GUIDANCE

on

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

The guidance for the pharmaceutical industry's Code of Practice for promotion, etc., of medicinal products aimed at healthcare professionals (Promotion Code) will be kept updated as practice develops or changes. The guidance will therefore be dated and also have a version number. All special abbreviations used are given at the back of the guidance.

NB! You can search the in guidance .pdf file by pressing "Ctrl + F" and entering your search word.

COMMENTARY TO CHAPTER 1 – PRELIMINARY PROVISIONS

Re: Article 1 Scope

New knowledge about medicinal products 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 best product for treating 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 medicine which in the final count benefits everyone.

This is the reason why the legislation permits certain so-called promotion activities, etc., between the pharmaceutical industry and healthcare professionals. This area is heavily regulated to ensure properly ethical relations based on professionalism and patient safety.

Parts of the pharmaceutical industry that are subject to the agreement on ENLI's rules and controls have chosen to go a step further and to supplement the legislation with a series of voluntary rules. The Promotion Code represents the totality of these rules. In a letter dated 15 January 2013 to ENLI, Lif specified that it wished the sector-specific ethical rules in Denmark to be interpreted so that:

- Insofar as possible, they reflect the comparable level in the rest of Europe as a result of the common European code of practice (the EFPIA HCP Code), and
- They reflect the purpose of the rules, based on the principle that from an overall point of view, an activity is not damaging to the industry's credibility and image.

Re: Sec. 1.2

Corresponds to Sec. 5.01 in EFPIA´s 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 taking a 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 mention 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: Sec. 2 (1)

It should be noted that the Medicines Act and the Advertising Order and associated guidance also regulate the areas noted in Sec. 2 (1). The Advertising Order is regulated by the Danish Health and Medicines Authority. ENLI's regulation thus supplements controls on the area by the Danish Health and Medicines Authority which always has, however, 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 rules that are most restrictive on the pharmaceutical company.

It should be emphasized that not all issues arising from Danish legislation have been included in the Promotion Code. So for example the provisions of the Advertising Order on price credits and cost-based discounts for pharmacies, etc., are not covered by the Code.

The fact that in some places the Promotion Code is worded differently than Danish legislation is therefore not due to Danish law not applying, since it is a minimum requirement for Danish law to be complied with, regardless of the wording of this Promotion Code.

About corporate responsibility:

The Promotion Code only applies to "pharmaceutical companies" as defined in Sec. 3.2, i.e. not to companies or legal entities that have not signed up to the agreement and are not members of Lif, IGL or PFL. This means that other companies, including national and international group companies are not subject to ENLI's rules and cannot be fined by ENLI since they are not parties to the agreement on ENLI. Similarly, neither can "pharmaceutical companies" noted in Sec. 3.2 be fined for activities that they are not themselves party to or have legal liability for (e.g. activities relating to Denmark by foreign companies associated with a group).

ENLI's view is that a company associated with ENLI can only be regarded as having joint liability for the activities of companies associated with a group if the associated company is regarded as being the co-organiser of these. This means that the company concerned must be sufficiently involved in the activity concerned. ENLI's assessment is that the company must have taken clear, direct steps in developing and/or undertaking the specific activity. The company could perfectly well assist the group member with knowledge about how the Danish rules should be construed so as to ensure compliance with them. On the other hand, if more active steps are taken in developing or undertaking the activity, the company concerned will be moving in the direction of liability as co-organiser. This could for example be by way of the company assisting in the selection of Danish healthcare professionals for participation in a specific medical event or if the company were to have influence on the content of a professional program or proceedings in a professional event.

In contrast, corporate responsibility applies in accordance with EFPIA´s HCP Code, cf. EFPIA´s 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 there has bee no clarification.

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

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 they also predicate

that operations are aimed wholly or partially at Danish "healthcare professionals" or involve activities in Denmark.

Where Danish healthcare professionals are concerned, Greenland and the Faroes are NOT regarded as part of Denmark in this respect, nor do they involve Danish healthcare professionals.

As noted below, the EFPIA HCP Code requires compliance with the national rules of the organiser as well as the rules of the state in which an event is held. Clearly, it would be difficult for ENLI to monitor compliance with international laws and codes (where for example a Danish subsidiary runs an event abroad). Nevertheless, companies are required to do their best to ensure compliance and the authorities of the country concerned have a responsibility to ensure that there are controls on compliance in place in the legislation of that country.

Accordingly, it follows from the preamble to 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 promotional activities or interaction to comply with each of the following applicable codes:

a) In cases of promotional activities or interaction undertaken, sponsored or organized by or on behalf of, or in conjunction with, a company located in Europe, the national code of the member association in the country in which such a company is located must be complied with; or in cases of sales activities or interaction undertaken, sponsored or organized by or on behalf of or in conjunction with a company located outside Europe, the EFPIA HCP Code must be complied with and

b) The national code of the member association in the country in which the sales promotional activities or interactions are being undertaken.

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 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 advertising medicinal products in the Medicines Act, Advertising Order and the associated guidance only apply, according to the Danish Health and Medicines Authority, to commercial activities carried out in Denmark and to advertising on the internet originating from pharmaceutical companies established in Denmark.

Re: Sec. 2.2

General comments re: Sec. 2.2): These rules naturally do not regulate the general prohibitions set forth in Sec. 2 of the Advertising Order that is situations in which advertising is totally prohibited. This ap-

plies for example to advertising medicinal products that cannot be lawfully traded or supplied in Denmark.

Re: Sec. 2.2 (a): This therefore also applies to pharmaceutical companies that sell other things than medicines, when the commercial activity concerned does not relate to advertising for a medicinal product but to the company's other products. If the opposite were to apply, these companies would be precluded from participating and competing on an equal footing with their competitors at for example medical technology congresses; that is subject to other advertising legislative rules, etc. (there are special rules for regulating medical devices, skincare products, etc. in their respective product areas which are controlled by regulators for these areas).

Re: Sec. 2.2 (b): If advertising is not directed at healthcare professionals, it would be comparable to advertising to the general public, which is not regulated by the Promotion Code but is regulated by the Advertising Order which is controlled by the Danish Health and Medicines Authority. 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.

Re: Sec. 2.2 (c): Sec. 2 of the Advertising Order states that the rules on advertising do not apply to:

1. *Labelling of medicinal products and package leaflets*

   This area is regulated by the Order on Labelling, etc., medicinal products, on which there is also guidance on labelling, etc., for medicinal products, including whether medicines are subject to supplementary surveillance. The Order and guidance for the time-being in force can be found at www.retsinfo.dk.

2. *Individual correspondence, if necessary accompanied by documents of a non-promotional nature that 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. *Necessary specific information or documentation that serves safety, and not advertising, purposes.*

   According to the guidance on the Advertising Order, this might for example be information about changes to packaging, new adverse reactions or production faults. 'Safety purposes' should be interpreted broadly so that for example information on how a medicinal product should be opened so as to prevent its suffering a serious physical impact would satisfy the definition of safety purposes within the meaning of the concept 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 profession-

als 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 really contains advertising for a medicinal product.

4. *Price lists, product catalogues, etc., containing no other information about the medicinal products than their names, pharmaceutical form, strengths, pack sizes, prices and images of the product packaging, including price lists, product catalogues, etc., published on the internet with a purpose to e-sales for medicines.*

5. *Informative material on health and disease provided there is no direct or indirect reference to specific medicinal products.*

   An example of material that would not be regarded as advertising for a medicinal product is information material for adults about children and depression, for example leaflets or websites where there is no direct or indirect reference to specific medicinal products. According to ENLI, specific medicinal products are construed as those referred to by an invented or generic name. If a generic or invented 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 the 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 Appeals Board held 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 would constitute medicinal product advertising.

6. *Patient information leaflets accompanying a prescription as part of prescribing a medicinal product, or supplied by the pharmacy when dispensing medicinal products, which only contain factual information of importance to patients and their relatives. The information in the leaflet must not conflict with product summaries.*

   Patient information leaflets can be supplied to patients in printed and digital format. Patient information leaflets are regarded as advertising if they contain statements, information, images, illustrations, etc. that are exclusively or mostly for marketing purposes. A patient information leaflet is for example regarded as advertising if it contains subjective claims for a medicinal product. Claims could for example be that the medicinal product is fast, it is effective, easy to handle, the best in its class, the most preferred medicine, easier to administer than competing medicines or it is one of the safest medicines available. As noted above, patient information leaflets must only contain objective information of significance to patients

and their relatives. Patient information leaflets should objectively describe how the medicinal product works and its side-effects/risks.

Patient information leaflets supplied to healthcare professionals are regarded as medicinal product advertising to healthcare professionals. This means that providing patient information leaflets is assessed in this connection in accordance with the rules of the Promotion Code and must therefore be accompanied by compulsory text. A covering letter must therefore also comply with the requirements of the rules of the Promotion Code. It should be noted that ENLI does not check whether the actual patient information leaflet possibly contains advertising for a medicinal product to the general public. On 3 November 2011, Lif reported that the previous Danish Medicines Agency (now the Danish Health and Medicines Authority) had held in three specific rulings that patient information leaflets did contain advertising for specific medicines to patients in contravention of Sec. 66.1.1 of the Medicines Act. The Danish Medicines Agency subsequently specified their practice/guidance in this area to Lif.

Patient information leaflets are not required to be reported, cf. Sec. 21.3 of the Promotion Code.

7. *Press releases containing brief, objective information on a medicinal product which has general news value, with the press as the target group and circulated or made available to a multiplicity of journalists or the media with a view to journalistic review and processing prior to publication.*

A **press release** will not be considered as a press release if it contains non-objective content, misleading information or appears in a very obvious way as advertising. It will be regarded as an advertisement for the medicinal product. If payment is made for a press release to be printed in the media, it is also regarded as advertising. A pharmaceutical company can make a press release available to the media in the press room of its website for about three weeks. After that, it will no longer be regarded as having general news value and may after a specific assessment be regarded as advertising.

8. *Unedited and unabbreviated reproduction of a package leaflet, the officially approved product summary or publicly available evaluation report cf. Sec. 72.1 of the Medicines Act, or an image of a medicine pack on condition that the information is made available in such a way that users have to actively search for the information*

This means that a company can for example post a list with the names of its medicinal products on its website with links to product summaries and patient 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 advertising when pharmaceutical companies issue **scientific articles** (or **reprints**) on clinical trials on medicines to healthcare professionals at their request, provided that these articles are sent

without comment and without supplementary material. The 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 on different medicines.

Re: Sec. 2.2 (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 are therefore not basically considered by ENLI. This also applies to sponsorship of clinical trials. However, the rules on venues, hospitality, etc., in accordance with Sec. 13.3-10 and the rules for the use of consultants and openness in these rules apply, cf. Art. 15 -16, also for clinical research.

It should be noted that the Danish Association of the Pharmaceutical Industry (Lif), Organisation of Danish Medical Societies (LVS) and Danish Medical Association (Lf) have made a joint declaration on clinical drug trials and non-intervention trials, in order to clarify the values that form the basis for collaborations between clinicians and pharmaceutical companies on clinical drug trials and non-intervention trials. It should be noted that contravention of the joint declaration can be processed by ENLI in accordance with specific guidelines drawn up by Lif.

Re: Article 3 Definitions

Re: Sec. 3.1

Advertising for medicinal products should be construed in accordance with Sec. 1.1 of the 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 Danish Health and Medicines Authority's Guidance on the Advertising Order defines advertising for medicinal products is interpreted broadly in accordance with the provisions, working and main purposes of the advertising rules which provide protection among other things for public health. The concept of advertising 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 advertising, 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's assessment is that the above ruling indicates an obligation for pharmaceutical companies to ensure that in writing about a pharmaceutical company's medicinal products in the social media, such as Facebook pages set up by the company itself, third parties comply with the rules on advertising. Pharmaceutical companies should therefore regularly monitor such a page. As part of this, it should be emphasized that the Promotion Code is only applicable if ac-

cess to the social media in use is restricted to healthcare professionals either by way of a personal code or in some other effective way. If not, the page would be publicly accessible and then the rules on advertising to the public in the Advertising Order would have to be complied with. It follows from the guidance to Sec. 8.1 of the Advertising Order that the party responsible for the advertisement is required to ensure effective access control so that only healthcare professionals have access to the site. On Facebook, a page can be set up to which there is generally no public access and healthcare professionals can then be invited and given individual access to the site. ENLI's view is that the Promotion Code means that companies cannot basically be held accountable for a third party mentioning competitors' products on the pharmaceutical company's site.

The fact that the concept of advertising should be interpreted broadly can further be seen directly from the guidance to Sec. 5.6 of the Advertising Order. Sec. 22 of the Advertising Order (prohibition against giving or offering financial benefits to healthcare professionals for advertising purposes) states that it also covers "image gifts" from pharmaceutical companies to healthcare professionals. *"It thus makes no difference whether or not the gift is directly related to marketing a certain medicinal product since the company's interest in offering such financial benefits must be assumed to be justified by a wish to market the company and its products. Consequently, image gifts shall also be regarded as being given for advertising purposes."*

Advertising accordingly covers all kinds of advertising, regardless of the medium, including but not limited to, written advertising activities, direct mail, **promotional activities 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 a healthcare professional may also be regarded as advertising, including a request or confirmation of a meeting in accordance with an appointment, cf. Sec. 9.3, a request for participation in an advisory body or expert group or otherwise. In other words, the medium used for advertising is irrelevant; cf. also IFPMA Code, Art. 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 advertising.

- The Danish Health and Medicines Authority has stated that advertising for a medicinal product is involved if the pharmaceutical company provides a direct link on its website from the name of its product or the active ingredient to information among other things on the indications, prices, pack sizes and reimbursement for the medicinal product at min.medicin.dk. The Danish Health and Medicines Authority regards the 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 home page at min.medicin.dk, since from there users have to navigate to the information they find relevant. On 28 May 2014, the Danish Health and Medicines Authority stated that a direct link to the head office's front page of their press releases from the Danish company's website was not the same as the above advertising situation.
- All activities **regardless of the medium** are covered by the concept of advertising. This means that invitations to medical events can be advertising. However on 31 January 2012, the Ap-

peals Board held 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. Advertising for a medicinal product could be involved if special product advantages have been emphasised for one or more groups of medicines when notifying for example groups of medicines. Be aware in this connection that giving a generic name (active ingredients) or invented name (product name) in the invitation means that it will be regarded as advertising medicinal products.

When running a professional event for healthcare professionals, a 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 or not they come from and are presented by an independent third party hired by the pharmaceutical company. However, ENLI's view is that presentations made by independent healthcare professionals are basically regarded as scientific presentations by virtue of their professional background in healthcare. They are thus not regarded as being for advertising purposes unless be the pharmaceutical company has influenced the presentation and must therefore be regarded as taking ownership thereof. By virtue of its responsibility for the event as a whole, the company is always however required to draw attention to the fact if their medicinal products are mentioned in contravention of the rules, for example outside the approved indication (**off-label**).

However, ENLI asses that there is no requirement to report **slides drawn up by a third party** unless the company has been influential in preparing them. Reference here is made to the ruling of the Appeals Board in AN-2012-3824, according to which a pharmaceutical company must in no circumstances exert influence on evaluations made by a healthcare professional or on the scientific documentation that the healthcare professional employed by the company to make a presentation that the professional finds suited for elucidating the professional health issue concerned, unless the medicinal product is mentioned in contravention of the legislation or the Promotion Code. If a pharmaceutical company decides to present slides prepared and used by a third party during their presentation, the material will be regarded as advertising the company, irrespective of whether presentation was made at the meeting, subsequently or during calls by medical representatives, and the material must therefore be reported.

Attention is drawn, however, to the fact that if a third party's material only contains information about disease without specifically mentioning the medicinal product, the material may be exempted from the rules of the Promotion Code, cf. Sec. 2.2 (c).

From time to time ENLI receives notice of material that does not constitute advertising matter. For example Christmas cards have been notified which only give the pharmaceutical company's name and a greeting to the recipient. Such material is basically not advertising for a medicinal product and is not required to be notified in accordance with Art. 21.

Healthcare professionals are defined in Sec. 1.3 of the Advertising Order as: *"doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmaconomists, midwives, bioanalysts, clinical dieticians, radiographers, social and health workers and students of these professions.""*. In contrast, for example psychologists, biologists, physiotherapists and ergotherapists and medical secretaries are not included in the definition and accordingly the latter are equated with the "general public", which is understood to include all those not defined as healthcare professionals, cf. Sec. 1.2 of the 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 given healthcare professionals are actually working in their profession.

Re: Sec. 3.2

Pharmaceutical companies are defined in Sec. 1.4 of the Advertising Order as "companies licensed in accordance with Sec. 7.1, or Sec. 9.1 of the Medicines Act, except for public hospitals."

The three associations' websites respectively state which pharmaceutical companies are members of the associations - Lif, IGL and PFL. There is a list of associated companies at www.enli.dk. The rules also apply to third parties operating on behalf of these companies, such as consultancies, including for example advertising agencies, communication agencies, etc., that are engaged to be working within the scope of these rules.

Re: Sec. 3.3

The definition of **medicinal products** here follows the definition in Sec. 2 of the Medicines Act, except for veterinary medicines that are not subject to the rules of this code.

Re: Sec. 3.3 (c): This merely codifies ENLI's practice and follows directly from Sec. 1.3 of the Medical Devices Order.

COMMENTARY TO CHAPTER 2 – MARKETING AUTHORIZATION AND REQUIREMENT FOR OBJECTIVITY, ETC.

Re: Article 4 Marketing authorisation and requirement for objectivity, etc.

Re: Sec. 4.1

Sec. 3 of the Advertising order states that no advertising shall be made for:

1) Medicinal products that cannot be legally traded or dispensed in this country, cf. Sec 64.1 of the Medicines Act
2) Magistral products, cf. Sec. 64.2 of the Medicines Act
3) Medicinal products for non-clinical and clinical trials when no marketing authorisation has been awarded for the products, cf. Sec. 7 of the Medicines Act
4) Medicinal products sold or dispensed in accordance with a special authorisation in accordance with Sec. 29 of the Medicines Act, and
5) Serums, vaccines, specific immunoglobulins and other immunological test products that are not covered by a marketing authorisation and which are sold or supplied by Statens Serum In-

stitute (SSI) or the National Veterinary Institute at the Technical University of Denmark in accordance with Sec. 30 of the Medicines Act.

The provisions of Sec. 4.1 of the Code are based on EFPIA´s HCP Code Sec. 1.01 and Sec. 64.1 of the Medicines Act, cf. Sec. 7 of the Medicines Act and the guidance to Sec. 3.3 of the Advertising Order, which states that a medicinal product can only lawfully be marketed in Denmark when approved by way of a marketing authorisation that is valid in Denmark.

- There are some further requirements for pharmacy-only medicinal products, as set forth in Sec. 77 of the Medicines Act, including the fact that the price of the product must have been notified to the Danish Health and Medicines Authority at least 14 days in advance of the price becoming effective. Advertising activities may start from the date that the price has been notified. If the price has not been published on medicinpriser.dk (tariff), the notified price must be documented to ENLI by submitting advertising matter, by way of a copy of the price notification and confirmation from the Danish Health and Medicines Authority. For radioactive medicinal products, documentation must be provided to ENLI that the price has been notified to the Danish Health and Medicines Authority at least 14 days in advance of the effective date of the price.

It can be difficult to assess whether mentioning a specific medicine before the date of its marketing authorisation (**pre-launch**) amounts to advertising.

- ENLI therefore regards 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 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. Art. 7 of the Promotion Code). Any mention relating directly to the pharmaceutical product is therefore not regarded as mention in scientific studies and data and may therefore be covered by the Promotion Code.
- After the publication date of the Phase III study, ENLI assesses whether the company's mention of a medicine that has been documented as having an effect *could* be advertising since the company will be assumed to be specifically working for a marketing authorisation from that date. This means that the company needs to assess whether mention of the medicinal product after the date of publication is being done on a scientific basis and in a scientific forum (for example at an independent international congress) which in ENLI's view should not be restricted by the workings of the Promotion Code, cf. also the principle in EFPIA´s HCP Code on access to "non-promotional medical, scientific or factual information". Accordingly, in a ruling handed down on 28 May, 2014, the Danish Health and Medicines Authority stated that teaching, or a professional presentation of scientific data or a professional review of studies made on the scientific basis and in a scientific forum, such as an international congress that does not have a purpose covered by the definition of promoting medicinal products, shall not be regarded as a reference to a medicinal product for promotional purposes (see also re: Sec. 13.1 below). If reference relates directly to a medicine and is regarded as promotion, 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 promoting medicines to Danish healthcare professionals.

Further, no advertising is allowed for magistral medicines cf. Sec. 64.2 of the Medicines Act and for certain special medicines, cf. Sec. 3.3-5 of the Advertising Order.

Re: Sec. 4.2

See also Sec. 63 of the Medicines Act, EFPIA´s HCP Code Sec. 1.02 and Art. 3, and Art 4.10 EGA's Code of Conduct on Interactions with the Healthcare Community.

Sec. 63 of the Medicines Act contains certain fundamental requirements for the content and format of medicinal product advertising, cf. also the guidance to the Advertising Order on Sec. 3.1, which states that: *Firstly, advertising must be **adequate**. For instance, an advertisement must contain adequate information so that recipients can understand and assess when and under which circumstances the medicine can and should be used and when not to use it. By contrast, an advertisement is not adequate if it uses such broad terms that it is likely to promote the consumption of a medicine when in fact it is not particularly suitable to use under the given circumstances. The provisions detailing an advertisement must contain a number of compulsory details; see sections 4.4 and 5.1., are based on the requirement for medicines advertising to be adequate.*

*Secondly, advertising must be **factual**. Therefore, medicinal products must not be marketed in the same aggressive and consumption-encouraging manner as general consumer goods. Advertisements for medicinal products must not be designed to or likely to generate unnecessary increases in the consumption of medicines. The advertisement must furthermore be based on professional and relevant information about the medicinal product. Whether an advertisement fails to be factual is determined by assessing the form and content in each specific case.*

*Thirdly, advertising **must not mislead** or exaggerate the properties of a medicinal product. This means that the form and content of an advertising must not lead medicine users and persons prescribing or dispensing medicinal products to form misconceptions about the medicinal product, including its effects, adverse reactions, price, ingredients, etc., disease or treatment. Nor must an advertisement put a medicinal product in a more favourable position than other corresponding and perhaps even more suitable medicinal products. An advertisement for a medicinal product must neither in form nor content mislead or be designed to mislead the persons it is aimed at.*

*Fourthly, the information contained in the advertisement must comply with the approved summary of product characteristics (SPC). **The particulars in the SPC** include information about the composition of the product, pharmaceutical form, therapeutic indications (applications), contraindications, adverse reactions, precautions for use, dosage and warnings, if any. This means that the factual content of the advertisement must not be inconsistent with the particulars of the SPC. It is possible to deviate from the wordings of the SPC to the extent that the requirement for factual information is met. An advertisement may include statements that supplements the information in the SPC, provided they confirm or specify information in the SPC and the information otherwise complies with the SPC. The information in the advertisement must not be misleading or exaggerate the properties of the medicinal product. An advertisement for a medicine must only include information about authorised indications as appearing from the authorised SPC.*

The latter is further supplemented by Article 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 product characteristics."* In a prejudicial ruling, the ECJ held on 5 May 2011 that Art. 87 (2) should be construed as a prohibition against information that conflicts with the product summary, but not a requirement for all information to be contained in the product summary or that information can be omitted 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 Arts. 87 (3) and 92 (2) and (3) of the Directive. The latter requirement is also set forth in the Medicines Act Chapter 7, and Sec. 13. 2 – 3 of the Advertising Order. ENLI also finds that there must be a reference to a legal source, cf. Sec. 7.5. In an overall assessment, an advertisement should thus appear correct, balanced, serious, precise and objective. The advertisement must contain, depending on the conditions, correct, adequate and well-documented information that is not misleading (by way of omission, ambiguity or the like). See also the guidance on Art. 5 and Art. 7. 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 Appeals Board has stated that comparative advertising based solely on product summaries may not always comply with the requirements of this clause. If for example further or more recent relevant data are available, the requirements for adequate 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 for Art. 8.

The use of **patient cases** in pharmaceutical companies' promotional material is not regarded as complying with the requirement in the Promotion Code that the formulation of advertisements should be serious, precise and objective. This is regardless of whether cases are fictional or true, cf. Sec. 4.2. Patient cases may further not be used as constituting the documentary basis for statements made by a pharmaceutical company as part of its promotional activity.

Patient cases are regarded as a subjective graphical claim for a medicinal product when used in a promotional context. A graphic illustration describing an individual effect cannot therefore be used to document its effect on clinical studies that can document how efficacy amongst the general population can be determined. An individual claim would not therefore be in accordance with the general principles of evidence based medicine and since claims must be documented by lawful references, cf. Art. 7, the documentary requirement for such a claim would not be met.

A single patient case cannot express how all patients would react to/benefit from the medicinal product and therefore patient cases do not meet the requirement for objectivity and seriousness in illustrating efficacy.

Patient cases are construed as claim-making direct or indirect product-individual relations based on an image or a series of images. Accordingly a photographic image of objective symptoms of a given disease is not regarded as a potential patient case unless viewed in conjunction with a medicinal product, for example by connecting text or by implicitly implying the efficacy of the medicinal product for symptoms or the disease as a whole.

Using videos of patients is assessed in the same way as images of patients and is basically not regarded as serious, objective marketing. Showing such videos on exhibition stands would thus be regarded as contravening the rules of the Promotion Code.

If it only involves information about health/disease, there is nothing to prevent the use of pictures /patient cases since the restriction solely refers to advertising medicinal products. It should be noted, however, that it is the general impression of the advertisement/material that forms the basis for the overall assessment of whether advertising is involved, and whether the patient cases used contravene the rules. For further information about patient cases, refer to Arts. 7 and 13.1 of the guidance.

Re: Sec. 4.3

The clause corresponds to EFPIA´s HCP Code Sec. 9.03 and is not replicated in the Advertising Order.

COMMENTARY ON CHAPTER 3 – ADVERTISEMENTS

Re. Article 5 Compulsory information

The rule is regulated in EFPIA's HCP Code Sec. 2.01 and the IFPMA Code of Practise Art. 5, and corresponds by and large to Sec. 11 of the Advertising Order, except for Sec. 11.3 regarding the Veterinary Medicinal Products that is not relevant to the present set of rules.

The compulsory information requirement can be met by providing information about the summary of product characteristics (SPC) with supplementary information about 1) reference to medicinpriser.dk, if an advertisement for a pharmacy-only medicinal product is involved; 2) dispensing group; 3) reimbursement rules and 4) the date of the last revision of the advertisement.

Re: Sec. 5.1.1

Sec. 11.1.1 in the Advertising Order states that the **invented name and generic name of medicinal products** must be given. It used to be a requirement in accordance with this clause for the generic name to be stated using the same typeface and in an equally obvious way as the invented name of the product but this requirement was excised with the amendment of the Advertising Order on 1 November 2014.

The Danish Health and Medicines Authority have stated to ENLI that it is sufficient for the generic name to be mentioned once in an advertisement, and that this may also be for example in the compulsory text. The Danish Health and Medicines Authority has further stated that this also applies for example to printed advertisements in which the product summary may be placed elsewhere than in the advertisement provided that the advertisement clearly states whereabouts in a journal, etc., the compulsory text can be found.

On this basis, ENLI's view is that Sec. 11.1.1 in the Advertising Order and Sec. 5.1.1 of the Code are complied with provided that the invented name and generic name are mentioned in the promotional material.

With respect to logos with invented names, the logo may display the invented name by itself if the logo is part of an advertisement which contains the generic name. If not, with the invented a generic name must be stated.

Re: Sec. 5.1.2

The requirement for the name of the holder of the marketing authorisation follows from Sec. 11.1.2 of the Advertising Order.

The requirement for the **name and address** of the pharmaceutical company responsible for marketing the medicinal product in Denmark follows from IFPMA's Code of Practice Sec. 5.1 and is thus stricter than the Danish legislation.

Re: Sec. 5.1.3

It follows from the guidance to the Advertising Order, sec. 5.1(3) that: *"Generally, the wording of the SPC should be included verbatim compulsory information. If the **indication text** in the SPC is so extensive that it would be inappropriate to include it verbatim, it may be rewritten and abbreviated, e.g. leaving out less relevant information. Under no circumstances may the indication text be rewritten in a way that could lead to misunderstandings, including suggesting that therapeutic indications are different or more extensive than indicated in the SPC. If the wording of the SPC is not reproduced verbatim, this must clearly appear from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. The following phrase can be used: "The indications text has been rewritten and/or abbreviated compared to the authorised summary of product characteristics. The summary of product characteristics can be ordered free of charge from xx (the marketing authorisation holder)". This information must be written in a font size which is larger than or otherwise clearly distinctive from the format of the compulsory text. If this information is missing, the advertisement is inadequate and consequently non-compliant with section 63 of the Danish Medicines Act."*

If the indication for a medicinal product is stated several times in an advertisement, for example in a presentation, the full indication for the given type of disease must be given first and where it is most prominent. ENLI accepts the possible use of abbreviated wording from the product summary in the compulsory text provided that important information, which is thought could be significant for the prescribing physician, is not omitted. ENLI accepts the use of abbreviations from this, for example pain relief, depression, etc., in the rest of the material.

Re: Sec. 5.1.4

It follows from the guidance to the Advertising Order, sec. 5.1 (4) that: "*Generally, any contraindications contained in the SPC must be included in the compulsory text. If the* ***contraindications*** *in the SPC are so extensive in length or terminology that it would be inappropriate to reproduce them verbatim, the text may be rewritten and abbreviated, e.g. leaving out less relevant information. Precisely which contraindications to include are based on an estimate. Such estimate must be based on objective criteria with due regard to the requirements of section 63 of the Danish Medicines Act. If contraindications from the SPC are omitted or rewritten, this must appear clearly from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrase listed under therapeutic indications above.*"

Re: Sec. 5.1(5)

It follows from the guidance to the Advertising Order, sec. 5.1(5) that: "*Generally, any* ***adverse reactions and risks****, i.e. interactions, warnings, overdose risks, withdrawal periods, etc., contained in the SPC must be included in the compulsory text. If the wordings of the SPC are so extensive in length or terminology that it would be inappropriate to reproduce them verbatim, the information can be rewritten and abbreviated, leaving out information considered less relevant in the specific case. If the wordings of the SPC are not used, this must appear clearly from the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrasing under therapeutic indications above.*

It follows from Directive 2001/83/EC (as amended by Directive 2010/84/EU) that there is a requirement for medicinal products subject to supplementary surveillance for the summary of product characteristics to state that: "*This medicinal product is subject to supplementary surveillance*". This information is to be followed by "the black triangle" symbol and a suitable standard explanation.

The Danish Health and Medicines Authority has stated that the Advertising Order does not in its present form require pharmaceutical companies to affix the black triangle or other wording relating to supplementary surveillance in promotional material for healthcare professionals, and that it should not be construed as so doing. If the Danish Health and Medicines Authority decides to impose this requirement, the Advertising Order will be amended.

For this reason, ENLI has decided not to require insertion of the black triangle or other wording in this respect prior to any decision by the Danish Health and Medicines Authority or Lif to decide on amendments to this area. This means that at the present time, ENLI will not monitor insertion of the black triangle in promotional material but companies could naturally decide to include information about this in their promotional material.

Re: Sec. 5.1.6

It follows from the guidance to the Advertising Order, sec. 5.1(6) that: ***The dosage*** *must be specified in compliance with the SPC. If the wordings of the SPC are so extensive in length or terminology that it*

would be inappropriate to reproduce them verbatim, the dosage information can be rewritten and abbreviated, leaving out information considered less relevant in the specific case. If the wording of the SPC is not used, it must clearly appear the advertisement. Furthermore, it must appear clearly that the full SPC can be obtained from the marketing authorisation holder. Reference is made to the proposed phrasing under therapeutic indications above. The rewriting of dosage information should be done very carefully as changed wordings must not lead to misunderstandings."

Re: Sec. 5.1.7

It follows from the guidance to the Advertising Order, sec. 5.1(7) that: *"Generally, the **pharmaceutical forms** must be specified. If a medicinal product is authorised in several pharmaceutical forms with different indications, and the advertisement only is only about one of the pharmaceutical forms, the advertisement must include information about that pharmaceutical form only. Further, it must appear from the advertisement that the medicinal product is also available in other pharmaceutical forms, cf. section 11(2) of the Advertising Order."*

Re: Sec. 5.1.8

It follows from the guidance to the Advertising Order, sec. 5.1(8) that: *All of the medicinal product's available **pack sizes** must be indicated. In special cases where only some of the indications are included in the advertisement, cf. above, any pack sizes that are irrelevant to the concerned indications should be omitted.*

Re: Sec. 5.1.9

It follows from the guidance to the Advertising Order, sec. 5.1(9) that: *"If an advertisement for a medicinal product gives information about the product's **price**, the price indicated must as far as possible be current, i.e. ruling at the time the advertisement reaches the recipient, cf. section 63of the Danish Medicines Act. An advertisement that compares prices is only adequate if it contains information about the current prices subject to the price comparison, cf. section 63 of the Danish Medicines Act*

For pharmacy-only medicinal products, the Advertising Order lays down in Sec. 11.1.9 that there must be a reference to the current price listed on medicinpriser.dk. Accordingly, there is no requirement for the Register Price, incl. VAT (AUP) or another price such as the Pharmacy Purchase Price (AIP) or the Retail Price (ESP) to be stated.

For non-pharmacy-only medicinal products there is no one single price corresponding to AUP or ESP, and it is not possible to be certain that a guideline price is given on www.medicinpriser.dk (tariff), since shops may decide to use another price. The wording of Sec. 11.1.9 of the Advertising Order only appears to refer to pharmacy-only medicinal products and accordingly ENLI does not require a statement of prices or reference to www.medicinpriser.dk for non-pharmacy-only medicinal products. It should however be clear from the compulsory information in the advertisement that it concerns a non-

pharmacy-only medicinal product, which could for example be done by way of the requirement to indicate the dispensing group, cf. Sec. 5.1.10 of the Promotion Code.

ENLI's view is that when stating prices in promotional material, these should insofar as possible be current, i.e. applicable at the time the advertisement reaches the recipient. The price is to be either AUP (Register/List price) or ESP(Retail price).

Re: Sec. 5.1.11

It follows from the guidance to the Advertising Order, sec. 5.1(11) that: "Whereas *the advertisement must include information about any* ***general reimbursement*** *available for the medicinal product, it should not include information about the possibilities of obtaining special individual reimbursement. If, in exceptional cases, there is reason to include information about individual reimbursement, e.g. single reimbursement, the advertisement must explicitly state that any reimbursement is individual and granted upon application only. All compulsory information must appear in a manner so clearly that the advertisement's natural target group has no trouble reading it, cf. section 11(4) of the Advertising Order."*

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

Re: Sec. 5.1.12

The requirement to **date** advertising matter derives from Art. 5.1 of the IFPMA Code. This rule is further set forth in Sec. 13.1 of the Advertising Order.

ENLI requires dates to be stated clearly, giving the month and year, and dating should normally relate to the date of transmission. Separate dating is unnecessary in advertisements if the magazine clearly gives a month and year.

Re: Sec. 5.2

The clause corresponds to Sec. 11.4 of the Advertising Order.

The Compulsory information must be easily **legible**. Legibility depends among other things on the 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 **correlate.** Product information must therefore not be separated from the advertisement but must follow immediately afterwards.

- If for practical reasons the compulsory text cannot (for example due to the advertising format) be placed in direct conjunction with the advertisement, ENLI accepts:
    - in printed media, a separation of at most three pages provided there is a clear reference in the advertisement to where the compulsory text is to be found.

- when using a roll-up, poster or the like, for example in meetings, the compulsory text on the roll-up, poster or the like to be replaced by visible information that: "The compulsory text is freely available on the stand."
- In electronic advertising, a direct link to the compulsory text from all pages in the material (including the front page), max. one click.

The advertisement must however, regardless of whether it is on a roll-up, poster or the like, comply with the Promotion Code, including the requirements for an integrated objective basis for comparison in comparative advertising, cf. Art. 8.

Re: Sec. 5.3

The clause corresponds to Sec. 11.2 of the Advertising Order.

Re: Article 6 Reminders

A comparable rule is given in EFPIA's HCP Code Sec. 2.02.

The rule corresponds to Sec. 12 of the Advertising Order, the so-called "**reminder rule**". In the guidance on this, s. 5.3 states that: "*Advertisements that are directed only at healthcare professionals may be limited solely to the name and common name of the medicinal product, cf.* section *12 of the Advertising Order. If other information is included, e.g. indications or prices, the advertisement falls outside the scope of this provision, which means all compulsory information must be included. Company name and logo that identify the sender of the advertisement can be included, however.*"

Logos can therefore basically also be used in reminders.

- However, a logo may *not* be used in a reminder if the logo in any way indicates or refers to the indication/use of the medicinal product, for example if the logo shows a bone and the product is for osteoporosis, or in some other way makes a reference to the product. In such case, the ordinary rules on advertising apply and all compulsory information must be included.

Note the prohibition against gifts in Art. 12, according to which pharmaceutical companies may no longer give, offer or promise gifts to healthcare professionals, including so-called gimmicks such as ballpoint pens, paper pads, etc. For more details on this, see the guidance to Art. 12 of the Promotion Code. Accordingly, the practical importance of the 'reminders rule' in Art. 6 will be significantly minimised in future.

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

Re: Article 7 Information material and documentation

By way of introduction, attention is drawn to Sec. 17 of the Advertising Order on retaining advertising material, which states that the party advertising a medicinal product shall keep a copy of, or other documentation for, the advertisement, cf. Sec. 68.1 & 3 of the Medicines Act and that the advertisement must be in print or a commonly accessible digital format. Documentation for the advertisement must be retained for two years, cf. Sec. 68. 2 of the Medicines Act. It also states that in addition to the actual advertisement, information is to be retained on:

1) The target group of the advertisement, i.e. key individuals at whom the promotion has been directed

2) The distribution system

3) A schedule of the media, where the advertisement was published and

4) The period of time for which the advert was in use.

Re: Sec. 7.1

The provisions of Sec. 7.1 correspond to parts of the EFPIA HCP Code's Sec. 3.01-3.03 and are not given in this form in the Advertising Order. The clause supplements Sec. 63 of the Medicines Act and the guidance for the Advertising Order, sec. 3.1.

Advertisements must not exaggerate the medicinal product's properties. The advertisement must contain, according to the circumstances, correct, adequate and well-documented information that is not misleading (by way of omission, ambiguity or the like).

The use of **patient cases/case histories** in pharmaceutical companies' promotional material is not regarded as complying with the requirement in the Promotion Code that the formulation of advertisements should be serious, precise and objective. This applies regardless of whether cases are fictional or true, cf. Sec. 4.2.

The use of patient cases/case histories, including pictures illustrating the effect on an individual patient on the basis of a medicinal product does not also comply with the requirements of documentation. For more details of patient cases, please see the guidance to Sec. 4.2 and Sec. 13. 1.

No documentation is required with respect to issues that are:

1) Stated in the approved summary a product characteristics (although reference is required to the summary of product characteristics).
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 (now Medicin.dk).

In contrast, the following information does require documentation.

a) Emphasis on **special product benefits**.

- If special product advantages are emphasised, that are not mentioned in the product summary, or which cannot be regarded as being common knowledge amongst medical professionals, documentation must be provided that directly supports the information given.
- 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", “easy to use” or in other ways has special benefits, there must be documentation for the statement.
- ENLI's practice is for the term "effective" or "effectively" only to be used when referring to almost 100% healing, for which there must be documentation. For treating symptoms, ENLI will accept that a medicine is effective if practically 100% of patients become symptom-free (and not just have symptoms relieved).
- 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 with Sec. 4.2 of the 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 medicine advertising provided Danish conditions and Danish prices are used and 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: Sec. 7.2

This clause corresponds to Sec. 13.1 of the Advertising Order.

Re: Sec. 7.3

Sec. 7.3 corresponds to Sec. 13.2 of the Advertising Order. The clause further implements the EGA’s Code of Conduct on Interactions with the Healthcare Community, Sec. 4.10.

References must be true and must include references 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: Sec. 7.4

This clause derives from the EFPIA´s HCP Code Sec 3.06 and 4.01 and corresponds in part to the Advertising Order Sec. 13.3.

Figures and tables taken from a reference must be faithfully stated with respect to the message in the reference employed, without omissions or distortions. A precise reference must also be given to the source.

> Depending on the circumstances, companies can accordingly make changes when stating the source material provided that this is done without significant omissions or distortions and the message is faithfully reproduced. Accordingly, the addition of arrows, etc. is not permitted but depending on the circumstances, changes to the colouration of figures in tables is acceptable provided that there is no colour loading and thus understanding is not influenced in the direction of product names or degrading a competing product. Colour changes can thus only be used to make appearance more "inviting," meaning for example that it would not be acceptable to change the colour of a figure or table for the company's own medicinal product to green and the competitor's to red.

Companies may only draw up their own figures and tables of results or messages in source material if such graphical reproductions are not found in the source material.

- In such cases, a figure in a table can be drawn up provided that the new figure or table precisely reproduces the results from the reference without omissions or distortions. It is therefore important for figures or tables to faithfully reflect the message in the source material. It should also be clearly stated that the figure or table has been constructed by the company on the basis of data faithfully reproduced from the source material.

Re: Sec. 7.5

This clause corresponds to Sec. 13.4 of the Advertising Order.

- The term "**recognised**" is not defined in the guidance to the Advertising Order. However, 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 Organization of Danish Medical Societies (LVS, formerly the Danish Medical Society) would also be regarded as recognized works.

- The concept of "**independent**" is to be construed in accordance with the guidance on the Advertising Order, sec. 5.4 which states that: *"Independent' means that the entity publishing the publication or journal has no interest in neither the sale nor any other promotion of medicinal products".* 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(s) with no personal interest cf. in this connection also how 'independent' above is construed, i.e. a 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.

The published article being cited should be able to demonstrate a pronounced product benefit. Emphasizing a positive statement about the medicinal product in the article would not be acceptable if the overall study 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 general 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. overall statistical data processing from several medical trials, can be used as documentation provided that there is full medical cover for the statements made and provided that the study has been published an a peer-reviewed scientific journal, cf. the requirements for this clause.

Casuistics (public description of an individual case of disease) cannot be used as documentation.

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

The details given in an advertisement must be in accordance with the product summary.

The following materials are, in ENLI's view, generally 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 articles in scientific journals. This fundamentally applies irrespective of whether the abstract or posters have been published and peer reviewed. If abstracts are involved relating to a scientifically supported investigation that is being published in a recognized, independent scientific journal which has been subjected to peer-review prior to publication, this can however be regarded as documentation. The Danish Health and Medicines Authority has stated that it is not sufficient for an investigation to have been subjected to peer review prior to presentation at a scientific congress or symposium and that publication of abstracts in abstract booklets published by congress organisers or publication on a medical society's website would generally not be comparable to publication in a recognized, independent Danish or foreign scientific journal.

- **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 an ongoing **clincial trial** that has been published, for example on www.clinicaltrials.gov, since such information does not comply with 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 Organization of Danish Medical Societies (LVS, formerly the Danish Medical Society) and reported as such in Denmark, they may be used as references.

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

- According to the guidance to the Advertising Order, sec. 5.4, reference may be made to information from medicin.dk and IRF (Institute for Rational Pharmacotherapy), which is based on an independent medical assessment.
    - Such information may only be used on condition that it does not conflict with the information in the approved product summary.
- By virtue of the permitted use of information from **IRF** (Institute of Rational Pharmacology), it is ENLI's view that references may be made to information from **RADS** (Council for the Use of Expensive Hospital Medicine) and **KRIS** (Coordination Council for the deployment of hospital drugs), which is based on an independent medical assessment.
    - Such information may only be used on condition that it does not conflict with the information in the approved product summary.
- In a case dated 19 December 2014, the Appeals Board found that **EPI-NYT** published by Statens Serum Institute (SSI) could be used in a specific case as the basis for documentation for a statement in a medical letter.

Re: Sec. 7.6

Sec. 7.6 implements EFPIA´s HCP Code Art. 3.07-3.09.

Words indicating safety such as 'safe' or 'safely' are not acceptable in an advertisement. Even though the term 'safe' or 'safely' can be used in another sense than 'not hazardous', the very fact of the possibility of its being construed as such makes it unacceptable to use words such as 'safe', 'safely' or other synonyms of the word indicating that it is safe to use the medicinal product, when the word is being used in a laudatory context that could be construed or regarded as indicating that the medicinal product is free of risk. Other terms should therefore be used that cannot be interpreted as safe, safely, etc. cf. AN-2011-1480. The term 'safety' can however be used in instances where it appears in an

objective neutral fashion, cf. AN-2013-2911, and does not, depending on the context, involve any description or indication that the medicinal product is safe.

When using the term 'new' or words indicating a new product, ENLI assumes that measures to promote sales will have been implemented from the date of grant of the marketing authorisation in Denmark or by the EMA and that its price will have been notified if required, and so terms indicating that the medicine project is new should only be used for a period of one year afterwards, unless it is possible to document otherwise to ENLI.

Re: Article 8 - Comparative advertising

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

Comparative advertising is required in addition to the requirements of this clause, also to comply with the other provisions of the Code. For example, a comparative advertisement based solely on product summaries would not always be adequate and objective, cf. Sec. 4.2 of the Code and AN-2012-2713 in which the Appeals Board held that a 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: Sec. 8.1

The wording of Sec. 8.1 is the same as Sec. 16.1 of the Advertising Order

Comparative advertising is lawful when an advertisement is **correct**, **relevant** and **loyal**, overall.

Comparisons must be objective and relate to documentable information. Consideration should be given in this respect as follows:

- 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, but in which these 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" or the product "works fastest," there must be full documentation for all relevant products on the market, in accordance with the rules for documentation in Art. 7. Less specific statements such as "other" or "competing products" would not normally be acceptable.
- Neither would a comparison with a group of products of a more undefined nature be 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; although the documentation rules must be complied with, cf. Art. 7.

- It follows from the guidance to the Advertising Order, sec. 3.1 that a comparison is basically only adequate if it covers all generics (and any parallel imports) which do not deviate by way of pharmaceutical form or strength or differ significantly in pack size. Medicines with an insignificant market share (2-3%) may however be omitted from a comparison.

Previously there was a requirement for comparative advertising to have to enclose a tabular form to make it possible to show all the parameters of the product summary. As from 1 July 2015, a **pilot project** has been introduced that will be assessed by ENLI after 30 June 2016, after which it is no longer a requirement for the tabular form to be used. The trial period means that companies have the option of choosing for themselves which parameters should be compared. The trial scheme thus accommodates the Danish Health and Medicines Authority's rules in the Advertising Order and associated guidance.

Price used to be considered an important competitive parameter which should as always be given in comparative advertisements. As from 1 July 2015, it is no longer necessary for prices to be given in comparative advertisements since this has been included in the **pilot project**, due to be assessed by ENLI after 30 June 2016. After this, prices should only be given in a comparative advertisement if price claims are being made in the advertisement. In comparative advertisements, prices must be absolutely current and correct at the point at which the advertising matter is being used.

After the end of the trial period, the Investigations Panel will consider whether the scheme should be made permanent. A factor in this connection will be whether the Investigations Panel notes an increase in decisions with sanctions, including appeals, disloyal advertising with a lack of price comparison in the prices claimed in an advertisement. The investigations panel will further be having discussions with the Danish Health and Medicines Authority as to whether the Authority has seen an increase in appeals cases, etc., during the trial period.

If it is wished to continue to use a tabular comparative form, it should be a faithful reproduction of the comparison.

- The Danish Health and Medicines Authority found in a ruling dated 3 December 2013 that an advertisement infringed Sec. 63 of the Medicines Act (advertisements should also be adequate and not misleading. The information in the advertisement must also be in accordance with the approved product summary of the medicinal product) since information about an elevated risk of bleeding from using the drug when using NSAIDs and acetylsalicylic acid at the same time, and that medicinal products that could increase the risk of bleeding should not be given simultaneously with the medicinal product concerned or that special care should be taken when using it. Such information should, in the view of the Danish Health and Medicines Authority, be clear from the advertisement's objective comparative basis.
- No differentiation is made between the medicinal product's dispensing groups.
- The objective basis for comparison must be integrated in the advertisement, i.e. as part of a roll-up, advertisement and the like. In comparative advertisements in electronic advertising formats, it is however acceptable for all the relevant pages of the material to have a direct link to the objective comparative basis set up by the company, meaning a maximum of one click as for the requirement for compulsory text, cf. sec. 5.2 of the guidance.

- Sec. 4.2 of the Promotion Code (Sec. 63 of the Medicines Act) requires advertisements for a medicinal product to be adequate. Therefore it should always be stated in the comparative basis that the information in the comparison is not exhaustive, while referring to the fact that further details can be sought in the full product summary.

Re: Sec. 8.2

The wording of Sec. 8.2 is the same as Sec. 16.2 of the Advertising Order.

It follows from the guidance to the Advertising Order, sec. 3.2 that comparative advertisements should be designed on the basis of the information given in the product summaries for the products to which the comparison relates. This applies insofar as the product summary contains information about the subject covered by the comparison.

There must be no comparison with products that cannot be legally traded in Denmark, cf. Sec. 4.1, so information about 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 Sec. 7.4 of the Code.

For add-on medicinal products (comparison between basic treatment and a basic treatment combined with an add-on product that can only be administered as a supplement to the basic treatment cf. SPC), the Appeals Board ruled on 24 February 2014 that the requirements for advertising would only be as follows:

1) All medicinal products mentioned in the advertisement are to be identified, cf. Sec. 8.1 of the Promotion Code and
2) The compulsory text must be submitted for companies' own medicinal products, cf. Sec. 8.2 and 5. 1.

If a specific comparison is involved, for example the prices of pharmacy-only medicinal products, a comparison can be made on the basis of the prices published on medicinpriser.dk. In **price comparisons**, the current price must be given.

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 invented 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 the onset of headaches. In such situations, price comparisons may be based on a comparison of prices for the recommended starting dose and for the dosing range 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: Sec. 8.3

Sec. 8.3 has been added to meet the requirements of EFPIA´s HCP Code Sec. 3.05 *in fine*.

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

In making a price comparison, calculating treatment prices on the basis of part of a pack of the company's own product and not do the same for a competitor is regarded as disloyal, cf. above re Sec 8.2.

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

Re: Article 9 - Distribution of promotion

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

Re: Article 10 – Transparency of sales promotional measures

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

Re: Article 11 - Prohibition against advising on personal medical issues

The clause corresponds to EFPIA's HCP Code Art. 8.

COMMENTARY ON CHAPTER 5 – FINANCIAL BENEFITS

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

Re: Sec. 12.1

The clause corresponds to the most restrictive rule in Sec. 22.1 of the Advertising Order (although there is no reference to the exceptions with respect to **public meetings**, **price credits,** etc., and discounts that are not regulated by these rules but only by the Advertising Order and which are regulated by the Danish Health and Medicines Authority) and EFPIA's HCP Code Art. 17. The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.8.

Accordingly, pharmaceutical companies must not give or offer financial benefits to healthcare professionals, be they gifts, pecuniary benefits or benefits in kind.

The stricter provisions of the **prohibition against gifts** are due to EFPIA's adoption of a new code on 24 June 2013, EFPIA's Disclosure Code, on the pharmaceutical industry's disclosure of payments to healthcare professionals. As a consequence of the Code, EFPIA also resolved that two new rules should be introduced in EFPIA's HCP Code, which is implemented in the Promotion Code, one of which is the prohibition against gifts implemented in Art. 12 of the Promotion Code.

Interpretation of the prohibition against gifts is based on relevant official practice and in areas where the EFPIA rule is more restrictive than Danish legislation, the guidance from EFPIA (FAQs) and supplementary guidance (FAQ) from Lif thereon. In EFPIA's FAQs from February 2014, posted at www.enli.dk, Q12 states that the prohibition against gifts means that companies must generally not give gifts. So only what is specifically allowed as a gift in accordance with EFPIA's HCP Code (as incorporated in the Promotion Code) is permitted.

The starting point for the prohibition of financial benefits and gifts is modified by a range of express exemptions in Chapter 7 of the Advertising Order, and in Art. 13 – 15 of the Promotion Code, that in certain areas contain more restrictions than as set forth in Danish legislation. Amongst other things, the Promotion Code has stricter rules with respect to gifts, meals and permitted venues than those laid down in Danish legislation.

The exemptions all arise from the need for professional collaboration, including the exchange of information between healthcare professionals and the pharmaceutical industry. In the final count, 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 of the Advertising Order) and in the EFPIA HCP Code, consolidated here in the Promotion Code.

The prohibition against giving gifts or financial benefits to healthcare professionals does not only extend to services of a direct nature, but also for example to loaning IT equipment or financial benefits by way of extraordinarily long credit or especially favourable interest rates on outstanding balances due to the supplier.

Lending equipment may thus have a value for the healthcare professional. Loaned equipment will therefore be subject to a specific assessment that also reflects the purpose of the loan, the value of the equipment and how long it is borrowed for. For example, loaning IT equipment such as a tablet may be permitted at a medical congress for a limited period of for example three days if the equipment also otherwise serves a relevant professional purpose. On the other hand, making a tablet available for several weeks/months would not be permitted if the loan is only because it contains information material that could just as well have been supplied in print.

When a tablet is supplied without forming an integral part of a consultancy agreement, ENLI imposes a basic requirement for the tablet to be "locked" for private use (such as private app downloads, watching films and music, etc.) so as to comply with the professionalism requirement (Lif's FAQs/ Q 16).

It should be emphasized that provided a tablet, mobile phone or other IT equipment is made available as an integral part of a contractual agreement for a legitimate consultancy service by a healthcare professional to a company, such equipment would not be regarded as a gift if the rationale and agreement for its return are clearly documented in the associated consultancy contract. Similarly, in such cases there is no requirement for such equipment to be locked so that healthcare professionals cannot use IT equipment in other situations (e.g. use apps etc.). Healthcare professionals must not retain loaned IT equipment after expiry of their consultancy contract.

The stricter prohibition against gifts in Art. 12 make it clear that **image gifts** from pharmaceutical companies to healthcare professionals are also covered by the provisions. It thus makes no difference whether or not a gift directly relates to marketing a certain medicinal product since the company's interest in offering such financial benefits must be assumed to be due to the wish to market the company and its products, cf. the guidance to the Advertising Order, sec. 22.1.(5-6).

On this basis, it is ENLI's view that among other things, **bursaries** and other more **general sponsorships** for healthcare professionals would basically not be permitted unless the conditions of Art.13 of the Promotion Code have been met, including the requirement for "professionalism", documentation for specific expenses and hospitality at a reasonable level. In AN-2014-0917, the Appeals Board held that insofar as a pharmaceutical company operates within one of the exemptions from this clear main rule, cf. Art. 13 - 15 in the Promotion Code, it is up to the pharmaceutical company to ensure that the conditions for derogating from the main rule are always met. The fact that a pharmaceutical company might allow parts of its business, for example in allocating financial benefits to doctors, to be administered by a third party does nothing to change this. The responsibility for complying with the rules, amongst other things in the Promotion Code, continues to fall fully on the pharmaceutical company. As a natural result of this, in such cases pharmaceutical companies should establish a scheme that reassuringly provides for proper administration of compliance in accordance with the rules. This could for example be done by ensuring that granting financial benefits should in each case be submitted to the pharmaceutical company for final approval, or by the pharmaceutical company ensuring that the third party is always properly informed about content and practice with respect to the relevant rules. A bursary should never appear as a competition, cf. the prohibition in re: Sec. 5.2.

Lif has specified (Lif's FAQs Q9) that when supplying cooler bags for medicines serves a **patient safety purpose** because medicine needs to be kept cold, Lif regards them as exempt from the general prohibition against gifts since this does not involve a gift or financial inducement to a healthcare profession-

al. Accordingly, supplying medicine cooler bags to individual healthcare professionals for subsequent delivery to patients continues to be permitted on condition that such cooler bags for medicines comply with the following criteria:

1) Medicine cooler bags are designed for patients' requirements;

2) Their value is insignificant;

3) Carry no product branding (no product name of logo) and

4) Do not constitute an inducement to recommend, prescribe, buy, supply, sell or administer specific medicinal products.

Other forms of equipment that are directly or indirectly aimed at patients and which are specifically assessed as serving the patient safety purpose can also be supplied to a healthcare professional.

ENLI does not regard **training material** given to a healthcare professional as part of a professional healthcare course in accordance with Sec. 13.1, as conflicting with Art. 12.

The prohibition applies amongst other things to so-called "**gimmicks**" or "**leave behinds**", such as post-it pads, note pads, etc., which are office articles of minor value and which were previously acceptable as gifts, cf. the former Sec. 12.2 of the Promotion Code. Accordingly, the prohibition against gifts means that giving ballpoint pens, paper pads, etc., at individual meetings with healthcare professionals is basically prohibited, (for example on visits by medical representatives to clinics or exhibition display) since these are regarded as gifts.

However on 1 April, 2014, EFPIA decided to provide more details of the prohibition against ballpoint pens and paper pads so that it is permitted to have relevant **practical meeting items**, such as ballpoint pens, paper pads, etc., for professional symposiums, conferences, congresses, etc., (both companies' own and third party events), although on condition that the items comply with the requirement to be of insignificant value, cf. Lif's FAQs Q12.

- For third party events, meeting articles must be completely without pharmaceutical company branding (no name or logo or corporate/product brand). Using a generic name is also covered by the prohibition against product branding. It is specified that hotel or congress names are not regarded as branding in this connection.

- For events that companies have organized themselves, meeting articles may have the corporate brand (company name and/or logo) but still without product brands (invented or generic names). Affixing the name of a therapeutic area is permitted (for example oncology, diabetes, cardiology, etc.).

- Ballpoint pens and paper pads supplied in conference bags/packs must not carry the corporate or product brand, cf. EFPIA's decision, and similarly the prohibition against supplying media items on display stands is absolute.

- On condition that the above criteria are complied with, the following are examples of permitted relevant practical meeting items: Ballpoint pens, writing pads, conference packs or bags, key ring lanyards for keycards, etc.

In the event of gifts being supplied to healthcare professionals contrary to the prohibition against gifts as part of **third party professional events**, the pharmaceutical company's liability for this depends on their involvement:

- Pharmaceutical companies that sponsor healthcare professionals' attendance in third party professional events such as professional scientific conferences/congresses are not responsible if the organisers or other parties sponsor on-site present gifts in contravention of the rules without the prior knowledge of the company. If the company (however) is aware in advance that a congress organize or the like wishes to present gifts as part of an event (for example by saying so on the invitation or program or it is known from previous congresses that this will happen) in contravention of the rules, the company must ensure that it can document its reservations about gifts being given to healthcare professionals sponsored by the company, or alternatively, that the healthcare professionals would refuse to accept them, cf. Lif's FAQs - Q13.
- Congress organizers that have received a sponsorship direct from a pharmaceutical company must not present gifts to healthcare professionals which would infringe the rules of the Promotion Code. The pharmaceutical companies would not, however, be held responsible for this if they expressly specify in the associated sponsorship contract that gifts should not be provided, cf. Lif's FAQs - Q14.

Re: Sec. 12.2

It follows from Sec. 23 of the Advertising Order that holding **competitions** and drawing prizes for healthcare professionals for promotional purposes or otherwise to promote sales of a medicinal product is not permitted. This is an absolute prohibition, cf. the guidance on the Advertising Order sec. 5.6.1.

The nature of the competition and the value of prizes make no difference. Nor does it makes 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 corresponds to a compilation of the provisions of EFPIA's HCP Code Art. 10 and Sec. 26 of the Advertising Order. The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Secs. 4.3, 4.4, 4.5 and 4.6.

Re: Sec. 13.1

General:

The provisions of Sec. 13.1 are not in EFPIA's HCP Code, but part of Sec. 13.1 reads: *"Pharmaceutical companies can give or offer a healthcare professional training and professional information in the form*

of payment of the direct expenses in connection with professional relevant courses, conferences, training etc., in which the healthcare professionals participate or arrange. In these activities, pharmaceutical information or other relevant information, relevant for the participants, must be included". This corresponds to the wording of Sec. 26.1(2) of the Advertising Order and ensures that ENLI's practice conforms to the spirit and objective of the provisions of Sec. 26.1. (2) of the Advertising Order.

Requirement for professionalism:

According to ENLI's regular practice, the concept of "**professional information and education**" should be taken to mean that the event must have special professional healthcare content and be intended as continuity training for healthcare professionals, including medical presentations on disease, areas of disease, products and methods of treatment.

On 27 March 2012, the **concept of professionalism** was nuanced by the Appeals Board and is nowadays construed more widely in the light of ENLI's various sets of ethical rules to also include more overarching healthcare policy and health economics 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 Sec. 13.1 of the 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 disease. The conference was intended for health professionals as well as public decision-makers, health economists and patient associations. Most of the presentations dealt with prevention and control of chronic disease, with the focus on health economic, political and general consequences for society and management mechanisms.

On the other hand, ENLI's regular practice means that offers of, or support for, non-healthcare related courses would generally not be acceptable, such as those also offered to other professional groups such as financial control, organisational development, leadership, computer and collaboration courses, planning meetings, coaching, practice management (accountancy assistance), comedy/entertainment, political presentations, communication, teacher training, etc. ENLI 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 pharmacists and not on sales and/or pharmacy operations.

Courses on for example **health economics** are permitted if it is assessed that the focus is on specific therapy-oriented or medication-oriented issues and not on the more overall political discussions of the issue.

Offers to assist in searches of a doctor's electronic patient journal (EPJ) records system as part of phasing out a medicine were found by the Investigations Panel to conflict with this requirement. In AN-2012-2584, the Appeals Board confirmed this view in that the emphasis had been on ensuring that no current safety issue problem was involved.

The use of **patient cases/case histories** in pharmaceutical companies' promotional material is not regarded as complying with the requirement in the Promotion Code that the formulation of advertisements should be serious, precise and objective. This applies regardless of whether cases are fictional or true.

However, patient cases can be used as part of professional events provided that the patient case is not selected by the pharmaceutical company but for example chosen by a hired healthcare professional. There is a requirement for the use of individual patient cases to be closely associated with the professional material at the event, for example to illustrate professional knowledge that has already been reviewed at the meeting and so medical presentations consisting of a general review of patient cases, such as those that attending healthcare professionals have brought with them for general discussion, do not always have the necessary degree of detail required for the professionalism of the presentation to be assessed. Such a presentation may therefore in certain circumstances have the character of a more general exchange of experience (cf. below under sponsorship)

It should further be noted that patients can basically not be used as speakers at professional events since they are not considered to have the necessary scientific background to be able to make a medical presentation in accordance with Sec. 13.1.

The use of videos with patients, regardless of whether the case is true or fictional, is assessed in the same way as pictures of patients and will therefore fundamentally be regarded as not being serious and objective marketing, cf. Sec. 4.2. For more details of patient cases, please see the guidance to Sec. 4.2 and Art. 7.

Own events:

When running a professional event 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 they come from an independent third party. The company must therefore set a minimum condition in the contract with the independent third party that presentations must be made in accordance with the rules. ENLI also holds that companies have a duty to react if a speaker make statements that for example contravene the rules of the Promotion Code.

In a ruling handed down on 28 May 2014, the Danish Health and Medicines Authority held that two satellite symposia at an international congress in Denmark did not amount to unlawful advertising for medicinal products. Accordingly, the Danish Health and Medicines Authority took the view that the contents of the speakers' presentations at the satellite symposia of the congress were professional and involved professional presentations of scientific data and studies to healthcare professionals. The presentations had also been made in a scientific forum. The Danish Health and Medicines Authority had also noted that the satellite symposia were part of the official scientific programme for the congress and that these involved external speakers who had themselves decided on the format, content and angle of the subject in their presentations (see also more in re: Sec. 4.1 above).

ENLI assesses that there is no requirement to report slides drawn up by a third party unless the company has been influential in preparing them. If a pharmaceutical company decides to hand out slides prepared and used by a third party during their presentation at the company's event, the material will

be regarded as advertising the company, irrespective of whether the material was handed out at the meeting, subsequently or during calls by medical representatives, and in such cases, the material would need to be reported to ENLI.

Sponsorship:

Sec. 13.1.a)-b) solely serves to give more details of activities and to differentiate between activities arranged or co-arranged by pharmaceutical companies themselves, and events arranged by a third party, where the pharmaceutical company is solely sponsoring activities by way of sponsorship to the organiser or directly to the healthcare professional to cover the specific expenses 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 health 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 Arts. 12 and 14), although cf. Sec. 29 of the Advertising Order on public meetings.

Further, sponsors may not in accordance with Sec. 13.1.b) make the sponsorship conditional on being able to influence 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 Art. 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 checked that all the relevant provisions of the Promotion Code have been complied with, cf. also Sec. 21.4 of the Promotion Code and the guidance thereon. The event must accordingly not be announced before all relevant information needed to assess the case is available, cf. Sec. 21.4 of these rules and within 10 working days of the pharmaceutical company having given a binding promise of financial support, cf. Sec. 21.5.

Program content requirement:

ENLI 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 continuity training, 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 should naturally be held. However, holding one cannot be done with the 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 Appeals Board's ruling above.

Only activities of a purely professional nature can be supported, cf. Sec. 13.1(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 nature in accordance with the rules of Art. 13 of the Code, including a requirement that any surplus from the sponsorship not used for professional activities in accordance with Art. 13 should be refunded. Further, ENLI asses 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 congress with a statement of all associated income and expenditure. This is to ensure that the organizers, for example an association of healthcare professionals, do not receive more money than required for professional continuity training activities which would otherwise be regarded as a financial gift in contravention of Sec. 12.1 of the Code.

Individual pharmaceutical companies are required to ensure that an activity being supported has the necessary professional content. *Financial support may therefore only be given to specific activities where the company is aware of 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. Sec. 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 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 'exchanging experience', or the like. 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 higher 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. Donation Code which prohibits donations and grants to individual healthcare professionals.

ENLI'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 specialist physicians organized by third parties on the basis of preceding year’s professional program could generally be assumed to be sufficiently professional.

Activities being supported should be **mostly professional** in accordance with the above. ENLI interprets this to mean that pharmaceutical companies can perfectly well support an event where part of it is not specifically professional if the part that is specifically professional forms the core of the event. This could for example relate to certain general meetings or other internal discussions in a professional body of healthcare professionals involving no aspects of entertainment, cf. Sec. 13. 9, and which comply with the stated requirements. It should however be remembered that only activities of a purely professional nature can be supported, cf. above.

Pharmaceutical companies should never provide support for events, parts of events or participation in events that include any form of entertainment, cf. Sec. 13.9 or other non-professional activities, cf. Sec.

13.1(b) (*in fine*). In a memorandum dated 1 June 2011, however, ENLI (Appeals Board) ruled that pharmaceutical companies can provide sponsorship/support for events of the types named provided that participants themselves expressly pay for any entertainment or other non-professional activities. 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 Sec. 13.9.

Support for hospitals or healthcare professionals?:

In 2007, NMI submitted a series of questions to the Danish Medicines Agency (now the Danish Health and Medicines Authority) on interpretation of the 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 the 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 the Advertising Order or this clause. Under certain conditions, support may be lawfully provided as a gift regardless of what the support is used for, in accordance with the rulings of the Danish Medicines Agency, below. (Reference is made in this connection to the requirements for donations and grants in the Donation Code)
- Support for individual, named healthcare professionals or associations of healthcare professionals (such as medical societies) for example for society operations, including for example setting up websites, distribution of material or drawing up treatment databases and the like, are regarded as conflicting with the Advertising Order and not covered by the exemptions therein. This is in accordance with the provisions of the Donation Code which precludes support for individual healthcare professionals, unless permitted in accordance with Art. 13.

The Danish Medicines Agency's rulings are discussed in detail in NMI's annual report for 2007, cf. Annex A.

Put-a-cross-in-the diary:

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 an assessment, it follows from the rules 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 Art. 13. Use of headings such as "Put a cross in your diary" or the like 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: Sec. 21.1 for notification dates. A non-binding invitation (alert) does not therefore have to be reported.

Re: Sec. 13.2

According to Sec. 13.2, the **purpose** of the event must 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 Sec. 13.2 that the invitation should state whether the event is being sponsored /supported by one or more pharmaceutical companies.

ENLI has specifically determined that the condition in Sec. 13.2 would be met by its 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 Sec. 13.2 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 matter for the event and on the website.

ENLI accepted these instances by virtue of the fact that the purpose of the provisions of Sec. 13.2 on **sponsors being stated on the invitation**, namely that participants should be able to see and decide whether the event is being supported by pharmaceutical companies, would 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.

ENLI accordingly finds that in accordance with the wording of the clause, it would be very difficult for pharmaceutical companies to provide sponsorship for professional events very close to the date of an event, and especially after conclusion of the event without the company then contravening this clause.

Re: Sec. 13.3

Sales promotional, scientific or professional meetings, congresses, etc., may for example be conferences, symposia and other comparable meetings, including among other things, meetings with consultant bodies (advisory boards), visits to research and production sites and planning/training or investigator meetings associated with clinical trials and non-intervention studies.

In Denmark, there is no "negative" or ”positive” list of "prohibited” and ”permitted” meeting venues. Competition law reasons preclude such a list. See also Sec. 13.7.

The rule on **suitable venue** corresponds to EFPIA’s HCP Code Sec. 10.01, and EGA’s Code of Conduct on Interactions with the Healthcare Community, Secs. 4.3 and 4.5.

ENLI has ruled that a venue is not suitable for the main purpose of activity which is to communicate factual information and training on medicinal products, cf. Sec. 13.1, if the venue does not have the facilities to provide a framework for a professional meeting, a so-called ‘non-industry' venue. This could for example be a boat trip, museums or elsewhere with cultural offerings for the public (e.g. on payment of an admission fee) and restaurants unless these places have separate suitable conference facilities. Without suitable conference facilities such places cannot basically be said to be a "suitable

venue" compared for example to a conference room at a company, hospital/medical practice, university, conference facilities, etc.

In contrast to Sec.13.10 that relates to meeting venues "known" for their entertainment facilities or to be extravagant or luxurious, and so involves places that are above what might be regarded as ordinary/standard, an assessment according to Sec. 13.3 thus depend on whether the venue is suitable for holding a professional event. The extent to which access to entertainment is also provided depends on a separate assessment, cf. Sec. 13.9.

Re: Sec. 13. 4

The clause corresponds to the sum of EFPIA's HCP Code Sec. 10.02 and Sec. 26.4 of the Advertising Order, although it is not possible, as in the Advertising Order, to take financial issues into consideration. In contrast, the requirement for 'significance' does not follow from the EFPIA HCP Code, but from Sec. 26.4 of the Advertising Order.

Logistical reasons could for example be:

- The possibility of the target group for attending the event (many/few/foreign participants)
- The possibility of speakers and other attendees to attend
- The possibility of undertaking the event's program (suitable premises, conference facilities, access to headquarters/research centre).

Given the purpose of the rule, the Investigations Panel construes this as also applying internally in Denmark. 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.

It is ENLI's view 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 Sec. 13.1 and would, in ENLI's view, also conflict with this clause. The same applies to events involving a tour of foreign branches (or head office) of a pharmaceutical company.

The Investigations Panel has previously accepted professional events conducted **abroad** at which the specific venue has been amongst other things a leader in the disease area concerned, practically all the professional presentations in the programme have been conducted by various healthcare professionals from the venue concerned and the physical environment of the venue has been actively involved in the program to ensure and support understanding of the professional content of the program. The purpose and content of the event concerned was strongly associated with precisely that venue and it was found that there were sufficient logistical reasons to justify the event not being held in Denmark.

Re: Sec. 13.5

According to Sec. 26.1(1) of the Advertising Order, "***hospitality*** *by way of payments for direct expenses incurred for meals, travelling, accommodation, etc., associated with advertising for and professional information about medicinal products*" can be provided. It is unclear what is meant by "etc.".

EFPIA's HCP Code does in contrast limit hospitality as it provides no option corresponding to 'etc.' in the Advertising Order. On the other hand, it is also specified here in that hospitality also includes "exact application fees" in accordance with EFPIA's HCP Code Sec. 10.04. According to the guidance on the Advertising Order, sec. 5.7*"for example hospitality associated with attending courses and other activities of a professional medical/pharmacy nature*." is covered.

The provisions of Sec. 13.5 may therefore be said to be more restrictive than Danish legislation.

The former Danish Medicines Agency (now the Danish Health and Medicines Authority) ruled in a consultation dated 7 January 2011 that: *"It is permitted to provide* ***hospitality*** *for a healthcare professional provided even for a a professional event not arranged by the pharmaceutical company concerned. This may for example involve the pharmaceutical company that pays for travel and accommodation expenses associated with a healthcare professional's attendance at a professional, international conference, even though the company is not an organiser of the conference*".

ENLI accepts on this basis that pharmaceutical companies can provide hospitality at professional events arranged by a third party if the pharmaceutical company concerned has in some other way **provided support for the professional content.** This could for example in addition to payment for travel and accommodation, by way of sponsorship for a speaker, conference rooms, etc. ENLI accordingly does not accept that a pharmaceutical company should only offer a healthcare professional hospitality by way of refreshments if the healthcare professional is participating in a professional event arranged by a third party. ENLI's view, however, is that sponsorship for the organiser does not justify inviting Danish healthcare professional attendees for meals at events unless the pharmaceutical company has in some other way supported attendees' involvement in the professional content, for example by paying for travel and accommodation as set out by the Danish Health and Medicines Authority (previously the Danish Medicines Agency).

Only **expenditure actually incurred** 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 Art. 12 of the Promotion Code, and also the remarks to Sec. 13.7 below. **Hotel expenses** can only be paid if the

nature of the event necessitates a stay in a hotel (cf. also "relevant", Sec. 13.3 *in fine*). If an event lasts 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 on both the day before and after the overnight stay. For intercontinental travel, ENLI does accept arrival up to 24 hours before the start of a professional meeting.

For payment for hospitality, including meals, etc. please see also Secs. 13.7 and 13.8.

Payment for **insurance** for participants during their stay and transport to and from the professional event is covered, in ENLI's view, by the wording of Sec. 13.5 and falls within acceptable hospitality.

Re: Sec. 13.6

The clause corresponds to EFPIA's HCP Code Sec. 10.06 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.4, and there is no comparable provision in the Advertising Order, which merely mentions (Sec. 26.2, *in fine*), 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 be brought to such events even though they might pay for their own costs associated therewith. This would be comparable to organising social events which is prohibited pursuant to Sec. 13. 9.

Accordingly, neither must pharmaceutical companies **act as** '**travel agencies**' for accompanying spouses/partners. People can decide for themselves where they will travel but it is not up to pharmaceutical companies to book tickets for flights, etc., for accompanying spouses/partners regardless of the fact that the pharmaceutical company is not paying for actual ticket. There is no comparable prohibition in the Advertising Order, cf. guidance thereon sec. 5.7.1.

However, in special cases hospitality may be offered to a **companion** if it is assessed 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), although it should be possible to document this.

Re: Sec. 13.7

The clause corresponds to the sum (highest common factor) of the Advertising Order's Sec. 26.2, EFPIA's HCP Code Sec. 10.07 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.3 and 4.4.

The essence is an assessment of the extent and level of hospitality with respect to the professional event. Sec. 26.2 of the Advertising Order was amended on 1 November 2014 so that the clause no longer states that the **timing** of the hospitality provided should be secondary compared to the advertising or professional activity. It thus now provides that hospitality should be kept at a reasonable level and should be narrowly limited to the main purpose of the promotional or professional activity.

"**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 and 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 (otherwise Sec. 13.9-10 become relevant and are therefore assessed as part of the framework for the professional event and hence under the direction of the company).

In cases relating to hospitality, ENLI's view is that the company will only be responsible for **meals** for attendees being within the framework of this clause and Sec. 13.8 if the companies pay for/support such meals. Accordingly, the company is not responsible for example a gala dinner (with luxurious service) if the company's sponsorship does not cover meals. In contrast, a company may not pay a reasonable amount towards or support luxurious meals for an amount equivalent to a reasonable level, cf. also Sec. 13.8 meaning partial self-payment for example.

Here, ENLI finds that the **overall hospitality** for which the company provides support must be at a reasonable level since the company would otherwise be providing luxurious hospitality in contravention of this clause. If a healthcare professional is invited to a professional event which an overall view would regard as luxurious with respect to the Promotion Code, this would only be in accordance with the Code if the self-payment component 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 on Sec. 21.1) and hospitality in general, for example choice of hotel, possibly restaurant, transport etc., the company will 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 Sec. 13.1 and Sec. 21.4. Such **documentation** for hospitality purposes could for example be a specified budget giving the standard of hospitality (e.g. the standard of the hotel, flight class, etc.) and departure dates /times. Provided that hospitality is kept within the given limits and on condition that venues in question are not known for their entertainment facilities and for being extravagant and/or luxurious, ENLI would regard hospitality as complying with the Promotion Code, including Sec. 13.7.

Hospitality may only be provided for specific professional events in accordance with the definition of professionalism in the commentary to Sec. 13.1, to which reference is made.

Further, the professional purpose and content must always be the overall objective. 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 Sec. 13.5. The same consideration applies to the prohibition against pharmaceutical companies facilitating accompanying trips by spouses, cf. Sec. 13.6.

The wording: "**What a healthcare professional is willing to pay**", comes from the EFPIA HCP Code Art. 10.07. This is naturally subjective and the wording should therefore be construed as a kind of guidance according to which no more should be given than what the average healthcare professional would be willing to pay for the activity concerned, whilst naturally also complying with the requirement for reasonableness, etc. On the other hand, there is no requirement for individual healthcare professionals to be asked what they would be willing to pay themselves.

Continuity training by way of a **medical representative visit** follows the rules of Art. 13 of the Promotion Code and so hospitality provided here should also be at a reasonable level. See more on medical representative visits in re: Sec. 20.2.

It should be noted that whether or not the company should provide hospitality depends on the meeting, such as an 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.

Accommodation:
With respect to choice of overnight accommodation, the general remarks made in the Appeals Board's ruling of 21 September 2011 on the choice of venue for professional events (see Sec. 13.10) does also apply, cf. AN-2012-2202.

Whether a hotel's standards appear extravagant and/or luxurious will 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. Hotel expenses can only be paid if the nature of the event necessitates a stay in a hotel (cf. also "relevant", cf. Sec. 13.3, *in fine*). If an event last less than six hours, it should normally be possible 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 on both the day before and after the overnight stay. For intercontinental travel, ENLI does accept arrival up to 24 hours before the start of a professional meeting.

Travel:
In a letter to ENLI on 6 February 2013, Lif submitted suggestions for interpreting the rule, as suggested in Sec. 9.08 of the EFPIA 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 professional 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 **overseas 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 economy or economy plus such as "Economy Flex" or "Premium Economy". Reference is also made to the requirements of Art. 15 and the guidance thereon.
5. Flights for consultants providing professional services to the company and who travel to **intercontinental destinations** can be in Business Class. Reference is also made to the requirements of Art. 15 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.

Meals:
The level for reasonable hospitality should always be assessed for a specific event and assessment should be made on the basis of Sec. 13.8. It has thus been determined that dinner or similar meals (sandwiches, coffee/ tea/ soft drinks, etc.) can only be offered at events consisting of **at least two hours of professional content**. In the event of less than two hours of professional content, there would have to be an assessment of whether the hospitality provided actually amounted to a meal and so for example offering large quantities of sandwiches could conflict with Sec. 13.7.

There should always be an assessment of whether catering is necessary at a specific meeting and it should be borne in mind that there is no requirement or obligation for hospitality to be offered but it is in contrast, an option if so justified by the nature of the meeting.

In this connection, careful consideration should be given to the signal value. If a short meeting is organised at around lunchtime and for example a sandwich is provided, this could mean a meal. There should never be any doubt as to whether attendees only come for the professional content or for a free sandwich at lunchtime, cf. Art. 1 of the Promotion Code.

It follows from the guidance to the Advertising Order Sec. 26.2 (s. 5.7.1), that *"events such as a full day seminar from 9:00 to 17:00 may include breakfast on arrival, lunch and possibly a light dinner to close the seminar".* Meals in excess of the permitted maximum conflict with the Promotion Code.

When it comes to hospitality, there must be differentiation between whether it actually involves **meals**, which can only be provided after a minimum of 2 hours professional content, or **refreshments**, which is on-going hospitality without actually being a meal and is only thought of as "keeping people awake along the way."

Re: Sec. 13.8

With the adoption of EFPIA's Disclosure Code on 24 June 2013 on disclosure of pharmaceutical industry's payments to healthcare professionals, it has further been resolved that each country should set a **price-cap** (max. price) in their own national codes for meals, including drinks for healthcare professionals. The rule is implemented in EFPIA's HCP Code Sec. 10.05, and in this clause of the Promotion Code. The notified prices reflect the market price for meals, i.e. not the prices achievable for example by way of volume discounts but in contrast the price that healthcare professionals would have to pay themselves if they bought similar meals.

Lif stated that adoption means:

- The cap on spending is absolute, meaning that prices in excess of this level are not permitted, while prices under this level are always permitted (on condition of compliance with the requirement for an event with at least two hours of professional content)

- The maximum amounts include drinks, VAT and any tips.

When it comes to other European countries, provision of meals outside Denmark must conform to the maximum amounts applicable in these countries, see the list of max. amounts/EFPIA meals list at www.enli.dk. (under Regelgrundlag/Reklamekodeks/Dokumenter). For meals in countries that are not in EFPIA, it is ENLI's view that the price level should be based on the Danish maximum amount and only where significant price differences can be documented compared to the level of Danish prices, should the cap be adjusted upwards or downwards accordingly.

Remember that it must be possible for the maximum amounts to be checked by ENLI. Regardless of fact that the reporting site does not require specified details, companies should remember that sums spent on meals must be specified in their report for example in situations where more than one meal has been paid for, whereas previously just the overall price had to be submitted. This can either be done in a comments field or in an uploaded appendix, for example a Word document. It should be emphasized with respect to the overall day/event price of DKK 1,200, the maximum price of DKK 400 for lunch and DKK 700 for dinner must still be complied with.

Re: Sec. 13. 9.

This clause corresponds to EFPIA's HCP Code Sec 10.08 that contains a prohibition against hospitality covering both *sponsoring* and *organizing* **entertainment events**, regardless of whether an event is wholly or partially professional in nature and regardless of whether the entertainment is subordinate to the professional element. 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. This clause also follows from Sec. 30.2 of the Advertising Order and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.3 and 4.5.

Following a request by Lif and ENLI, the Appeals Board 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 organised by a third party, especially including international scientific congresses. Lif sent a letter to ENLI on 15 January 2013 with a suggested interpretation of how the rule should be construed, cf. the suggestion therefor in EFPIA's HCP Code Sec. 10.08, and thus supplemented ENLI's guidance on the meaning of "entertainment" as follows:

1) There is a total prohibition against organizing/sponsoring entertainment with respect to pharmaceutical companies' own events (both in Denmark and abroad).
2) With respect to sponsored third party events (where the company is not the organiser or co-organiser 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., - amount to 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 specified that the Appeals Board 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 **self-payment** or if the sponsorship comes from a non-pharmaceutical company

ENLI welcomes Lif's supplementary interpretation in that it is regarded as perfectly natural for the 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, s. 10.08. ENLI would however note that in specifying its understanding, Lif has placed most emphasis on the EFPIA Code and ignored the international IFPMA industry code, 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 Sec.. 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 possibly background music or the like which is not sponsored by the pharmaceutical company, cf. also ENLI's previous interpretation and practice.

With respect to any **self-payment**, the Investigations Panel has emphasised that for health professionals, getting sponsorship depends on the company ensuring it would 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 element to attendees. The Investigations Panel has also approved sponsorship for attending a professional congress in which the fees included activities with elements of entertainment, since participation required separately ticking a box when signing up. In this connection, ENLI requires documentation that sponsored healthcare professionals do not have access to the social event.

The decision rests on a specific assessment of relevant documentation to show that sponsored healthcare professionals do not receive hospitality contrary to the clause, including whether the documentation shows that the healthcare professional only arrives at the entertainment session for example after the welcome reception. In contrast, a briefing to participants that they must not participate in the entertainment scheduled in the programme or an invitation to a parallel meeting held by the pharmaceutical company at the same time as the entertainment session would not be sufficient documentation unless healthcare professionals have confirmed their attendance at the parallel meeting in writing and in advance.

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 the before mentioned conditions are met (entertainment expressly paid for 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 financial support has been given, and used, in accordance with this rule.

The guidance to Sec. 30 of the Advertising Order states that pharmaceutical companies must not fund healthcare professionals to attend purely social or cultural events. This prohibition should be interpreted broadly and covers for example payment for tickets for visits to theatres, museums or football matches. The prohibition applies regardless of the amount paid. The guidance further states that neither may pharmaceutical companies arrange entertainment as part of professional activities covered by Sec. 26.1.2, cf. Sec. 30.2 of the Advertising Order (corresponds to Sec. 13.9 of the Promotion Code).

Re: Sec. 13.10.

Derives from EFPIA's HCP Code Art. 10.08 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.3.

In Denmark, there is no "negative" or "positive" list of "prohibited" and "permitted" meeting venues. Such a list could conflict with competition law rules

In contrast, venues are required to be at a "reasonable level" as also set forth in Sec. 26.2 of the Advertising Order, and pursuant to these rules, they must not be extravagant (meaning they must be of ordinary standard and not luxurious).

ENLI interprets "**reasonable level**" and "**ordinary standard**" with respect to the 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/permits such venues on certain conditions.

As part of dealing with the two principle cases on 21 September, 2011, and as most recently held in AN-2014-5624 (NB: the ruling has not been published since it is based on a pre-assessment), the Appeals Board held as follows on the general interpretation of this clause:

"Financial benefits must not be given or offered to healthcare professionals for advertising purposes or otherwise to promote the sale of a medicinal product, cf. Art. 12 of the Promotion Code [There is now stricter wording: supplying, offering or promising healthcare professionals gifts or financial benefits in the form of money or in kind shall not be permitted, cf. however Art. 13-15.]. When as in the Promotion Code Sec. 13.9 (now Sec. 13.10) exceptions are made for the choice of venue from the prohibition against financial benefits, it should be interpreted in the light of Art. 1.2(a) in the 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 benefits should be interpreted restrictively.

*Venues for meetings, 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. Basically, holding professional events at for example five star hotels, gourmet restaurants (taken to mean 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., would not comply with Sec. 13.9 (now Sec. 13.10) of the Promotion Code. Here the criterion is not 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. Sec. 13.9 of the Promotion Code (now Sec. 13.10).*

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*
- *local availability of alternative venues.*

The price for using the venue's facilities, hospitality, etc., could be used as a guideline, in the Appeals Board'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 Sec. 13.9 (now Sec. 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 Sec. 13.9, (now Sec. 13.10) this is not to say that other specific circumstances could 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 a prior assessment of a planned event, cf. Sec. 21.7 of the Promotion Code.

With respect to the above classification issues, ENLI is aware that it is possible to use such **booking sites** as Trivago.com, Booking.com and on VisitDenmark's website, where it is possible to see a hotel's official classification, which could be used to assist in an overall assessment of the general reputation of the venue. The overall assessment of the venue's reputation continues to be crucial and not the classification alone.

Following countless discussions between Lif and ENLI with member companies that have found it very difficult to comply with the rule on venues, in a letter dated 15 January 2013 Lif submitted a contribution to interpreting how the rule should be construed, as urged by Art. 10.08 EFPIA's HCP Code, and supplemented by ENLI's guidance on venues that are "known" for their entertainment facilities or for being 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 of the Opera, DR's Concert Hall, Tivoli's Concert Hall or the Aquarium constitute attractions that cannot be used as venues.*

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 is taking place.
    b. *For example: Parken 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. The significant factor here is that it is not likely that holding an event at this location would mean that attendees or the general public (by far the majority) would associate this with entertainment.
   c. *For example: DGI Byen Conference Centre, Danish Design Center, Conference Dahl's Concert Hall (when there is no concert), Tivoli Congress Center, Black Diamond.*

ENLI draws attention to the fact that companies should continue to be aware of the other conditions in Art. 13 of the Promotion Code when considering a venue selected for an event. So for example tickets provided by a venue to attendees for exhibitions and the like adjacent for example to the venue but for which the venue is not generally known, would conflict with Sec. 13. 9.

Lif considers ENLI's interpretation of the rules on a "suitable" venue and the prohibition against "extravagant and/or luxurious" venues are reasonable and that the Appeals Board 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 consider it to conflict with the rules, non-compliance is sanctioned with an order for the first breach. The first breach means that no company has previously been sanctioned (order 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 Appeals Board'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 its assessments, ENLI will continue to focus on **independent quality reviews** 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 feels that this clause imposes requirements on pharmaceutical companies, even if they are not themselves the organiser or co-organiser, but merely the sponsor of the professional event, cf. also the guidance to Sec. 13.1. Accordingly, a pharmaceutical company cannot provide funding for a professional event that makes use of a venue that conflict with this clause.

In AN-2012-2202 and AN-2012-2203, the Appeals Board held in assessing overnight accommodation in hotels that the extent to which a hotel standard appears as extravagant and or luxurious depends on

an overall assessment of how the hotel by and large appears in publicly available information and hence whether its general reputation is luxurious, cf. above Sec. 13. 7. The Investigations Panel finds this view applicable to assessment in accordance with Sec. 13. 10.

Horesta introduced a new set of criteria for hotel classifications on 1 January 2015 with a 'superior' classification meaning that it is now possible for example for a 4* hotel to be classified as '4* Superior' if in addition to the obligatory criteria, the hotel meets a series of options. In a ruling handed down in March 2015, the Appeals Board stated that the new superior classification will not for the time being influence the previous practice of a 'star-based' classification. However the Appeals Board has reserved the right to revisit the issue at a later date when it is possible to assess the implementation of the 'superior' classification in practice.

ENLI regards the concept of **venue** to cover all locations for a given event. An overall view is therefore 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 Sec. 13.10. It is the Investigations Panel's view that pharmaceutical companies may provide support for events that are not in accordance with Sec. 13.10, with respect for example to subsequent meals at a venue that is known for its entertainment facilities insofar as this is expressly funded by attendees themselves, in line with entertainment in accordance with Sec. 13.9.

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.

When assessing general reputation, as above, the classification of conference facilities for a venue is basically not relevant since it depends on the venue's technical issues on site.

Re: Secs. 13.11-12

The provisions correspond to Art. 13 of the EFPIA HCP Code, since the last clause on Danish and other relevant legislation was inserted to supplement the EFPIA HCP Code, as it was suspected that such rules would often be invariable in the host country. Clarification should therefore be sought from the Danish Health and Medicines Authority 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 should also apply.

Re: Sec. 13.13

The clause corresponds to Sec. 28 of the Advertising Order and derives from the **association rules** in Danish legislation. Since compliance with this rule is regulated by the Danish Health and Medicines Authority by way of publication of the information, it has been decided by the parties supporting ENLI that it should not control or sanction companies' compliance therewith.

According to Sec. 27 of the Advertising Order, healthcare professionals are required to notify the Danish Health and Medicines Authority when they are paid for their expenses for attending professional

activities abroad. Notifications must be submitted digitally using a form posted on the Danish Health and Medicines Authority's website. Notifications must include the following information:

1) Identity of the healthcare professional.
2) Identity of the company paying the expenses person to Sec. 26.1 of the Advertising Order.
3) Identity of the organiser of the professional activity if this is not the same as the company that has paid the expenses in accordance with Sec. 26.1 of the Order.
4) Information about the professional activity.
5) The concluding date of the activity.

Notified information is published on the Danish Health and Medicines Authority's website and deleted from there two years after the conclusion of the activity, cf. Sec. 27.3 of the Advertising Order.

Re Article 14 Information and training material and medical equipment

Re: Sec. 14.1

The clause corresponds to EFPIA's HCP Code Art. 9 and was introduced together with greater stringency in the gift prohibition, see also the guidance for Art. 12. The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.8.

Interpretation of Art. 14 is based on relevant official practice and in areas where the EFPIA rule is more restrictive than Danish legislation, the guidance on EFPIA (FAQs) and the supplementary guidance (FAQs) from Lif, both of which are available at www.enli.dk.

According to EFPIA's FAQs from February 2014, **information and training material** generally refers to material designed to promote education on disease or treatment and aims to teach patients or healthcare professionals and has no personal value for the healthcare professional. Examples of this could be educational brochures about disease, tools for patients to examine themselves and control their own treatment and brochures for healthcare professionals to use in instructing patients on complying with therapeutic regimes, healthier lifestyle choices or the option of participating in a in patient support programme.

The clause also applies to online materials. Material may also be supplied on a **USB stick**. ENLI maintains in this connection that the capacity of such a USB stick must be the least available for storing the material concerned so that it reflects a reasonable balance between the needs of the information material and available alternatives (USB stick etc., with smaller capacity). According to EFPIA's FAQs (Q6), pharmaceutical companies are not allowed to offer healthcare professionals a **medical textbook**, regardless of the book's content.

Lif's supplementary FAQs of 20 January 2015 (available at www.enli.dk) specify (Q1) that the Danish Health and Medicines Authority's advertising guidance of 28 December 2014 differentiates between whether **medical scientific articles** and **reprints** are supplied on or without a request by the healthcare professional, cf. also the guidance to Sec. 2.2(c) above. Generally speaking, the prohibition against gifts in the Promotion Code is more extensive than the legislation in the area. The sector provisions are set on the basis of this (within the framework of the Advertising Order and guidance) so that

medical scientific articles and reprints are always covered by the provisions of Sec. 14.1 of the Promotion Code on information and teaching material and may thus be perfectly properly supplied in accordance with this clause.

Q4 specifies that supplying **medical reprints** to a healthcare professional is permitted on condition that (i) this is directly relevant for clinical/pharmacy practice and (ii) it directly benefits patients. Overall, reprints must also be of insignificant value. Similarly, textbooks that are part of and are actually used as training material during a healthcare professional's attendance on a medical course /continuity training event (the company's own or third party events) are not a gift and can therefore continue to be supplied.

Lif has further stated (Q6) that providing **subscriptions** to medical/scientific journals is permitted, although on condition that the journal concerned is medically relevant and that the subscription is of insignificant value, i.e. does not exceed DKK 300 p.a. for the healthcare professional.

Lif has specified (Q1) that there basically cannot be a convergence between an **advertisement** and the information material that can be supplied in accordance with Sec. 14.1, since this clause specifically provides that information material must not aim to promote the prescription of a medicinal product. Generally, printed advertising material that serves advertising purposes therefore continues to be covered by the other advertising provisions of the Promotion Code and may be supplied as hitherto.

It also follows from this specific exemption of information and training material that can be supplied pursuant to Sec.14.1 from the advertising concept that this material is not covered by the **notification requirement**, cf. Lif's FAQs (Q2).

The meaning of "**insignificant value**" is laid down in Sec. 14.3, but with respect to material designed to be supplied to the patient, ENLI's view is that the cap of DKK 300 for the total annual value from the pharmaceutical company to a healthcare professional set by the Danish authorities for gifts to doctors does NOT apply. Here, the individual information and instructional material for patients must specifically be of insignificant value.

Re: Sec. 14.2

The clause corresponds to EFPIA's HCP Code Art. 9 and was introduced together with greater stringency in the gift prohibition, see also the guidance for Art. 12. The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.8.

Interpretation of Art. 14 is based on relevant official practice and in areas where EFPIA rules are more restrictive than Danish Legislation, the guidance on EFPIA (FAQs) and the supplementary guidance (FAQs) from Lif, both of which are available at www.enli.dk.

According to EFPIA's FAQs **medical equipment** generally covers equipment suited to improving healthcare professionals' clinical or pharmacy operations and treatment of patients and which is of no personal value to a healthcare professional. Examples of this could be medical equipment for example for inhaling (without active ingredients) and equipment designed to help train patients for example to inject themselves.

It follows from EFPIA's FAQs (Q3) that medical equipment must not be supplied if the equipment replaces healthcare professionals' **normal running costs** of clinic/pharmacy operations, such as administrative expenses, office supplies, (including paper pads, ballpoint pens, etc.) or equipment required to undertake a patient consultation, i.e. gloves, paper towels, stethoscopes, blood pressure tester, etc. Accordingly, it is not permitted for a pharmaceutical company to supply such equipment to healthcare professionals but only to supply medical equipment of insignificant value and only insofar as this cannot be used instead of the usual equipment necessary for the recipient's clinical or pharmacy operations. Supplying **practical conference equipment** is permitted, such is ballpoint pens, paper pads, etc. at medical symposia, conferences, congresses, etc. (both the company's own and third party events), although on condition that this equipment complies with the requirement to be of insignificant value, cf. above re: Art. 12.

Lif has specified (Q7) that supplying **anatomical models** to healthcare professionals is basically permitted. However, anatomical models must amount to insignificant value for the healthcare professional, i.e. their value must not exceed DKK 300 p.a. for the healthcare professional.

Branding with the product name or product logo is basically not permitted on medical equipment unless branding serves a relevant information or patient safety purpose. One example of where having the product name is permitted on demonstration equipment such as inhalation or injection devices in situations where the purpose of the product name is to prevent errors so that the right product can be identified for the equipment concerned. Placing the company name and/logo on such medical equipment is permitted if this does not amount to obvious advertising, cf. Lif's FAQs (Q8).

The meaning of **insignificant value** for medical equipment is set forth in Sec. 14. 3.

The permitted supply of medical equipment is not subject to the requirement for **notification**, unless supplied as part of a company's own activities which are subject to the requirement for notification.

Re: Sec. 14.3

It follows from Lif's FAQs (Q5) that **insignificant value** is determined on the basis of a specific assessment that reflects the general sentiment of reasonableness compared to the type of material/ equipment and within the framework of any official practice. Existing **official Danish practice** means that the total value of gifts to an individual healthcare professional must not exceed DKK 300 in a calendar year. The company must be able, in the event of a possible proceedings at ENLI, to document to ENLI the total value (of items) from the company to a healthcare professional.

It should be noted that there are some exemptions that apply where insignificant value is determined on the basis of a specific assessment since such instances are not regarded as covered by the official annual DKK 300 cap. This applies to equipment justified by patient safety issues, for example certain types of equipment used for demonstration purposes to patients which are intended to be supplied to patients or information/training matter that can be supplied in accordance with Sec. 14.1-2.

Re: Article 15 Use of consultants/professional services

This clause is based mainly on Art. 14 of the EFPIA Code, supplemented with rules from Danish legislation. The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.2.

Whether or not a healthcare professional is regarded as a **consultant** or an adviser to a pharmaceutical company does not depend on whether the healthcare professional concerned is employed for is limited assignment or for a restricted number of hours. Healthcare professionals are basically regarded as consultants or advisers under this provision if they are able to run a business as healthcare professionals alongside their employment by/association with a pharmaceutical company.

Re: Sec. 15.1

The clause corresponds to EFPIA HCP Code Sec. 14.01, and in principle to Sec. 24 of the Advertising Order which does not however contain the criteria set forth in (a-f) which derive from EFPIA's HCP Code, which thus goes slightly further than Danish legislation. In contrast, (g) is not in the EFPIA HCP Code, but does incorporate Sec. 24.2 of the Advertising Order.

It should be noted that the guidance to Sec. 24 of the Advertising Order, sec. 5.7.2 states: "*The prohibition against providing financial benefits 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. …Fees may only be paid in money. They must not be paid by way of offsetting, transfer of benefits in kind or other indirect ways cf. s. 24.2 Advertising Order." Accordingly, healthcare professionals may 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 doctors' professional assistance in undertaking clinical trials or drawing up information material on medicinal products. it could also be remuneration to a healthcare professional who sits on an advisory board or remuneration to a healthcare professional who is to be a speaker at a professional event. Whether or not payments are reasonable compared to the services depends on a specific assessment of the content, duration and scope of the agreed service. Doctors, dentists and pharmacists are required to apply for consent or report their association with a pharmaceutical company to the Danish Health and Medicines Authority when receiving payment for a professional service in accordance with the rules of s. 1 pursuant to the rules of s. 202(a) Health Act."*

Individual pharmaceutical companies are (strongly) urged to include in their **written contracts** with consultants, the provisions on the requirements of individual consultants to state that they are acting as consultants for the company concerned when writing or speaking in public about an issue covered by the agreement, or on any other issue relating to the pharmaceutical company concerned. Pharmaceutical companies that employ healthcare professionals on a part-time basis who continue with their main work are similarly (strongly) urged to ensure that these individuals are required to provide information on their employment with the company when writing or speaking in public about an issue covered by the employment or on any other issue relating to the pharmaceutical company concerned. This applies even though the Code does not otherwise relate to general, non-promotional information.

Re: Sec. 15.1(f):

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 statements and 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 register consultancy agreements to ENLI.

Re: Sec. 15.*1(g):*

This clause is not in EFPIA's HCP Code, but implements Sec. 24.2 of the Advertising Order.

It should be noted that pursuant to Sec. 24 of the Advertising Order, paying for services from a healthcare professional or a pharmacy is permitted if the **fee** is reasonable and commensurate with the service. When so requested by the Danish Health and Medicines Authority, both the payor and payee of fees must provide information to the Authority on the basis for determining fees. Fees may only be paid on a monetary basis and not by setting off, transferring benefits in kind or in some other indirect way. This does not prevent a pharmaceutical company from paying the consultants expenses associated with the work agreed, such as travel expenses, cf. also Sec. 15.6. ENLI's practice for activities arranged by pharmaceutical companies in which healthcare professionals undertake work in return for the company donating an amount per participant to charity or similar constellations do not comply with Sec. 15.1(g) of the Promotion Code.

Re: Sec. 15.2

The association of doctors, dentists and pharmacists with a pharmaceutical company requires prior notification to/or the permission of the Danish Health and Medicines Authority, cf. Sec. 202(a) of the Health Act. Pharmaceutical companies are required to brief healthcare professionals on this and to notify the Danish Health and Medicines Authority of any association of doctors, dentists and pharmacists with the company, cf. Art. 16.2, which relates to the legislation thereon. More information on this is available on the Danish Health and Medicines Authority's website.

Re: Sec. 15.3

It is apparent from the Association Order and the associated guidance that anonymous surveys of pharmacists, doctors and dentists undertaken by a third party and where the **anonymity** of the underlying company and the pharmacist, doctor and dentist respectively is maintained after completion of the survey, are not regarded as an association as such, provided that the company and the pharmacist, doctor and dentist respectively are not made known to each other.

The Investigations Panel's view is that the fact that an interview/survey only deals with a single medicinal product thus enabling the healthcare professional to possibly identify the company concerned does not necessarily indicate a breach of anonymity. In such cases, there is basically no requirement to apply for permission to be able to participate in an interview. It is however essential for anonymity between the assisting healthcare professional and the underlying pharmaceutical company to be maintained both before and after the survey has been completed.

It is clear from Sec. 15.3 that anonymous surveys are not covered by Sec. 15.2 although it should be noted here that neither are these covered by the requirement for a written agreement, cf. Sec. 15.1.2.

Re: Sec. 15.4

This clause follows from EFPIA's HCP Code Sec. 14.03. However, requirements still apply in accordance with Danish legislation, cf. Sec. 15.1(c, e, f and g), and Sec. 15. 2.

Market analyses/ market surveys

If a marketing authorisation is regarded as advertising for a medicinal product, the general rules of medical advertising must be complied with, cf. Promotion Code Arts 4-8.

If a market survey is regarded as being a promotional activity, advertising must only relate to medicinal products that can be lawfully treated or supplied in Denmark. If the market survey mentions the company's own medicinal product, the compulsory text must be supplied at the end of the survey. If the survey contains a comparison with the other medicinal products, a comparative schedule must also be supplied. Market surveys must be notified to ENLI as they are regarded as advertising.

Re: Sec. 15.5

The clause is a translation from Sec. 14.04 of the EFPIA HCP Code and should be 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 Art. 13 (EFPIA HCP Code's Art. 10).

Following proposals from Lif in February 2013 this doesn't apply to flights for consultants providing professional services to the company. According to the guidance to Sec. 13.7, the following applies:

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".
b) Flights for consultants providing professional services to the company and who travel intercontinentally may be in Business Class.

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 ON CHAPTER 6 – TRANSPARENCY

Re: Article 16 Transparency

On 24 June 2013, EFPIA's General Meeting adopted a new code, EFPIA's Disclosure Code, which is binding on Lif and Lif's members.

Those EFPIA states that have no national legislation on the area are required to implement the provisions of EFPIA's Disclosure Code directly into their international code. EFPIA's Disclosure Code does however provide for the possibility of implementation by way of rules that differ from the specific rules in EFPIA's Disclosure Code, where dictated by national legislation and regulation.

This 'flexibility provision' is significant in Denmark since Lif decided to implement the requirements of EFPIA's Disclosure Code by way of a registration, approvals and openness scheme in the Danish legislation effective from 1 November 2014.

The provisions of Sec. 16.2.1 therefore apply to all pharmaceutical companies in Denmark whereas the provisions in Sec. 16.2.2 apply to all companies associated with ENLI.

Implemented by way of an official Danish model would appear to result in Danish companies avoiding considerable new administrative requirements since the primary responsibility for reporting in Denmark falls to healthcare professionals.

In the autumn of 2014**, ENLI's steering group** stated that ENLI is not required to exercise controls and sanctions on obligations specifically imposed on pharmaceutical companies in accordance with the new Association Order since the authorities are responsible for compliance and sanctions under the rules.

The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.11.

COMMENTARY TO CHAPTER 7 – NON-INTERVENTION STUDIES, EXHIBITION AND MEDICAL SAMPLES

Re: Article 17 Non-intervention studies of marketed medicinal products

The clause corresponds to EFPIA's HCP Code art. 15. Additionally thereto, the Joint Declaration on clinical drug trials and non-intervention trials between Lif, the Organization of Danish Medical Societies and the Danish Medical Association and its appendix apply. The rules in the appendix must at the very least be complied with and in certain areas; this also imposes more requirements than the present set of rules.

This clause overlaps to a certain extent with the above-identified agreement with the Danish Medical Association and has been included in the Promotion Code to ensure control with respect to the EFPIA's HCP Code's provisions on non-intervention trials and pharmaceutical companies.

Re: Sec. 17.2

Re: Sec. 17.2(d): The **Joint Declaration** on clinical drug trials and non-intervention trials between Lif, the Medical Societies and the Danish Medical Association and its appendix states: "*Non-intervention trials shall be undertaken on the basis of a trial plan which constitutes the scientific basis for collaboration. This requires the sponsor and investigator to have agreed on the trial plan. The parties are aware that certain non-intervention trials must be notified to and approved by the Danish Health and Medicines Authority. Processing personal information associated with non-intervention trials must be notified to the Data Protection Agency. However, while non-intervention trials requiring approval by the Danish Health and Medicines Authority are exempted from this, they are still subject to the rules of the Personal Data Act.*

LF, LVS and Lif further agree to:

- *Recommend their members to make use of the Danish Health and Medicines Authority's offer of guidance. In responding to a request, the Danish Health and Medicines Authority may provide guidance on whether a trial is, or is not, an intervention trial. The Danish Health and Medicines Authority may also in the event of a specific request provide guidance on the advertising rules and their interpretation in connection with non-intervention trials.*

- *The trial plan shall be submitted for a statement by the Multi-practice Committee if the trial involves general practice.*"

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

Reference is also made to the Association Order according to which healthcare professionals' association with pharmaceutical companies must be notified to the Danish Health and Medicines Authority.

Re: Sec. 17.3

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

Re: Article 18 Exhibitions, etc.

This clause is not in the EFPIA HCP Code but is an extension of Art. 9 of the previous "Collaboration Agreement" for NSL.

As for all other relevant information, it must be possible as part of notification to document the conditions set forth in Art. 18, cf. Sec. 21.4 of the Promotion Code.

Whether or not this involves purchase of an exhibition stand or the provision in reality of **sponsorship** depends on whether the price is regarded as reflecting the actual purchase of the stand or whether it should be regarded as payment of an amount exceeding this and hence becoming sponsorship. For further details see also the guidance to Sec. 18.3.

An exhibition stand reflects the purchase of a display area and must be notified, cf. Sec. 21.1(c). If payment exceeds the exhibition stand's true value, this would involve sponsorship of the event which would then require notification as sponsorship, cf. Sec. 21.1(b). It should be noted in this connection that in purchasing an exhibition stand, only professionalism is assessed, cf. Sec. 13.1, whereas assessing sponsorship involves the whole of Art. 13.

An exhibition area is fundamentally regarded as a commercial area. Whether or not **advertising** is involved depends on a general assessment of the company's overall activities in the area of the stand and whether specific medicinal products can be identified there. If this is not the case, it could for example only involve **information about disease**, and not advertising activity.

It should be noted that the material taken to the exhibition stand must comply with the rules on advertising in the Promotion Code, see also the guidance to Sec. 4. 2.

Re: Sec. 18.1

Pharmaceutical companies are accordingly permitted to advertise as part of holding professional events, typically by way of advertising, displays, posters and notices, film shows, product information, etc. However, it must be clear to participants at a professional event just when advertising is involved and when it is professional education. Accordingly, advertising and marketing must be **kept separate** from the professional content of the event. At a medical congress, no exhibitions are permitted in the training rooms. Advertising activities must be kept separate from the professional part of the congress, for example in a foyer outside the training rooms.

It should be noted that advertising activities on a stand must comply with the rules on advertising 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 other individuals than those from pharmaceutical companies are present on stands, such as pension companies, patient associations, etc., unless

these areas are kept clearly separate. The rules on advertising to the general public are not regulated by ENLI but by the Danish Health and Medicines Authority.

It should further be noted that if a healthcare professional goes to a stand to ask a question, the pharmaceutical company on the stand may perfectly well answer but only within the approved product summary, cf. the exemption from the definition on advertising in Sec. 2.2 of the Advertising Order on individual correspondence.

Re: Sec. 18.2

Even though advertising activities are kept separate from the professional part of the congress, exhibitions can only be permitted if the content of the congress is of such a professional nature that it complies with the rules in Sec. 13.1. Conversely, it is ENLI's view that the clause does not provide powers to require compliance with all the other conditions in Sec. 13.3-12 for purchasing an exhibition stand, including for example the rules on venues. This basically also leads to the fact that no hospitality can be offered at exhibition stands since this would conflict with Art. 12 of the Code.

Re: Sec. 18.3

The terms and conditions for advertising medicinal products as part of professional events must be pre-arranged, with a **written contract** on the financial terms for this. Any hire charges for rooms or exhibition stands, 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 organiser's costs for exhibition arrangements and the advertising value for the pharmaceutical company. ENLI's view is thus that the price should reflect the market price for an exhibition stand, which will depend among other things on the timeframe for using the stand, the level of exposure and the nature of the location.

When assessing the square metre **price** of a stand, it must include VAT and administration fees. External administration fees (that is when fees do not go to the actual organisers) should not however be included in the square metre price. Any attendance fees for the event for company employees on the stand and expenses for meals must similarly not be included in the square metre price.

The square metre price must accordingly comprise the actual stand price including VAT and any administration fees to the organiser. As a rule a thumb (June 2015), it can be reckoned that a square metre price of DKK 2,000 for a whole-day event in an rented, external location with about 50-80 delegates is acceptable. A higher square metre price would only be acceptable if so indicated by the market price due to the possibility of exposure or the like, cf. above.

ENLI has discussed this issue with the Danish Health and Medicines Authority and it has been agreed that sponsorship and advertising (stand space) must be kept separate. Accordingly, there must be no hidden sponsorship in the square metre price. However, sponsorship can always include a stand.

It follows from Sec. 24.4 of the Advertising Order that payment for advertising space at a pharmacy must not exceed the market price for similar advertising space and payment should not depend on the pharmacy's sales of the medicinal product.

Re: Article 19 Medical samples

The clause further implements the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.9.

Re: Sec. 19.1

The implementation of EFPIA´s HCP Code amended Sec. 16.01 (adopted by EFPIA on 14 June 2011 (the so-called 4x2 rule) with an effective date of 1 January 2012) provides a further restriction compared to Danish law, thus making Art. 19 more restrictive than Art. 16.02 of the EFPIA HCP Code. Hence a pharmaceutical company may as a result only supply one sample a year of each medicinal product for a maximum of two years after the **date of introduction**.

Re: Sec. 19.2

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 entail a new marketing authorization and hence a new introduction date.

Re: Sec. 19.3

The provisions of Sec. 19.3.1 are aimed at products covered by the Medicines Act in accordance with the definition in Sec. 1.3.2 of the Medical Devices Order, cf. Sec. 3.3(c) of the 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 products are defined in the legislation as a single product covered by the Medicines Act and are therefore **medicinal products**. Here, the rules of Sec. 19.1-2 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 other changes are based on a new or supplementary indication.

The final subsection in Sec. 19.3 exempts other equipment from the rules of Sec. 19.3.1-2. These products are covered by the general rules on **medical devices**. Supplying samples of medical devices is regulated by the requirement for objectivity in Order on advertising for medical devices. Supply must have an objective purpose, such as giving a doctor the opportunity to learn about changes to functionality, 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 medical samples in association with such devices can be done when it is necessary to understand or test a new or modified device, although only for a maximum of two years after the new or modified 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: Sec. 19.4

It is important to be aware that the rules in the Order on supplying medical samples still apply.

As noted above, the supply of medical samples is regulated in the Order, and the supply of medical samples is subject to controls by the Danish Health and Medicines Authority. 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.

ENLI has been notified by the Danish Health and Medicines Authority that the condition in the order for the product summary to be supplied when supplying a medical sample cannot be replaced by supplying the compulsory text.

COMMENTARY ON CHAPTER 8 – PERSONNEL, EDUCATION/TRAINING, ETC.

Re: Article 20 Personnel in pharmaceutical companies

This clause corresponds to EFPIA´s HCP Code Art. 18.1. Sec. 20.1.2 includes provisions corresponding to Sec. 18.2 of the 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 representative's course at Lif (Danish Pharmaceutical Academy) and who thus 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 (Danish Pharmaceutical Academy) at their date of employment, comply with the following requirements:

- They must take the exam within 12 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, REPORTING REQUIREMENT AND PRE-APPROVAL

Re: Article 21 Reporting requirement

General: According to the EFPIA HCP Code, there is a requirement for the rules to be controlled but there is no requirement to ensure that this is reported. **The notification requirement** is therefore restricted by the Code and in the appeals process, should be viewed in accordance with the collaboration agreement on ENLI and the control exercised by the Danish Health and Medicines Authority.

The notification requirement basically applies to all the companies responsible for the activity concerned if several companies **are collaborating** on an advertising activity. However, it is ENLI's view that it is sufficient if an individual activity is only reported once. Notifications 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 an individual event 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 notifications. 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 assessed 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 notification requirement in accordance with these rules are restricted to **continuity training events** and **exhibition stands** and **printed advertising matter** (apart from tender documentation) and must as noted below be regarded as a supplement to the Danish Health and Medicines Authority's controls.

Re: Sec. 21.1

Re: Sec. 21.1 (a-b): The notification requirement in (a-b) is restricted only to activities that wholly or partially relate to **Danish healthcare professionals** in or outside Denmark. So if an event in Denmark or abroad is only attended by foreign healthcare professionals, there is no requirement to report. Such events in Denmark are still however subject to the rules of the Promotion Code.

The notification requirement relates only to events at which healthcare professionals are not required to provide any kind of service in return for payment/support, cf. Sec. 21.2. This means for example that there is no requirement to report advisory board and investigator meetings since in such case healthcare professionals are providing a service in return by way of their expert knowledge. In contrast, in continuity training events solely attended by healthcare professionals to receive training,

there is no service in return and this must therefore be reported, which further requires compliance with the other conditions. **Visits by medical representatives** need not be notified either, although see the commentary to Sec. 21.2 below.

So-called **"Put a cross in the diary"** invitations need not be notified to ENLI. Such 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 confirmation of the event to the healthcare professional 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 Art. 13 for an assessment of when the information on an event is sufficient, including its professionalism, hospitality, etc.

Specially re: Sec. 21.1(c): Pharmaceutical companies' payment for **exhibition stands** at congresses, annual meetings, etc., in Denmark are to be reported to ensure that pharmaceutical companies only have exhibition stands at events of proven professionalism. This applies regardless of the nationality of the healthcare professionals targeted by the exhibition.

Exhibitions abroad are not to be reported, regardless of whether the exhibition is aimed at Danish or foreign healthcare professionals.

Re: Sec. 21.2

Sec. 21.2 states that the kind of continuity training provided in visits by **medical representatives** is not covered by the notification requirement. A medical representative being accompanied by a speaker means this is no longer just a medical representative's visit but in contrast, a classic continuity training event which must be notified. 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 notification has to be made and when it continues to be regarded as an ordinary, standard medical representative's visit. If the visit is in the shape of a more classic continuity training event for a healthcare professional or if it involves a visit which is more by way of a major event, in terms of the time, number of participants or resources employed, it must be reported. Regardless of their format, medical representative visits must comply with the rules in Art.13 of the Promotion Code, including the rules on hospitality. For the use of practical conference equipment during medical representative visits, see the guidance to Art. 12 according to which such visits are regarded as individual meetings.

The notification requirement relates only to events at which healthcare professionals are not required to provide any kind of service in return for payment/support. This means for example that there is no requirement to report **advisory board** and **investigator meetings** since here healthcare professionals are providing a **service in return** by way of their expert knowledge. When first approaching a healthcare professional about participation on for example an advisory board or some other meeting, the company must report the approach if the approach is an advertisement for a medicinal product. In contrast, in continuity training events solely attended by a healthcare professional for training purposes, there is no reciprocal service and this must therefore be reported, provided that other conditions have been met.

Re: Sec. 21.3

PowerPoint and other electronic text and presentations are deemed to be the same as **printed advertising matter** and are covered by the reporting requirement, provided that it also involves "**advertising**" as defined in the Advertising Order. It should be noted that ENLI regards textbooks that mention specific medicinal products as printed advertising matter that requires notification.

It should be specified that there is no notification requirement for materials exempted from the rules of the Promotion Code, cf. Sec. 2.2(c), see the guidance on this, including **patient information leaflets** (also supply of these with the accompanying compulsory text), safety information and **press releases.** It should emphasised that material which, despite headings or otherwise in its entirety, appears to be medicinal advertising (in comparison to information) must comply with the rules of the Promotion Code and be reported in accordance with the Promotion Code cf. Sec. 21.3.

Re: Sec. 21.4

All reports must include the information required by the current online reporting system on ENLI's website and any further information of relevance for assessing the notification, in accordance with the rules of the Promotion Code. Companies are required to ensure that the **requisite information** is available at the date of notification so that ENLI can make a full assessment of the activity in accordance with the rules of the Promotion Code.

With respect to **electronic advertising matter**, especially including **Apps**, documentation must be by way of a link to the app, or the loan of a tablet on which the app can be used and screen dumps with associated 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 that the notified documentation is **examined**. Assessment for compliance with the rules is therefore based on the actual circumstances at the time of reporting. At the request of ENLI, companies should therefore be able to document that the circumstances concerned existed prior to notification to ENLI. This means that during the assessment process, a pharmaceutical company cannot amend reported material to bring it into compliance with the rules so as to avoid sanctions. This position was confirmed by the Appeals Board on 23 November 2011 with its rulings in AN-2011-1927 and AN-2011-1480.

The fact that a pharmaceutical company decides to set the framework for an activity at a late stage which thus ends up contravening the Code cannot justify proceeding with the activity. The company could otherwise wait to plan an activity until the last moment or to notify ENLI briefly before the start date and thus circumvent the rules.

If there are **changes** to an otherwise notified activity, this should be reported to ENLI giving the notifier's file reference number. This might for example be a change of venue for a medical event. If an activ-

ity notified to ENLI is cancelled, this should also be reported to ENLI, giving the notifier's file reference number. This ensures that ENLI has all the current details of the activity, enabling it to always consider the latest information about the activity. If the company should subsequently decide even so to run the event, possibly with a change of date, the activity should basically be re-notified to ENLI.

Re: Sec. 21 5

According to Sec. 21.5, reporting an event in accordance with Sec. 21.1(a) 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 service for the healthcare professional begins. For events entailing travelling time, this would therefore be the day of departure.

Invitations to healthcare professionals to participate in for example international congresses are regarded as sponsorship for the healthcare professional's attendance at a third party event, cf. interpretation of Sec. 13.1 of the Code and must therefore be reported as sponsorship. For more details of documentation requirements for companies regarding events and sponsorships, see the guidance to Sec. 13.1. It is clear that Sec. 13.1(a-b) solely serve to give more details of activities and to differentiate between activities arranged or co-arranged by pharmaceutical companies themselves, and events arranged by a third party, where the pharmaceutical company is solely sponsoring activities by way of sponsorship to the organiser or directly to the healthcare professional to cover the specific costs associated with attendance.

The fact that the company only has to notify ENLI when all the necessary information is available does not mean that notification can be submitted later than as laid down in Sec. 21.5. This means that the company can only agree to the healthcare professional's attendance when **sufficient information** is available, for example that hospitality is entailed. Information about hospitality does not need to give the name, address and price of hotels or the cost of flights and departure times but may well provide the general framework for hospitality, such as the fact that the hotel is maximum 4* and costs 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, Sec. 13.7.

Re: Sec. 21.7

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. If insignificant changes are involved, these may be considered as a supplementary application to the original assessment.

It should be noted that a pre-assessment will always be specific and cannot be regarded as general approval of individual parts associated with an approved activity, cf. Sec. 6.3 of ENLI’s case processing rules. If there are subsequently changes to the format, content, etc., of the pre-approved activity, it is automatically nullified.

It is not possible to say anything about how long pre-approval remains valid. Pre-approval is done on the basis of specific information and conditions. 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 in re: AN-2012-2713, in which the Appeals Board reversed an assessment made by the previous board (NSL).

Re: Sec. 21.8

In the invitations 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 all invitations issued 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 the expenses of health professionals in attending 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 (pre-approval) or the pharmaceutical company as compliant with the rules. This also complies with the wording of the Code's Sec. 21. 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, since it is ENLI's view that this does not meet the requirements of Sec. 21.8 with respect to the purpose of the clause.

It is the Investigations Panel's view that the purpose of the clause also means that a pharmaceutical company should provide the same information regardless of whether it decides to invite a healthcare professional, for example by way of a poster for example at a hospital or by oral invitation.

Re: Article 22 Enforcement

Reference is made to the Collaboration agreement on ENLI for further comments and to ENLI's Sanction and Fees Rules.

Index

Abbreviations

Consumer price Order	Order on calculating consumer prices etc. for medicinal products
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
IGL	Danish Generic Medicines Industry Association
Lif	Danish Association of the Pharmaceutical Industry
Medicines Act	Medicines Act
Marketing Act	Order on the Marketing Act
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
PFL	Parallel Importers' Association
Pharmacists' Act	Act on pharmacists
Advertising Order	Order on Advertising, etc., for Medicinal Products
Promotion Code	The Pharmaceutical Industry's code of Practice on Promotion, etc., of Medicinal Products aimed at Healthcare Professionals
Guidance on the Advertising Order	Guidance on Advertising, etc. for Medicinal Products

Annex A (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