schemes), castles and mansions, golfing, skiing and beach hotels (in season), boat trips, etc., must comply with section 13 (9)[today: section 13(10)] Promotion Code. Here it is not decisive whether those attending the professional event do actually have access to the leisure and entertainment activities concerned or otherwise have luxurious hospitality. The critical factor is whether the planned venue is generally regarded as "known" for its entertainment facilities, is extravagant and/or luxurious, cf. section 13 (9) [today: section 13(10) Promotion Code.
In assessing whether a specific venue complies with the requirements for "reasonable level" and "ordinary standard", an overall view must be taken of various relevant issues relating to the venue concerned, including namely:

- *Price*
- *Location (inter alia with respect to parking and road access)*

- *Facilities,*
- *Classification and*
- *Availability of alternative venues locally.*

The price for using the venue's facilities, catering, etc., could be used as a guideline, in the Board of Appeal's view. If the price is in line with the typical price for a comparable standard event, the venue should be acceptable in accordance with section 13 (9) [today: section 13(10)], although assuming that the venue is not otherwise in conflict with the Promotion Code, for example because it is generally regarded as extravagant. The price for facilities, hospitality, etc., should be based on what attendees would have had to pay for the service in normal circumstances.

Even though the price for using the facilities of the venue could be used as a guideline for whether a planned event complies with section 13 (9) [today: section 13(10)], this is not to say that other specific circumstances could not lead to another outcome. For example, approval of a higher priced 5-star hotel as the venue for a professional event might not be excluded if for example the location at a traffic hub and the extent of conference facilities were to indicate in a specific case that special weight should be given to the choice of precisely this venue.

If in doubt, pharmaceutical companies can request pre-assessment of a planned event, cf. section 21 (7)[today: section 23(7)] Promotion Code."

After this, both Lif and ENLI have had countless discussions with member companies that have found it very difficult to comply with the rule on venues and in a letter dated 15 January 2013, Lif submitted a contribution to interpreting how the rule should be construed, as urged by section 10.08 EFPIA HCP Code, and supplemented by ENLI's guidance on venues that are "renowned" for their entertainment facilities or are extravagant /luxurious.

It has been determined that a venue may be used in instances where:

1) The venue is not an attraction in itself.
    a. *For example: The main stage at the Opera, DR's Concert Hall, Tivoli's Concert Hall or the Aquarium may be regarded as just such an attraction. The following also applies:*

2) It is obvious that attendance at a professional event at the venue must be at a time when there is no general access to entertainment, or that no kind of entertainment takes place.
    a. *For example: The Park (Parken, Copenhagen) at a time when there is no sport or concerts on the grass, Tivoli out of season when the amusements are otherwise closed; museums or exhibition centres when meetings are held outside opening hours and when there is therefore no access to the exhibitions.*

3) Irrespective of 1) or 2) above, it is ultimately a matter of how well the venue is known for its meeting /conference facilities and whether these could generally be regarded as separate from the entertainment facilities at the venue. Separation does not necessarily require *de facto* physical separation, for example by a locked door, but where it is obvious that entertainment facilities will

not be relevant or used by attendees on the day. A significant factor here is that it is not likely that holding an event at this location would mean that attendees from the outside world in general (by far the majority) would associate this with entertainment.

a. *For example: In Copenhagen, DGI Byen Conference Centre, Danish Design Center, Conference Dahl's Concert Hall (when there is no concert), Tivoli Congress Center, The Black Diamond (The Royal Library).*

Please note that companies are also responsible for all other conditions of Article 13. This means that if a meeting venue offers free tickets to meeting participants to exhibitions etc., this is likely in contradiction to section 13(9) of the code, even though the meeting venue is not regarded as “known” for its entertainment facilities.

Lif finds that ENLI’s interpretation of the rules on a "suitable" venue and the prohibition against "extravagant and/or luxurious” venues is reasonable and that the Board of Appeal has issued various appropriate pointers. With respect to other European countries, it is understandable that there are nuances and differences in implementation and Denmark does not appear to differ significantly from the standard in other countries. Lif has reservations about the alternative which would require drawing up highly specific standards, prices, criteria, etc., since there would be the risk that this could conflict with competition rules. At the same time, such a model would result in a stiff, inflexible system with no possibility of taking appropriate individual assessments and considerations into account. When a venue does not obviously conflict with the rules of the Promotion Code (for example on the basis of the current guidance or published rulings) but where overall ENLI finds it does conflict with the rules, non-compliance is sanctioned with a reprimand for the first breach. The first time means that no company has previously been sanctioned (reprimand or fine) for using the venue (since these are published on ENLI’s website).

On this basis and on the basis of a restrictive interpretation in line with the Board of Appeal's ruling, ENLI will continue to assess venues according to the above-identified criteria and hence ensure that a venue is not generally regarded as "known" for its entertainment facilities, or is extravagant and/or luxurious. In making assessments, ENLI will continue to focus on assessing quality and other similar publicly available information such as reports in various newspapers, journals and other publicly available communication forums and/or thus fundamentally not on the basis of the venue's own marketing. ENLI finds that these provisions impose requirements on pharmaceutical companies, even if they are not themselves the organizer or co-organizer, but merely the sponsor of the professional event, cf. also the guidance to section 13 (1). Accordingly, a pharmaceutical company cannot provide support for a professional event that makes use of a venue that conflicts with this clause.

ENLI regards the concept of venue to cover all locations for a given event. An overall view is taken of the location, for example with regard to the location for the professional part of the event, for any subsequent activities and for any subsequent meals when it comes to compliance with the requirements of section 13 (10). The Panel of Investigators finds that pharmaceutical companies may provide support for events that are not in accordance with section 13 (10), with respect for example to subsequent meals at a venue that is known for its entertainment facilities insofar as this is expressly financed by attendees themselves, in line with entertainment in accordance with (9).

When assessing venues abroad, ENLI applies the same standards and criteria as described above although consideration is given to other criteria such as safety and local rules for hotel rankings/classification.

Re: Section 13 (11) and (12)

This clause corresponds to Art. 13 EFPIA HCP Code, although the last clause about Danish and other relevant legislation was inserted to supplement the EFPIA HCP Code, since there was a suspicion that such rules would often be invariable in the host country. Clarification should therefore be sought from the Danish Health and Medicines Authority (formerly the Danish Medicines Agency), as to whether payments for foreign attendees at international congresses, etc., held in Denmark should be solely in accordance with the rules of the healthcare professional's own country or whether Danish legislation's should also apply. In the consultation, the Danish Health and Medicines Authority did not remark on the provisions.

Re: Article 14 Information and educational material and items of medical utility

Re: Section 14 (1)

This provision corresponds to the EFPIA HCP Code Article 9 and has been implemented with the ban on gifts, cf. guidance re: Article 12.

The interpretation of this new Article 14 will reflect relevant authority practice as well as in areas, where the EFPIA provision is more strict than Danish legislation, guidance notes from EFPIA (FAQ), whoich are available on www.ENLI.dk, as well as supplementary guidance from Lif, if any.

It follows from EFPIA's FAQ from February 2014 that informational or educational material generally include items that advance disease or treatment education, are designed for the education of patients or HCPs, and have no personal benefit to the HCP. Informational or educational material might include educational borchures on diseases, patient self-assessment and tracking tools, and brochures that HCPs use when instructing patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programmes.

The provision also includes materials provided on-line or on a memory-stick. ENLI maintains with regards to the latter that the memory of any such stick should be the least available to meet the particular need of the material in question. According to the EFPIA FAQ (Q6) the EFPIA Board has decided that textbooks to HCPs are within the scope of the ban on gifts. Conversely, ENLI finds that this entails that e.g. reprints can be given to HCPs as long as the content is in accordance with this provision.

The meaning of "inexpensive" has been determined in section 14(3), however as regards materials which are aimed at giving to a patient, ENLI finds that the guidance from the Danish authorities, saying that the total value given to an individual HCP shall not exceed DKK 300 in a calendar year for gifts given to HCPs, does NOT apply. In the case of materials to patients, each material to a patient shall each be inexpensive.

Re: Section 14 (2):

This provision corresponds to the EFPIA HCP Code Article 9 and has been implemented with the ban on gifts, cf. guidance re: Article 12.

The interpretation of this new Article 14 will reflect relevant authority practice as well as in areas, where the EFPIA provision is more strict than Danish legislation, guidance notes from EFPIA (FAQ), whoich are available on www.ENLI.dk, as well as supplementary guidance from Lif, if any.

It follows from EFPIA's FAQ from February 2014 that items of medical utility generally include items that are beneficial to enhancing the provision of medical services and patient care, and have no personal benefit to the HCP. Items of medical utility might include inhalation devices (with no active ingredient) and devices intended to assist patients to learn how to self-inject.

It follows from EFPIA's FAQ (Q3) that items of medical utility are allowed to provide certain inexpensive items of medical utility to HCP only to thre extent that they do not offset costs that would otherwise be routinely incurred by a HCP. A HCP practice generateds certain routine costs, such as rent, administrative costs, office supplies (including stationary, pens, etc.) or items that are needed in order to conduct patient consultation, i.e. gloves, tissues, stethoscopes, sphygmomanometers, etc. As a general principle, member companies should not provide such items to HCPs.

The meaning of "inexpensive" follows from section 14(3).

Re: Section 14 (3):

"Inexpensive" will in fact currently follow the existing authority practice, meaning that the total value given to an individual HCP shall not exceed DKK 300 in a calendar year for gifts given to HCPs.

Re: Article 15 Donations and grants that supports healthcare or research

For donations or grants for hospitals, this clause has now been supplemented by Lif's ethical rules for donations and grants for hospitals by the pharmaceutical industry which took effect on 1 September 2011. The new code supplements and further restricts Article 15 in some areas with respect to donations and grants to hospitals, including the fact that companies should ensure that grants or donations are used for the intended medical scientific purposes (or make these conditional) and that it is the hospital /hospital department that controls the donation or grant and that the actual transfer must be approved by a duly authorized person from the hospital and there must in any event be written and signed documentation for the terms and conditions.

This clause does not cover issues regulated by Article 13 on sponsorship for individual participants' attendance at professional meetings, including hospitality.

The clause corresponds to EFPIA HCP Code Art. 11 and is also in line with Article 21 Advertising Order, and Article 25, although the clause does go a little further than the Advertising Order with respect to the

requirement for documentation, registration and publication. The clause also clarifies the fact that sponsorship must not be equated with promotion for a medicinal product, cf. also the definition of promotion.

It is a requirement that any support must be aimed at medical or scientific purposes covered by (1), i.e. support for healthcare services or research. The investigations panel understands the term 'healthcare services' in accordance with the Promotion Code as meaning professional healthcare services that a healthcare professional is authorized to undertake. The Panel of Investigators therefore finds that donations and grants must be made in connection with an activity that is an integral part of prevention, examination, diagnosis, treatment or subsequent checks on the patient. The Panel finds that a similar conclusion is supported by Arts. 4 - 5 Donations Code which provides that such donations and grants must be made respectively for *"healthcare services or research or other medical activities for the benefit of treatment for patients or the hospitals."* The supported service must therefore specifically relate to professional healthcare in accordance with the concept of healthcare services above.

The former Danish Medicines Agency did however state that in assessing lawfulness, it emphasised the importance of funds going to the operation of medical services, that the hospital, association or individual hospital department could make dispositions over the funds they had received; and that sponsors generally would have no influence on operations, tasking or what the funds should specifically be used for, cf. for example the Agency's ruling on the Network for Heart Failure Clinics dated 22 May 2007 (end).

It should be noted that the Agency took a different, more lenient view of the concept of "professionalism og a medical/pharmacy nature" then that historically taken by the Committee. The Agency accordingly accepted that support for management courses, etc., was lawful whereas the Committee does not regard such courses as "professional," cf. also re. (13) above.

In a specific prior assessment, the investigations panel found that on certain conditions, loans of iPads to hospital departments could be made in accordance with this clause as well as Arts 4 - 5 Donations Code. In this specific case, iPads were loaned for an agreed period and contained a specially designed web application with information about an area of disease for patients, and also a web application aimed at healthcare professionals with two modules with e-learning and product information respectively. Access to the information aimed at healthcare professionals was effectively restricted and the iPads concerned were fitted with a technical system to prevent them from being used for other than the intended purpose. It was accordingly not possible for users to install their own programs or games, download music and films or check e-mail, etc, since any access by users to the internet was barred. The purpose of loaning the iPads concerned was to optimize healthcare professionals' communication with especially young patients with the specific condition. The group of patients was characterized by having poor understanding of their condition and poor awareness of their life situation. So for this group of patients, it was especially important to use a form of communication with which patients were comfortable and which did not appear intimidating.

Re: Section 15 (2).

The prohibition against sponsoring individuals follows from the EFPIA HCP Code, but also from the practice laid down by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency) and the

former NSL. The then Danish Medicines Agency's rulings are discussed in detail in NMI's annual report for 2007 (Annex B). This provides that:

- Support for hospitals, groups of hospitals and specific hospital departments (in contrast to individual healthcare professionals in hospitals) does not conflict with the rules. In a meeting on 27 June 2008, the Agency stated that this would also apply to private hospitals operated on a corporate basis with more than one shareholder.
- Support for individuals and groups of individuals (healthcare professionals) is not lawful. This also applies, according to the practice of the former Danish Medicines Agency, to support for medical societies (which are associations of individuals), regardless of whether the support is for a medical or scientific purpose (e.g. for setting up websites, distribution of material or drawing up treatment databases, etc.).

Lawful support naturally predicates that the support is for the professional purposes set forth in (1).

Re: Section 15 (3):

For donations or grants to hospitals, this rule has now been supplemented by the requirement for pharmaceutical companies to publish a schedule on their website, cf. Lif's ethical rules for the pharmaceutical industry's donations and grants to hospitals that took effect on 1 September 2011. The new code supplements and further restricts Article 15 in some areas with respect to donations and grants to hospitals, including the fact that companies should ensure that grants or donations are used for the intended medical/scientific purposes (or make these conditional), that the hospital /hospital department controls the donation or grant and that the actual transfer must be approved by a duly authorized person from the hospital, and there must in any event be written and signed documentation for the terms and conditions.

Re: Section 15 (4):

The clause corresponds to EFPIA HCP Code section 12.01

Re: Article 16 – The use of consultants /professional services

This clause is based mainly on Art. 14 EFPIA HCP Code, supplemented with rules from Danish legislation.

Whether an HCP is regarded as a consultant or advisor for a pharmaceutical company does not depend on whether the HCP in question is employed for a limited scope or time. An HCP is as a starting point regarded as a consultant or advisor pursuant to this provision, if such HCP has the option to conduct business as an HCP in parallel with his/her employment with the pharmaceutical company.

Re: Section 16 (1)

The rule corresponds to EFPIA HCP Code section 14.01 and in principle to Article 23 Advertising Order which does not however contain the criteria set forth in (a-g) which derive from the EFPIA HCP Code, which thus goes slightly further than Danish legislation. In contrast, (h) is not in the EFPIA HCP Code, but it does incorporate section 23 (2) Advertising Order.

It should be noted that section 5.5.2 in the guidance of Article 23 Advertising Order states: "*The prohibition against providing financial inducements for healthcare personnel does not cover payment for services from individual healthcare personnel or a pharmacy if the fees are commensurate with the service provided. At the request of the Danish Medicines Agency, both the giver and recipient of the fee are required to provide information on how the fee was determined, cf. Advertising Order s. 23(1).*
Fees may only be paid in money and must not be paid by way of offsetting, transfer of benefits in kind or other indirect ways cf. Advertising Order s. 23(2).
Accordingly, healthcare personnel can only receive payment for a service to a pharmaceutical company if the service forms part of a normal, mutually obligating agreement between the person and the company and if the service and consideration are commensurate. This might for example be payment for renting window space for advertising a medicinal product at a pharmacy, advertising in pharmacy papers, etc. Similarly, it would be possible to pay for doctors' professional assistance in undertaking clinical trials or drawing up information material on medicinal products. With respect to payment for doctors' professional services, it should however be emphasized that commercial relations with a pharmaceutical company do require the prior consent of the Danish Medicines Agency, cf. Pharmacists' Act s. 3(2)."

Re: (g):

To ensure compliance with the rules and avoid fines for any contravention, pharmaceutical companies would preferably have had guideline tariffs for the area. The Competition Authority has been asked and it is unfortunately not possible to draw up such guideline tariffs for competition law reasons.

It is important to bear in mind that in the final count and by giving the above consents in Denmark, the Danish Health and Medicines Authority acts as the guarantor that relations are on a proper basis which is why there is no requirement to report the activity to ENLI for further control.

Re: (h):

This clause is not to be found in the EFPIA HCP Code, but it does implement section 23 (2) Advertising Order.

It should be noted that pursuant to section 23 (2) Advertising Order, paying for services from a healthcare professional or for a pharmacy is permitted if the fee is reasonable and commensurate with the services provided. When so requested, both the giver and recipient of the fee must provide information on the basis for determining the fee to the Danish Health and Medicines Authority (formerly the Danish Medicines Agency). Fees may only be paid on a monetary basis and not by setting off, transferring benefits in kind or in some other indirect way.

Re: Section 16 (2).

Doctors, dentists and pharmacists can only be affiliated with a pharmaceutical company if such individual has received a prior permission from the Danish Health and Medicines Authority, cf. section 3(2-3) Pharmacists' Act.

There is a requirement for pharmaceutical companies to notify the Danish Health and Medicines Authority cf. section 43a(1) Medicines Act . More information on this is available on the Danish Health and Medicines Authority's (formerly the Danish Medicines Agency) website.

Re: Section 16 (3)

This refers to a request and so the rule cannot be enforced.

Re: Section 16 (5)

The clause is a translation from section 14.04 EFPIA HCP Code and has by ENLI been taken to mean that there is no basis for assessing the framework for a healthcare professional's terms of consultancy, including hospitality, differently than for sponsorship for a comparable healthcare professional, in accordance with Article 13 (EFPIA HCP Code's Art. 10).

Having received Lif's supplementary guidance in February 2013, this does not however apply to air travel for consultants providing professional services to the company. The following applies in accordance with the guidance to section 13 (7) above:

a) For consultants travelling in Europe, air travel should primarily be either in the economy class or in economy plus, such as "Economy Flex" or "Premium Economy". Reference is also made to the requirements of Article 16 and the guidance thereto.

b) Flights for consultants providing professional services to the company and who travel intercontinentally may be in Business Class. Reference is also made to the requirements of Article 16, including section 16 (1) and the guidance thereto.

c) If justified by special logistical issues, ENLI can derogate from the above on the basis of a specific assessment of logistics, price, class and any alternative solutions and accept flights in a higher class than stated above.

d) Further, the use of Business Class is acceptable at all levels if the traveller is in a wheelchair, etc.

e) Air travel in First Class (where First Class is at a level above Business Class) is never permitted.

COMMENTARY TO CHAPTER 6 – TRANSPARENCY

Re: Article 17

EFPIA's General Assembly decided on 24 June 2013 on a new EFPIA Disclosure Code, which obligates Lif and Lif's member companies.

All EFPIA countries, which do not have national legislation concerning transparency, shall implement the provisions of the EFPIA Disclosure Code in its national code. The EFPIA Disclosure Code does however allow implementation via regulation which may vary compared to the specifics of the EFPIA Disclosure Code, if this is due to national legislation and regulation.

This flexibility provision will be used in Denmark, as Lif has decided to implement the requirements of the EFPIA Disclosure Code via the anticipated Danish disclosure legislation, which currently has yet to be passed, and which subsequently will be followed by further requirements as laid down in executive orders. The provision of section 17 (2)(1) is hence applicable to all pharmaceutical companies in Denmark, whereas section 17(2)(2) only applies to affiliated companies and associations.

It follows from the act sent out in consultation that it was originally the intention that the new transparency requirements would apply as from 1 July 2014, but this has now been postponed to 1 September 2014. The Danish legislation model will likely result in less administrative burdens on the pharmaceutical companies, since the primary reporting obligation in the legislation rests with the individual HCPs. The specific requirements will be further commented by ENLI, once the specifics of the legislation is known and decided later in 2014.

COMMENTARY TO CHAPTER 7 - NON-INTERVENTION STUDIES AND EXHIBITION

Re: Article 18 - Non-interventional studies of marketed medicinal products

The clause corresponds to EFPIA HCP Code Art. 15. As a supplement to this, Lif's agreement on clinical research with the Danish Medical Association must also be complied with at the very least, and in certain areas, there are more requirements than in these rules.

To a certain extent, Article 18 overlaps with the above-identified agreement with the Danish Medical Association and has been included in these rules to ensure control with respect to the provisions in the EFPIA HCP Code on non-intervention trials with respect to pharmaceutical companies.

Re: Section 18 (2)

Re: (d): In a formal sense, non-intervention trials do not require approval in Denmark by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency) or the bioethics committee system and there are no special Danish laws or orders that specifically regulate this type of trial. In Lif's agreement with the Danish Medical Association on clinical trials, there is however a requirement to submit trial plans to the Danish Medicines Agency (now the Danish Health and Medicines Authority). The Danish Medicines Agency stated to Lif that if there was a specific query, it would provide guidance on whether a trial is an intervention trial or a non-intervention trial and in response to a specific query, they could provide guidance on the rules on promotion and their interpretation associated with non-intervention trials. On this basis, provisions were included in the collaboration agreement between Lif and the Danish Medical

Association on clinical research according to which, in order to receive the guidance noted above, members of the Danish Medical Association and Lif should submit trial plans relating to non-intervention trials to the Danish Medicines Agency. The requirement thus follows from the agreement on clinical research between the Danish Medical Association and Lif (not from legislation). Further, attention is drawn to the fact that the Data Protection Agency also has to approve certain issues relating to clinical trials, although further details of this fall outside the present guidance.

The above corresponds in principle to the requirement in section 15.02 (d) EFPIA HCP Code.

In general it should be noted that Lif and the Danish Medical Association are working to have an official approvals scheme established for non-intervention trials.

Reference is further made to section 3 (2) Pharmacists' Act on notification to the Danish Medicines Agency on doctors' relations with pharmaceutical companies (and section 3 (3) with respect to pharmacists).

Re: Section 18 (3)

Insofar as the clause is only a request, it is not enforced by ENLI.

Re: Article 19 – Exhibition etc.

This clause is not in the EFPIA HCP Code but is a continuation of Article 9 of the previous "Collaboration Agreement".

As for all other relevant information, it must be possible as part of the reporting to document the conditions set forth in Article 19, cf. section 23 (4) of these rules.

Re: Section 19 (1)

According to this, pharmaceutical companies are permitted to advertise when holding professional events, typically by way of promotion, exhibitions, putting up posters, film shows, product information, etc. However, it must be clear to those attending the professional event when promotion is involved - and when it is professional instruction. Accordingly, promotion and marketing must be kept separate from the professional content of the event. If it relates to a medical congress, no displays are permitted in the auditorium or lecture rooms. Promotion activities must be kept separate from the professional part of the congress, for example in a foyer outside the lecture rooms.

It should be noted that promotion activities on a booth must comply with the rules on promotion to the general public if non-healthcare professionals are present as part of the professional event. This would for example be the case for exhibition activities if others than pharmaceutical companies are present in booths, such as pension companies, patient associations, etc., unless these areas are kept clearly separate.

The rules on promotion to the general public are generally not controlled by ENLI but by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency).

Re: Section 19 (2)

Even though promotion is kept separate from the professional part of a Congress, displays can only be permitted if the content of the Congress is of such a professional nature that it complies with the rules in section 13 (1). On the other hand, ENLI finds that the clause does not provide powers to require compliance with all the other conditions in section 13 (3-11) for purchasing an exhibition booth, for example the rules on venues.

Re: Section 19 (3)

For events organized by healthcare professionals, the terms and conditions for promotion medicinal products as part of the event must be pre-arranged, with a written contract on the financial terms for this. Any hire charges for rooms or exhibition booths, displays or the like must be separately agreed, independently of any sponsorship for the professional event. Payment for the exhibition must be reasonable compared to the organizer's costs for exhibition arrangements and the promotion value for the pharmaceutical company.

Re: Article 20 – Medical samples

The supply of samples of medicinal products is regulated by the Medicinal Samples Order, ORDER No. 1244 of 12/12/2005 and is controlled by the Danish Health and Medicines Authority (previously Danish Medicines Agency). According to the Order, only one medicinal product sample may be supplied each year for each product to each doctor and then only to doctors, dentists or veterinarians. Various other requirements and conditions apply to supply, as set forth in the Order. These are now supplemented by this Article 20.

Re: Section 20 (1)

Implementing the EFPIA HCP Code's amended section 16.01 (adopted by EFPIA on 14 June 2011 (the so-called 4*2 rule) for entry into force on 1 January 2012) has meant further restrictions compared to Danish legislation and Article 20 is accordingly also more restrictive than section 16.02 of the EFPIA HCP Code. Thus in accordance therewith, a pharmaceutical company may only supply one sample a year for each medicinal product for a maximum of two years after the date of introduction.

Re: Section 20 (2)

ENLI's understanding is that amending the marketing authorisation as a result of for example a merger or if a company takes over a product from another company does not mean a new marketing authorization and hence a new introduction date.

Re: Section 20 (3)

The provisions of section 20 (3.1) are aimed at products covered by the Medicines Act in accordance with the definition in section 1 (3.2) of Order No 1263 of 15 December 2008 on medical equipment, cf. also section 3 (3 c) Promotion Code. This relates to single-use products marketed so that the device and the drug constitute an integral product which can only be used in the given combination. Examples of such products might be a disposable nasal spray or a single-use penicillin pen syringe.

These are defined in the legislation as a single product covered by the Medicines Act and are therefore medicinal products. Here, the rules of section 20 (1-2) must be complied with, meaning that there is only a new product when the product is marketed for the first time, when it has a new indication or where the changes are based on a new or supplementary indication.

The final subsection in section 20 (3) exempts other devices from the rules of (1 - 2). These products are covered by the general rules on medical devices. Supplying samples of medical devices is regulated by the requirement for professionalism in Order No. 695 of 28 September 1998 on promotion for medical devices. Supply has to serve an objective purpose, for example allowing the doctor to become acquainted with functionality changes, etc. Neither must supplying samples be done in such a way that it leads to contravention of other provisions in the Order, for example the prohibition against influencing fallacious self-diagnosis or the prohibition against being mainly intended for children. Supplying drug samples in association with these devices can be done when it is necessary to understand or test a new or altered device, although only for a maximum of two years after the new or altered device has been introduced. Supply must be restricted as much as possible and is otherwise covered by the general rules on medical samples in the Medicines Act.

Re: Section 20 (4)

It is important to be aware that the rules of the Order on supplying medical samples is still in force, including the rule on supplying at most one sample annually of each medicinal product to each doctor. Reference is made generally to the provisions of Order No. 1244 of 12/12/2005.

COMMENTARY ON CHAPTER 8 – STAFF, TRAINING, ETC

Re: Article 21 – Pharmaceutical company staff

The clause corresponds to EFPIA HCP Code Art. 18 and a clause has been inserted at section 21 (1.2) corresponding to section 18 (2) Advertising Order.

It should be noted that in accordance with Lif's Articles of Association, members are required to only use medical representatives who have completed the medical representatives' course at Lif and who hence also comply with the conditions for listing in Lif's register of medical representatives.

Quite specifically, the above requirement means that Lif's member companies are required to ensure that medical representatives, who have not completed the medical representative course at the date of employment, comply with the following requirements:

- They must take the exam within twelve months of employment.
- They must have passed the exam within 25 months of employment, regardless of their educational background.

Member companies are also required to have all their medical representatives registered at Lif, so that Lif can check that all personnel providing information about medicinal products have passed the exam within the deadlines noted above.

COMMENTARY ON CHAPTER 9 – ENFORCEMENT, OBLIGATION TO REPORT AND PRE-APPROVAL

Re: Article 22 – Enforcement

Reference is made to the co-operation agreement on ENLI for further remarks and for the regulations on fines and fees.

It is not possible to say anything about how long a pre-approval from ENLI remains valid. Pre-approval is done on the basis of information and conditions submitted specifically. If these change, the assumptions for approval may no longer be valid. Accordingly, a pharmaceutical company is required to regularly check for compliance with the terms and conditions of the Promotion Code cf. also AN-2012-2713, in which the Board of Appeal reversed an assessment made by the previous board (NSL).

Re: Article 23 – Obligation to report

General: According to the EFPIA HCP Code, there is a requirement for the rules to be subject to control but there is no obligation to ensure that this happens through an obligation to report such as the current to ENLI. The obligation to report is therefore limited in the code and should be viewed with respect to the right to appeal, cf. the co-operation agreement on ENLI and the controls exercised by the Danish Health and Medicines Authority (formerly the Danish Medicines Agency), among other things in accordance with section 3 (2-3) Pharmacists' Act. The obligation to report applies basically to all responsible companies if several companies collaborate on an promotion activity. The secretariat does however find that it would be sufficient for the same promotion activity only to be notified once. The reporting should clearly state if several companies are responsible for the activity. This is due to the fact that sanctions could apply to all responsible companies for non-compliance (if subject to ENLI's control). This would also have an impact on

repetitions. There is no special box to be checked in the reporting system for such collaborations but the information can be entered in the text box or uploaded in a separate document.

It should be noted that all notified cases are not necessarily checked. Reporting is therefore no guarantee in itself that the arrangement or support complies with the rules. This would require proper "pre-approval". At the very least, checks are made at random on a minimum of 15% of reports. If the resources are available, the head of secretariat may decide to check a greater number of cases. Experience from the former NSL shows that out of approximately 7,000 annual reports notified in 2009, NSL only imposed fines in 2.3% of the cases. It is therefore felt that reviewing 100% of reports would not necessarily mean the best utilisation of ENLI's resources and/or lead to a greater level of compliance with the rules but that best use could be made of the resources for preventive work, information, etc.

The reporting obligation according to these rules is limited to professional events of a medical/pharmacy nature and exhibition booths relating to those as well as printed advertising matter (apart from tender documentation) and should as noted below be seen as a supplement to the Danish Health and Medicines Authority's (formerly the Danish Medicines Agency) control of doctors' relations with pharmaceutical companies, cf. section 3 (2) Pharmacists' Act - which states that: *"A person running a business as a dentist or doctor may not without the consent of the Danish Medicines Agency (now the Danish Health and Medicines Authority) operate or be associated with a business that has approval in accordance with Article 7 or section 39 (1) Medicines Act*." The Danish Health and Medicines Authority (formerly the Danish Medicines Agency) thus controls for example the consultancy services offered by healthcare professionals to see that they are provided on reasonable terms (the same applies to pharmacists in section 3 (3)).

Reference is also made to the Danish Health and Medicines Authority's (formerly the Danish Medicines Agency's) guidance No. 9010 of 13 January 2010 on notifying information about doctors, dentists or pharmacists' relations with a pharmaceutical company.

Re: Section 23 (1)

Re: (a-b): The obligation to report in (a-b) is limited only to activities that wholly or partially relate to Danish healthcare professionals in or outside Denmark. So if an event is only attended by foreign healthcare professionals, there is no obligation to report.

The obligation to report relates only to events at which healthcare professionals are not required to provide any kind of service in payment /support, cf. section 23 (2). This means for example that there is no obligation to report advisory board and investigator meetings since here the healthcare professional is providing a service in return by way of his/her expert knowledge. In contrast, in professional events of a medical/pharmacy nature solely attended by healthcare professionals to receive education, there is no service and this must therefore be reported, which further requires compliance with the other relevant conditions. Visits by medical representatives should not be notified either, although see the commentary to section 23 (2) below.

So-called "Save-the-date" invitations need not be notified to ENLI. These invitations are a good, practical way of getting doctors, etc., to reserve a date for an event until sufficient information is available for the pharmaceutical company to give binding consent to the event in accordance with the rules. Only then can

the company send out a real invitation with the option of signing up and only then must the event be notified to ENLI.

Reference is made to the guidance to Article 13 for an assessment of when sufficient information is available on the event, including its scientific content, hospitality, etc.

Specially re. (c): Pharmaceutical companies' paying for exhibition booths at congresses, annual meetings, etc., in Denmark are to be notified to ensure that pharmaceutical companies only have exhibition booths at events where the scientific content is in order. This applies regardless of the nationality of the healthcare professionals targeted by the exhibition.

Exhibitions abroad are not to be notified, regardless of whether the exhibition targets Danish or foreign healthcare professionals.

Re: Section 23 (2)

Visits by medical representatives are not covered by the obligation to report. A medical representative being accompanied by a speaker would mean that this is no longer only a visit by a medical representative. If the medical representative him/herself speaks to the whole department, this would in contrast still be a medical representative's visit. A specific assessment is required to determine the borderline as to where reporting is required and when it continues to be regarded as an ordinary, standard medical representative's visit. If the visit is actually to provide training for one or more healthcare professional(s), or the visit is more of the nature of a major event, it must be notified.

The obligation to report relates only to events at which healthcare professionals are not required to provide any kind of service in return for payment /support, cf. (d). This means for example that there is no obligation to report advisory board and investigator meetings since here healthcare professionals are providing a service in return by way of their expert knowledge. The company’s first letter to an HCP concerning possible participation e.g. in an advisory board or other meeting must be notified to ENLI, if the letter is regarded as an ad for a medicinal product. It should be noted that whether or not the company may provide hospitality depends on the meeting (e.g. investigator meeting) being held in connection with the pharmaceutical company's own research project or a research project in which the pharmaceutical company is involved in some other way. In contrast, in training events solely attended by a healthcare professional for education purposes, there is no service and this must therefore be reported which further requires compliance with the other relevant conditions.

Re: Section 23 (3)

PowerPoint and other electronic text and presentations are deemed the same as printed advertising matter and covered by the reporting obligation, provided that it also involves "advertising" or promotion as defined in the Advertising Order. It should be noted that ENLI considers textbooks that name specific medicinal products as printed advertising matter which would therefore require reporting, cf. also section 2 (2)(c), 5.

It should be noted that there is no obligation to notify ENLI regarding the use of materials, which are exempted from the Promotion Code cf. section 2 (2) (c), ref. also guidance to this provision, including patient information leaflets (also the handing out to HCPs with accompanying compulsory text), safety-related information and press releases, which ENLI does receive from time to time. ENLI underlines that material which despite its heading is regarded as promotional material (as opposed to informational or educational material) must be compliant with the provisions of the Promotion Code and notified to ENLI pursuant to section 23(3) Promotion Code.

Re: Section 23 (4)

All reports must include the information required by the current online reporting schedule on ENLI's website and possibly further information of relevance for assessing the report, cf. the requirements of the Promotion Code. The company is responsible for ensuring that the necessary information is available at the time of reporting. For electronic material, including apps, documentation should be included both by links to the material or access to tablets with the material, and screen dumps with relevant descriptions and/or flow charts.

Immediately after filing the report, the company will receive an automatic receipt for it, stating that lack of reaction to the report should not be considered as a guarantee of the lawfulness of the material and that random checks are made on reports. It follows from ENLI's case processing rules, including Article 6 and section 8 (4) that checks are done on the notified documentation. Assessment for compliance with the rules is therefore based on the actual circumstances at the time of reporting. Upon request, the company should be able to document that any such circumstances have taken place prior to the notification to ENLI. This means that during the assessment process, a pharmaceutical company cannot amend the reported material to bring it into compliance with the rules so as to avoid sanctions. This position was confirmed by the Board of Appeal on 23 November 2011 with its rulings in AN-2011-1927 and AN-2011-1480 and is also now codified in the sanctions regulations, article 1.

The fact that a pharmaceutical company only becomes aware at a later stage that planned promotion activities contravene the code cannot justify running advertisements which would otherwise be regarded as in breach of the rules. Otherwise, a company could wait to plan an activity to the last moment or report the activity to ENLI shortly before launch date and in this way avoid the rules.

Re: Section 23 (5)

According to section 23 (5) Promotion Code, giving notice of an event in accordance with section 23 (1a) must be submitted at least ten working days before the opening day of the event. ENLI takes this to mean that the opening day of the event is the day when the pharmaceutical company's general services for healthcare professionals begin. For events entailing travelling time, this would therefore be the day of departure.

Invitations to healthcare professionals to attend for example international congresses are regarded as a sponsorship for such healthcare professionals to participate in a third party event, cf. understanding of section 13 (1) of the code, and must therefore be notified as a sponsorship. For more details of

documentation requirements for companies' own events, third parties' events and sponsorships, see the guidance to section 13 (1). Among other things, section 13 (1.a-b) solely serves to give more details of the activity, and to differentiate between the activities that pharmaceutical companies organize for themselves or when they act as co-organizers of an event where a third party is the organizer and the pharmaceutical company solely sponsors the event, be this by way of sponsorship to the organizer or direct to the healthcare professional to cover specific expenses associated with attendance.

The fact that the company only has to report to ENLI when all the necessary information is available does not mean that the reporting can be submitted later than as laid down in section 23 (5). This means that the company can only agree to a healthcare professional's attendance with sufficient information when for example hospitality is available. Information about hospitality need not give the name, address and price of hotels or the cost of flights and departure times but may well provide the framework for hospitality such as the fact that the hotel is maximum 4* and less than DKK 1,500 per night, or that flights are booked in economy class with arrival as close to the start of the event as possible, cf. guidance to the Promotion Code, section 13 (7).

Re: Section 23 (7)

A pre-assessment is done on the basis of the documents submitted with the application. If changes are made to circumstances along the way, possibly following dialogue with ENLI about these, a new request is required before new circumstances are assessed.

It should be noted that a pre-assessment will always be specific and cannot be regarded as a general approval of individual parts associated with an approved activity, cf. section 5 (3) of ENLI's case processing rules. If there are subsequently changes to the format, content, etc., of the pre-approved activity, it automatically becomes invalid.

Re: Section 23 (8)

In invitations are sent out by pharmaceuticals' companies themselves, they must ensure that the text set forth in a) and b) or c) is included. This applies to any invitations sent out by a pharmaceutical company to healthcare professionals, regardless of whether this might involve the pharmaceutical company's own event, an event sponsored by the company, or where the company pays for healthcare professionals to attend a third party event. The purpose of the text in a) and b) or c) is thus to give healthcare professionals the chance to see that the event to which they are being invited has been notified to ENLI and has been assessed either by ENLI (prior approval) or the pharmaceutical company as in compliance with the rules. This also complies with the wording of the code's section 23 (8). The text must be easy to read and it will not normally receive approval if it is printed for example vertically at the edge of the invitation and in a very small font size, in which case ENLI will rule that it does not meet the requirements of section 22 (8) with respect to the purpose of the clause.
The Investigations Panel finds that the purpose of the clause also means that a pharmaceutical company should give the same information regardless of whether it decides to invite a healthcare professional, for example by way of a poster for example at the hospital or by oral invitation.

Abbreviations

ABPI	The Association of the British Pharmaceutical Industry (ABPI)
ABPI Code	The Code of Practice for the Pharmaceutical Industry 2011
Consumer price Order	Order on calculating consumer prices etc. for medicinal products (Order No. 1152 of 30/09/2013)
Disclosure Code	EFPIA Code on Disclosure of Transfers of value from Pharmaceutical Companies to healthcare Professionals and Healthcare Organisations (EFPIA HCP/HCO Disclosure Code), approved at the General Assembly on 24 June 2013
Donation Code	Lif's ethical rules on the pharmaceutical industry's donations and grants to hospitals.
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EFPIA HCP Code	EFPIA Code on the Promotion of Prescription-only Medicines to, and Interactions with, Healthcare Professionals 2007, ("EFPIA HCP Code") as amended latest at the General Assembly on 24 June 2013
ENLI	Ethical Committee for the Pharmaceutical Industry in Denmark (the Committee)
HCP	Healthcare Professional
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IFPMA Code	IFPMA Code of Practice 2012
IGL	Danish Generic Medicines Industry Association
Lif	Danish Association of the Pharmaceutical Industry
Medicines Act	Medicines Act No. 1180 of 12/12/2005
Marketing Act	Order on the Marketing Act No. 839 of 31/08/2009
NMI	Danish Board of Drug Advertising (Nævnet for Medicinsk Informationsmateriale)
NSL	The Danish Legal Board of Self-Regulation concerning Pharmaceuticals (Nævnet for Selvjustits I Lægemiddelindustrien)
Personal Data Act	Act on Processing Personal Data No. 429 of 31/05/2000 with subsequent amendments
PFL	Parallel Importers' Association
Pharmacists' Act	Act on pharmacists No. 855 of 04/08/2008 with subsequent amendments
Advertising Order	Order on Advertising, etc., for Medicinal Products (ORDER No. 272 of 21/03/2007 with subsequent amendments)
Promotion Code	The pharmaceutical industry's code for advertising, etc., medicinal products to healthcare professionals 2011
Guidance on the Advertising Order	Guidance on Advertising, etc. for Medicinal Products No. 29 of 24/05/2007

Change Log

Date	Document Edition	Re. Article/ Section:	Amendments (in general)
10 June 2013	1.10		Document established, translation of the Danish guidance paper "Vejledning til reklamekodekset", version 1.10 – versioning corresponds to the Danish paper
20 November 2013	1.11	Sec. 2 (2) (c), 6	Clarification in relation to patient information leaflets
		Articles 3-8	Overall change in layout
		Sec. 3 (1)	Clarification concerning activities outside Denmark
		Sec. 4 (2)	Clarification relating to patient cases in advertising
		Sec. 5 (1), 1	Correction of practice concerning the requirement to always state the generic name of a medicinal product
		Sec. 5 (1), 3	Clarification concerning the therapeutic indication area
		Sec. 5 (1), 9	Pricing information for medicinal products which can only be provided to hospitals
		Sec. 5 (2)	Electronic advertisements must have a link to the obligatory information from all individual pages
		Article 6	Clarification
		Sec. 7 (1)	Claims which are included in the SPC do not require further documentation, however reference should be made to the SPC
			Guidance on meta-analyses moved to sec. 7 (5)
			Clarification on claims moved from sec. 7 (3)
		Sec. 7 (3)	Clarification on claims moved to sec. 7 (1)
			Electronic advertisements must have a link to the obligatory information from all individual pages
		Sec. 7 (4)	Clarification concerning changes to figures and tables
		Sec. 7 (5)	Guidance on meta-analyses moved from sec. 7 (1)
			Information from RADS, KRIS and IRF not in accordance with

			requirements to documentation
		Sec. 7 (6)	Change of practice, allowing use of words associated with ”safe”, e.g. safety, as a consequence of ruling from The Board of Appeals, AN-2013-2911
			Rule of thumb concerning when a medicinal product is regarded as ”new”
		Sec. 8 (1)	Clarification of the requirement for pricing information in comparative advertising reflecting the committee’s practice
		Sec. 8 (2)	Electronic advertisements must have a link to the obligatory information from all individual pages
		Sec. 12 (1)	Changes due to EFPIA’s Disclosure Code, prohibition of gifts to HCPs as from 2014
		Sec. 12 (2)	Deleted section on memory sticks
		Sec. 13 (5)	Clarification of requirements for documentation of costs
		Sec. 13 (7)	New section concerning hotel costs
			Rule of thumb concerning hospitality (meals) on a reasonable level
			Changes due to EFPIA’s Disclosure Code, new threshold for meals on a reasonable level as from 2014
			HCPs subsequent change of transportation mode and similar with no aid from company
		Sec. 13 (9)	Note to pay attention to all requirements concerning meeting venue
		Sec. 21 (4)	Documentation of electronic materials in notifications
			Clarification of the committee’s assessment, including documentation of time and events
21 March 2014	1.12	Sec. 2 (1)	Further guidance concerning affiliated companies’ responsibility for promotional activity in Denmark carried out by e.g. a foreign company associated with the group
		Sec. 2 (2)(c), 1	Update regarding the Order No. 869 of 21 July 2011 on labelling, etc., of medicinal products (additional monitoring)
		Sec. 2 (2)(c), 4+5	Informational material regarding health and disease or patient information leaflets are not required to be notified to ENLI, cf. sec.

			23 (3)
		Sec. 2 (2)(d)	Change due to the amended Promotion Code Document Edition 1.7
		Sec. 3 (1)	Clarification of pharmaceutical companies' responsibility for presentations by contracted third parties
		Sec. 4 (1)	Clarification of the notification of price and requirements to advertising for new medicinal products
		Sec. 4 (2)	No requirement for display of "black triangle" or other information regarding additional monitoring in promotional material
		Sec. 5 (1)(1)	Clarification of requirements to state the generic name
		Sec. 5 (1)(5)	No requirement for display of "black triangle" or other information regarding additional monitoring in promotional material
		Sec. 6	Commentary to the new ban on gifts in Article 12
		Sec. 7 (4)	Clarification of possibility to create new figures or tables on the basis of source material
		Sec. 8 (1)	Clarification of the documentation requirements for comparative advertising
		Sec. 8 (2)	Change to the requirements for comparative advertising for add-on medicinal products
		Article 12	Commentary to the new ban on gifts from the EFPIA HCP Code
		Sec. 13 (1)	Overall change of layout, comments on third party presentations given on behalf of a pharmaceutical company
		Sec. 13 (2)	About sponsorships provided close to the event date or after the event
		Sec. 13 (3)	Clarification of "appropriate" venues
		Sec. 13 (5)	Addition of commentary previously made re: sec. 13 (7)
		Sec. 13 (7)	Overall change of layout, comments re: the new sec. 13 (8)
		Sec. 13 (8)	Commentary to the new section from the EFPIA HCP Code
		Sec. 14	Commentary to the new sections from the EFPIA HCP Code
		Article 16	Clarification of the definition of a consultant pursuant to the

			Promotion Code
		Sec. 16 (2)	Changes due to the amended promotion Code Document Edition 1.7
		Article 17	Commentary to the new provision from the EFPIA Disclosure Code
		Sec. 23 (2)	Clarification of obligation to notify ENLI regarding HCP participation in an advisory board

ANNEX A (to Guidance on the Pharmaceutical industry's code on promotion, etc., for medicinal products aimed at healthcare professionals")

Re: Danish Regulatory Authorities' assessment of clinical drug trials

Clinical drug trials must be approved by both the Danish Health and Medicines Authority (formerly the Danish Medicines Agency) and a regional bioethics committee before the trial can start.

The Danish Health and Medicines Authority assesses safety (risks and disadvantages) and possible therapeutic gains from drug trials intended to investigate:

- Clinical, pharmacological or pharmacodynamic effects
- Adverse drug reactions
- Absorption, distribution, metabolism or secretion

There is an assessment of whether the trial is suitable for obtaining new knowledge and whether the trial can be assumed to provide therapeutic gains that could justify the risks of the trial. The Danish Health and Medicines Authority's assessment also includes an assessment of all the individual parts of the trial protocol (cf. Danish Health and Medicines Authority's Guidance on applying for permission for clinical trials on medicinal products on humans, most recently updated 23 September 2010).

As the basis for the Danish Health and Medicines Authority's assessment of the trial material and the intended trial, the following documentation must also be submitted to the Danish Health and Medicines Authority:

For products for which a marketing authorization has been issued or for which an application for a marketing authorization has been submitted, and for products for which documentation has been submitted as part of a previous application, reference to the previously submitted material will normally be sufficient. For other products, documentation must be attached relating to their chemical, pharmaceutical, animal pharmacological, toxicological and human pharmacological properties and information about existing clinical experience. As part of this, the Investigator’s Brochure and Investigational Medicinal Product Dossier must be submitted.

Further, it should be noted that in accordance with section 90 (2-3) Medicines Act, the Danish Medicines Agency (now the Danish Health and Medicines Authority) may inspect trials for which consent has been given. An inspection of a clinical trial would normally consist of an inspection of the sponsor and of the investigator with a view to determining that the trial has been undertaken in accordance with national legislation (including the Order on Good Clinical Practice, GCP regulations, the trial protocol and the sponsor’s quality assurance system, and that the data is correct and reliable). With respect to the practicalities of an inspection, the Danish Health and Medicines Authority makes an assessment of the application to start a clinical trial to ensure that trial subjects have given consent for the authorities, etc., to have access to their records.

Finally, in accordance with section 3 (2) Pharmacists’ Act, an investigator must have the consent of the Danish Medicines Agency (now the Danish Health and Medicines Authority) to be associated with a pharmaceutical company. In assessing whether a doctor or dentist should be granted consent to participate in a clinical trial, the Danish Health and Medicines Authority also considers whether the bioethics committee has approved the actual project and assesses the scope of financial support, including any remuneration for the researcher and any personal interest in the project. For further details see Danish

Medicines Agency Guidance No. 9012 (of 13 January 2010) on the requirement for doctors and dentists to apply for permission to be associated with a pharmaceutical company.

The Bioethics Committee System

In accordance with section 1 (3) Committees Act, the Bioethics Committee System is tasked with ensuring that biomedical research projects (including clinical medicinal product trials) are conducted in a scientifically correct way and that trial subjects who participate in a biomedical research project are protected with respect to their rights, safety and welfare whilst also providing the opportunity to develop valuable new knowledge.

The issues assessed by the committee's are set out in section 12, 14 and 15 Committees Act (special issues are assessed in trials on XX trial subjects cf. section 13 Committees Act). For further details, please see the Central Bioethics Committee's "Guidance on reporting biomedical trials" (of 6 October 2008). (http://www.cvk.sum.dk/forskere/vejledning%20modul.aspx)

The committee system's deliberations focus on the ethical dimensions of the trial, including particularly ensuring the rights and safety of trial subjects and on any economic and contractual relations between investigators responsible for trials and a private pharmaceutical company. The bioethics committee system therefore primarily assesses the scope and quality of participant information cf. Information Order section 9-12 (No. 806 of 12 July 2004) and the formulation of trial subjects' consent to participate in the trial, cf. sections 4 – 5 Information Order.

In accordance with section 22 (5) Committees Act, the committee system does not regulate clinical trials - this is done by Danish Medicines Agency (now the Danish Health and Medicines Authority). The committee system may make suggestions for clinical trials that should be controlled by the Agency (Authority). Similarly, bioethics committees have a standing invitation to attend the Agency's inspections as observers.

Committees Act:

Section 12. The committee may only grant consent if:
1) The possible risks associated with undertaking the project are not in themselves, or compared to the project's predicted benefits, unwarrantedly great;
2) The anticipated gains from a therapeutic point of view and for public health can justify the project;
3) The project's scientific standards meet the requirement for the project to contribute to the development of valuable new knowledge, cf. (3), and
4) There are sufficient grounds for undertaking the project and the project's conclusions are justified.

(2). When considering an application for approval of a biomedical research project, the committee shall balance the predictable risks and disadvantages against the gains for individual trial subjects and for other present and future patients, including the fact that the pain, discomfort, fear and other predictable risks are minimized with respect to the illness of the trial subject and the stage of development. This balance shall be made with due respect for trial subjects themselves being able to give informed consent or whether consent is to be obtained from next-of-kin and the general practitioner, alternatively the medical officer of health or the holder of parental rights or a guardian in a guardianship that covers personal issues, including the authority to grant consent for participation in a biomedical research project, cf. section 5 Guardianship Act.

Section 14. The committee may otherwise only grant consent if:
1) The financial support that the lead investigator receives from private companies, foundations, etc. for undertaking the research project concerned, and whether the lead investigator otherwise has financial relations with private companies, foundations, etc., which have interests in the research project concerned, are clearly stated in the written or electronic information;
2) Any fees or other remuneration for participating in a biomedical research project are not such as to influence the provision of consent;
3) The right of the trial subject to physical and mental integrity and the right to a private life are respected and information relating to the trial subject is protected in accordance with the Act on Protection of Personal Data;
4) The lead investigator has ensured that trial subjects can access further information about the project;

5) Projects leading to biological material and data being sent to a third country are undertaken in accordance with the rules in the Act on Protection of Personal Data;
6) Both negative and positive results of the trial are published has rapidly as possible and medically feasible.
Publication shall be in accordance with the Act on Protection of Personal Data.

(2). The Minister of Science, Technology and Development may lay down further specified rules on the issues set forth in (1).

Section 15. When considering an application for approval of a biomedical research project dealing with clinical trials on medicinal products covered by the Medicines Act, the committee shall in its deliberations ensure that, in addition to the issues set forth in (12 -14):
1) The Danish Health and Medicines Authority (formerly the Danish Medicines Agency) is involved in approval of the project, cf. section 9 (1);
2) There is a compensation or indemnification system if the trial subject comes to harm or dies as a result of the project and that insurance cover has been taken out or a compensation scheme is available to cover the liabilities of the lead investigator and the sponsor;
3) The amount and the precise rules for paying out any fees or any compensation for the lead investigator and the trial subjects and the content of the relevant clauses in every intended contract between the sponsor and the trial location are known, and
4) The lead investigator is qualified to take decisions on treatment and has an appropriate scientific education and training as a doctor or, where relevant, dental and clinical experience.

(2). The Minister of Science, Technology and Development may lay down further specified rules on the issues set forth in (1).

Annex B (to the pharmaceutical industry's code on promotion, etc., for medicinal products aimed at healthcare professionals):

Extract from NMI's Annual Report 2007

Re: ”Financial support for hospital departments, medical societies, etc”.

Industry support in recent years for hospital departments, etc., has given rise to a series of cases and fundamental deliberations by the Board. On this basis, the Board decided to submit a series of specific cases to the Danish Medicines Agency which has the ultimate responsibility for administration of the relevant provisions of the Advertising Order.

The Board submitted a series of reports on support for various kinds of knowledge gathering/databases.

This also related to a report from GlaxoSmithKline, that had provided DKK 75,000 to support publication of the Den Danske HIV kohort's (DHK's) annual report.

The Board stated in its covering letter to the Danish Medicines Agency that it was open to doubt whether or not this kind of support conflicts with the Advertising Order. The Board also stated that in recent years there had been increasing awareness that the pharmaceutical industry was providing support for projects of a similar nature, and indeed often with very considerable amounts. The Board further emphasised a range of cases in which support had been provided directly to hospital departments or for projects associated with hospitals. These generally involved especially creditable purposes, fundamentally in the interest of patients, and taken by themselves, also in the interest of the public health service.

The first time that NMI considered a case of this nature was in 2002, when a company sponsored technical equipment for two hospital departments. The issue was discussed in the Board's annual report for 2002, sec.2.4.

On the basis of various other cases, the problem was also mentioned in the Board’s annual report for 2005, p.18.

As a result, the Board has formulated its position that there is nothing to prevent the pharmaceutical industry from providing support for the hospital sector, but if so, sponsorship should be given more generally, for example to the hospital where their associated independent research committee, funding board or the like could decide on the purposes for which the funding provided should be used. Up till now, the Board has held that sponsorship should not be targeted at named doctors or specific hospital departments since this could risk the parties’ not remaining independent of each other and that the sponsoring company would gain unacceptable good-will.

As a further example, the Board previously considered a case in which two nurses applied to a company for support to publish a folder relating to travel vaccination. The company reported that it had provided financial support to help publish and print the folder. The Board declared that the sponsorship provided conflicted with sections 8 and 9 Advertising Order. Regardless of the creditable aims of the support, here

too the Board felt that support of the type noted should not be targeted at named nurses since this could risk the parties not remaining independent of each other and that the sponsoring company would gain market benefits on an non-objective basis.

The Board stated to the Danish Medicines Agency that its fundamental view was that a hospital department or one or more healthcare professionals who had received funds from a company for a desirable purpose would thus obviously risk becoming dependent and this could possibly affect the choice of future collaborative partners in the field of medicinal products or could have critical influence on the choice of medicine in significant therapeutic areas. In this respect, the Board also found that DHK could potentially have non-objective market-related consequences. The Board therefore found that a more fundamental elucidation of cases of the present nature would be extremely desirable.

The Board stated that the problem not only related to situations in which sponsors could be characterized as directly supporting operations but also situations in which money was given for more idealistic or research/project oriented purposes.

In a letter dated 20 December 2007, the Danish Medicines Agency responded:

"In a letter dated 22 March 2007, the Danish Board of Drug Advertising asked the Danish Medicines Agency to assess whether support given by GlaxoSmithKline Pharma A/S to the Danish HIV Cohort complies with the Advertising Order.

As a result, the Danish Medicines Agency would comment as follows:

In a letter received on 6 December 2007, Dr N.N states that DHK (Danish HIV Cohort) is a cohort aimed at quality assurance and undertaking scientific projects. DHK was established as a collaboration between the public hospital departments that treat HIV in Denmark. Overall management of DHK is undertaken by a steering committee/team consisting of one member from each of the participating hospitals (eight centres in all). The members of the steering group are appointed by the clinical departments of the hospitals. Day-to-day operations at DHK are overseen by Dr N.N., a consultant at Copenhagen University Hospital.

N.N further states in the letter that DHK's financial resources have been paid into a research account at the hospital at which the study is taking place (currently Copenhagen University Hospital). Funds are used for running the project, primarily for paying project personnel. The steering group and N.N receive no salary from DHK.

N.N told the Agency on the telephone that members of the steering group represent the hospital departments by which they were appointed and that members report to the management of the hospitals concerned on the decisions made by the steering group. The steering group makes all overarching decisions for DHK. All scientific projects have to be submitted in writing to the steering group for approval. Dr N.N is responsible for paying routine operating expenses and he reports to the steering group.

In a letter dated 16 May, 2006, GlaxoSmithKline Pharma A/S notified N.N. that the company would provide DKK 75,000 in financial support for DHK's annual report 2006.

Pursuant to section 8 (1.1) of the then Advertising Order, financial inducements including discounts, bonus payments or the like or benefits in kind must not be given, offered or promised to healthcare professionals

for promotion purposes or otherwise to promote sales of medicinal products. The prohibition in section 8 (1.1) does not relate to benefits in kind of insignificant value associated with the exercise of the healthcare professional's duties, cf. section 8.2 of the Order.

The Agency's view is that section 8 (1.1) Advertising Order also covers "image gifts", including gifts of money from pharmaceutical companies to healthcare professionals. Accordingly, it is irrelevant for the gift to be directly associated with marketing a certain medicinal product since it has to be assumed that the company's interest in providing such financial benefits is based on a desire to market the company and its products, regardless of whether the gift for example is given as individual support for a healthcare professional's research or as support for operating expenses for a private association of healthcare professionals (association or the like). In contrast, the Agency's view is that it would be lawful for the pharmaceutical company to provide financial support for public hospitals, groups of hospitals and for specific hospital departments. This would apply to financial support for equipment and for research, and for when money is given to a hospital, group of hospitals or hospital department which can then dispose over the funds. In this situation, this would be a gift to a public hospital for a group/collaboration consisting of public hospitals, not for a healthcare professional or an association of healthcare professionals.

The Danish Medicines Agency's assessment is that the financial support provided by GlaxoSmithKline Pharma A/S to Den Danske HIV Kohorte (DHK) did not contravene section 8 (1) Advertising Order. The Agency specially took into consideration that DHK is a collaboration of public hospital departments and that the financial support was provided to fund the cohort's activities (publication of an annual report). The Agency further took into consideration that a steering group had been appointed with representatives from each of the departments involved (eight centres) and that the individual members of the steering group report to the hospital management with respect to the issues on which the steering group makes decisions. The Agency's view is accordingly that the financial support was provided to a collaboration consisting of public hospital departments. GlaxoSmithKline (A/S) did not therefore provide financial support for healthcare professionals or a private association of healthcare professionals in contravention of the Advertising Order".

In a similar case, the Board submitted a case on funding from the industry for the Heart Failure Clinics Network.

The Danish Medicines Agency accordingly commented as follows:

"The articles of association for the Heart Failure Clinics Network state that Danish heart failure clinics, that have a nurse-based program for treating patients with heart failure and use a common reporting database (HjerterPlus - HeartsPlus), can become members of the association. Currently, the Heart Failure Clinics Network has twenty public heart failure clinic members

The purpose of the association, according to the articles of association are: 1) To further develop, update and maintain the HjerterPlus database, to use this to report and communicate applications of data gathered by the association for quality assurance and scientific purposes; 2) to draw up and maintain a manual for Heart Failure Clinics, and 3) to create a forum for heart failure clinics to exchange experience on, and to help coordinate educational activities and patient information for, heart failure clinics.

The Heart Failure Clinics Network is managed by a board consisting of six members from the participating heart failure clinics. Members are elected for two years by the general meeting with the option of standing once for reelection. The chairman of the board is elected by the board. The ultimate authority of the association is the general meeting.

It follows from the articles of association that the association cannot charge its members fees. On the other hand, the association's board can decide to apply for public and private financial support to cover the association's expenses.

It is clear from the case that the Heart Failure Clinics Network has received sponsorship from two foundations and 11 pharmaceutical companies. The chairman, Per Hildebrandt, has told the Agency that sponsorship moneys were paid into a research account held by the accounts department at Roskilde Hospital and audited by Region Sealand. The chairman of the network is authorized by the board to pay the network's day-to-day expenses within a framework set by the board. According to Per Hildebrandt, sponsors have no influence on the operations and tasking of the network.

According to section 21 (1) Advertising Order, financial inducements shall not be given or offered to healthcare professionals for promotion purposes or otherwise to promote the sale of medicinal products, although cf. section 2, section 23, section 25, section 26, section 29 and section 30. The prohibition in section 1 does not cover gifts of insignificant value when the gift can be used for the recipient's profession or to mark a red-letter day for recipients, for example an appointment or major birthday, cf .section 21 (2). No maximum limit is set in the Advertising Order for the value of such gifts but if the total value from a donor to the individual health care professional does not exceed DKK 300 in a calendar year, the Agency's view is that the gift(s) should be lawful.

The Agency finds that section 21 (1) should be construed broadly. The clause also covers "image gifts" from pharmaceutical companies to healthcare professionals. Accordingly, it makes no difference if the gift is directly associated with marketing a certain medicinal product since it has to be assumed that the company's interest in providing such financial benefits is based on a desire to market the company and its products, regardless of whether the gift is for example provided as individual support for a healthcare professional's research or as support for operating expenses for a private association of healthcare professionals (association or the like).

The Agency finds, in contrast, that it is lawful for pharmaceutical companies to provide financial support for public hospitals, groups of public hospitals/hospital departments and for specific hospital departments. This applies to support for equipment and research and when money is given to the hospital, association or individual hospital department which can then make use of the money. In this situation, this would be a gift to a public hospital or a group/collaboration consisting of public hospitals, not for a healthcare professional or an association of healthcare professionals.

The agency finds that pharmaceutical companies can lawfully provide financial support to the Heart Failure Clinics Network. The Agency has especially considered that the financial support is given to an association consisting of public hospital departments (heart failure clinics) and that the funds go to running the association's professional activities. Accordingly, this does not involve providing funds to healthcare professionals or an association of healthcare professionals. The Agency has further considered that fact that

external sponsors have no influence on the operations or tasking of the network, including what specifically sponsorship funding should be used for.

The Danish Medicines Agency held the opposite in a third case of support being given to Dansk Knoglemedicinsk Selskab (The Danish Bone Society). Here, among other things the Agency stated as follows:

"Art*. 1 of the "Statutes of the Danish Bone Society" states that the purpose of the society is to promote and coordinate hard tissue research and hence related research in Denmark, including holding scientific meetings".*

It follows from the statutes of the Danish Bone Society that the board consists of a chairman, a secretary, a treasurer and four other members. At least for the board's membership must either be doctors, dentists or veterinarians. It follows from the same clause that the board runs the company's day-to-day operations. The company's website (www.dkms.dk) states that all members of the board of management are doctors. The general meeting is the ultimate authority of the company cf. section 7 in the statutes of the Danish Bone Society.

Section 10 of the statutes of Danish Bone Society state that the company's operations are funded by way of fees, gifts and returns on these. An annual general meeting may decide to transfer part of the company's funding into funds. If the company is offered external financial funding for research purposes, the funds are administered by the board. The board also generally adopts guidelines for allocating moneys from any funds established by the general meeting, cf. section 11 of the statutes of the Danish Bone Society".

"Eli Lilly and Nycomed each provided DKK 100,000 in January 2007 in financial support for the Danish Bone Society's Database for PTH treatment". It is clear from the case that funds were provided to cover salaries, software development and software expenses associated with operating the database. The database is owned and operated by Danish Bone Society.

Pursuant to section 8 (1.1) of the then Advertising Order, financial inducements including discounts, bonus payments or the like or benefits in kind must not be given, offered or promised to healthcare professionals for promotion purposes or otherwise to promote sales of a medicinal product. The prohibition in section 8 (1.1) does not relate to benefits in kind of insignificant value associated with the exercise of the healthcare professional's duties, cf. section 8 (2) of the Order. The Agency finds that the clause contains a comparable prohibition against providing gifts to healthcare professionals and private associations of healthcare professionals as described above.

The Agency's immediate view is that the financial support provided by Eli Lilly and Nycomed to the Danish Bone Society contravened section 8 (1) Advertising Order. The Agency has especially taken into consideration that considerable financial support has been provided for a private association where the members are (mainly) doctors with a shared professional interest and which has a management consisting of doctors and makes dispositions over funds for private (professional) purposes. Alternatively, payroll and other expenses for the database should have been borne by the members (via subscription fees) or the Society would have been directed to seek funding from other external parties (foundations, etc.). The

Agency's view is that in reality this involves gifts to a private association of doctors in breach of the provisions. The funding is not covered by the exemption provisions of the Advertising Order".

1 Order No. 793 of 10 September 2001 on Advertising for medicinal products, as amended by Order No. 58 of 6 February 2002 and Order No. 468 of 3 June 2003

2 Order No. 272 of 21 March 2007 on Advertising, etc., for medicinal products

3 Order No. 793 of 10 September 2001 on Advertising for medicinal products, as amended by Order No. 58 of 6 February 2002 and

Order No. 468 of 3 June 2003

ANNEX C (to "The pharmaceutical industry's code of promotion, etc., for medicines aimed at healthcare professionals"):

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

The following guidelines for internet websites available to healthcare professionals, patients and the general public in the EU have been transformed from Annex B to EFPIA's (European Federation of Pharmaceutical Industries and Associations) code on the promotion of medicines to, and interactions with, healthcare professionals ("EFPIA HCP code"), and adapted to relevant Danish rules, including the pharmaceutical industry's code on promotion, etc., for medicines aimed at healthcare professionals (Promotion code) and relevant Danish legislation.

The guidelines are a supplement to the EFPIA HCP Code and the Promotion code and are regarded by ENLI solely as recommendations for good practice on the internet. It may be necessary for associations and companies to modify the guidelines in this annex to meet the particular requirements or needs og the company. Associations and companies are therefore urged to introduce additional measures which extent beyond the provisions of this annex. It must be emphasized that companies are responsible for always ensuring they comply with ENLI's rules and Danish legislation in this area.

By way of introduction, it should be noted that it follows from section 9 (1) of the Order on Advertising, etc., for Medicinal Products (Advertising Order), that promotion for medicines on the Internet is covered by the same rules as any other promotion for medicines. In accordance however with the guidance to section 8.1 Advertising Order, the rules should insofar as necessary be read and interpreted with due consideration for the special nature of the Internet. According to the guidance to the Advertising Order, the rules also apply to mention of medicinal products on for example pharmaceutical companies' websites when any such mention can be regarded as falling within the concept of promotion.

Section 9 (2 - 3) Advertising Order further provides that promotion for medicines on the Internet should be regarded as promotion to the general public since the information is available to anyone. **This does not apply however if the access to the information is restricted by way of the requirement for a personal password or in some other effective way limited to healthcare professionals.** It is not sufficient for the website to state that the content is intended for healthcare professionals or that users themselves can enter a password to get access to the website. At the very least, user identification is required by way of a unique user name, authorisation number, or the like, and an associated individual password. This may involve a system specially adapted for the website concerned or a general system such as the user's digital signature cf. section 8.1 in the guidance to the Advertising Order. The company (web sponsor) is thus apparently required to ensure that the user concerned is a healthcare professional. This may be done on the basis of the person's name, work address and for doctors, their authorisation ID with reference to for example the Danish Health and Medicines Authority's listing of doctors with Danish authorisation. When no authorisation number is available, the company may use a statutory declaration to ensure that the person

concerned is a healthcare professional. Reference is also made to the guide on the use of social media drawn up by ENLI.

Section 1. 'Transparency of website origin, content and purpose.
Each website shall clearly identify:

(a) The identity and physical and electronic addresses of the website's 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.

Section 2. Content of Websites

(a) Information included in the website shall be regularly updated and shall 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 section 1(3) Advertising Order, including any measures to promote sales; and

(iv) Non-promotional information for patients and the general public about specific medicines marketed by the company.

Re: (i) General information about 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 R&D programmes, discussions of regulatory developments affecting the company and its products, information for prospective employees, etc. If the content of this information is regarded as promotion for a medicinal product, the relevant advertising or

promotion rules will apply, including the rules of the promotion code and legislative requirements in general, cf. also the introduction.

Re: (ii) Health information: Websites may contain non-promotional (non-advertising) 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. Websites may provide an edited and abbreviated, officially approved information about a medicinal product by way of the patient leaflet, product summary or other publicly accessible assessment reports cf. section 2 (8) Advertising Order, provided that the information is made available in such a way that users have to actively search for the information (”pull”). If the website links to information about the medicinal product that is not unedited and unabbreviated officially approved information, such as information about the medicinal product at www.min.medicin.dk, the Danish Health and Medicines Authority would regard this as door-to-door information intended to promote sales and usage of the medicinal product, which would conflict with the rules. However, links to the home page of www.min.medicin.dk are permitted. Relevant information may be provided on alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require the use of medicinal products. Websites containing health education information must always advise persons to consult a healthcare professional for further information.

Re: (iii) Information to healthcare professionals: All promotion for and communication on medicinal products on websites intended for healthcare professionals (as defined in section 1 (3) Advertising Order) must comply with the promotion rules, including the Promotion code and relevant applicable sector codes (as defined in the EFPIA HCP Code cf. also the guidance on section 2 (1) Promotion code on "Activities outside Denmark") and relevant legislation relating to the content and format of advertisements and other measures to promote the sales of medicinal products. It must be clearly stated that this information is intended for healthcare professionals and that access to the website is restricted as described in the introduction.

Re: (iv) Non-promotional information for patients and the general public: Except as required by Danish legislation and rules, websites may include non-promotional information to patients and the general public on medicinal products distributed by the company. For prescription medicines, however, there is a restriction in that websites that provide public access may only reproduce unedited and unabbreviated officially approved information about a medicinal product by way of a package leaflet, product summary or publicly accessible assessment reports issued for example by CHMP (Committee for Medicinal Products for Human Use) or by a relevant competent authority, cf. section 2 (8) Advertising Order, provided that the information is given in such a way that users are actively required to seek information (”pull”). These documents may be posted on the website or a clear link to the documents may be inserted. In Danish Health and Medicines Authority practice, the company (web sponsor) is also responsible for the content of the first linked external page. The brand name of the medicinal product (the trademark) shall be stated together with the

international generic name. If the website links to information about the medicinal product that is not unedited and unabbreviated officially approved information, such as information about the medicinal product at www.min.medicin.dk, the Danish Health and Medicines Authority would regard this as door-to-door information intended to promote sales and usage of the medicinal product, which would conflict with the rules. However, links to the home page of www.min.medicin.dk are permitted.

Section 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 communicationswith patients or members of the general public, discussion of personal medical matters must be avoided. Personal data must be kept confidential. Where appropriate, replies shall recommend that a healthcare professional be consulted for further information. See also the guidance on section 2 (2.c) Promotion code.

Section 4. Links from other websites:

See section 2 (b) re. (ii) and (iv) above.

Section 5. Website addresses in packaging:

Website addresses on medicinal product packaging are regarded as conflicting with the Order on labelling, etc., for medicinal products (Labelling Order) cf. section 6 and 33. The e-mail address of the holder of the marketing authorisation can be stated but details of web/internet sites are not permitted.

Section 6. Scientific review:

Companies should ensure that the scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the applicable codes. This task can be assigned to the R&D Department established by the company in accordance with section 19 (2) Promotion code or can be done by other persons with the necessary qualifications. If the information directly or indirectly mentions specific medicines, it would probably be regarded as promotion and hence unlawful with respect to the general public, but with respect to healthcare professionals, it should comply with the rules of the Promotion code, including section 5 on compulsory text and effective access controls for the website.

Section 7. Protection of personal data/privacy:

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