



# **GUIDANCE**

**on**

**"The Pharmaceutical Industry's Code of Practice**

**on Promotion etc.,**

**of Medicinal Products aimed at Healthcare Professionals" (Promotion Code)**

The guidance for the Promotion Code will be kept updated as practice develops or changes. The guidance is therefore dated and will also have a version number. All special abbreviations used are given at the back of the guidance.

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

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## 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. The sector-specific ethical rules in Denmark are 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 Code of Practice), 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 in EFPIA's Code of Practice and implement the purpose of IFPMA's Ethos.

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 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 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 Medicines Agency. ENLI's regulation thus supplements control on the area by the Danish Medicines Agency, 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 rules that are most restrictive on the pharmaceutical company applies.

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 The Danish Association of Parallel Distributors of Medicines. 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. This could also be the case, for example, if the Danish company assist with visa applications and the like for foreign healthcare professionals. On the other hand, if more active steps are taken in developing or undertaking the activity, the Danish 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 Code of Practice. Companies that are a member of EFPIA are always obliged to comply with the ethical rules in those countries in which they conduct their activities.

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 Medicines Agency.

It is further noted that Lif has entered into agreements with the five regions and that the regions have requested for the control of the framework regarding the activities that the companies involve HCP's employed by hospitals in, to be carried out by ENLI. ENLI can only monitor companies that are subject to ENLI's competence. Please refer to [www.enli.dk](http://www.enli.dk) for further information on the agreements with the specific regions.

### **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 Code of Practice, 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 Faroe Islands** are not regarded as part of Denmark in this respect, nor do they involve Danish healthcare professionals.

As noted below, the EFPIA Code of Practice requires compliance with the national rules of the organiser as well as the rules of the state in which an event is held, e.g. where a Danish subsidiary runs an event abroad.

Accordingly, it follows from the preamble to the EFPIA Code of Practice 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 Code of Practice 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 Code of Practice 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 provision 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 Medicines Agency, to commercial activities carried out in Denmark and to advertising on the internet originating from pharmaceutical companies established in Denmark.

It is also noted, that advertisements in magazines that are, entirely or partly, directed to Danish healthcare professionals must, in principle, comply with the Danish advertising rules; especially if the magazine specifically has Danish healthcare professionals as a target group. If the magazine has Scandinavian healthcare professionals as a target group, the advertisements will have to comply with the laws of each Scandinavian country. If, on the other hand, it is a magazine that is not obviously targeted to Danish healthcare professionals, entirely or partly, it will be required to comply with the legislation of the country in which it is registered in published. Here, e.g., large English or American scientific journals, which are also sold in Denmark.

### Re: Sec. 2.2

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 Medicines Agency. Additionally, the other codes apply, which are also controlled by ENLI.

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](http://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.

The specific exception for individual correspondence applies to written communication, and only to individual persons.

In a written reply regarding individual correspondence, one can answer specific questions relating to e.g. off-label use. However, it must be ensured that one does not articulate an answer so wide that it takes on the character of advertising, including illegal advertising claims for off-label use. Thus, there must only be replied to the specific question.

An oral answer of a question in an assembly is thus not covered by this exception, because it no longer has the characteristics of individual correspondence, nor is it in writing. Regarding oral questions in meetings, one should only mention what one's medicinal product is approved for and nothing else. Otherwise, there is a risk of a commercial situation, since the definition of advertising is interpreted very broadly.

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 Medicines Agency has stated that direct healthcare professional communication (DHPC), which usually contains new safety information and is subsequently included in the product summary that is agreed with the authorities, and training materials which for example EMA requires to be circulated to a defined group of healthcare professionals as part of approval of new central medicinal 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.*

It is ENLI's assessment, that order lists in relation to pharmaceutical companies' commercial material, is to equate with price lists, product catalogues, etc., why these as a starting point is not to be regarded as advertising material, as long as they are not of a laudatory character. This means that there is no notification requirement to ENLI for such order lists.

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 basically 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.

In connection with educational events organized by pharmaceutical companies, disease areas and/or medicine groups in invitations can be stated without being, as a starting point, considered an indirect mention of specific medicines. However, this is subject to the fact that no special product advantages have been highlighted in one or more groups of medicines, since in that case, advertising of a drug might be the case.

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 group, 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.

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.

It should be noted that if the press release is made available only to a single journalist because of a solo agreement, the terms of the derogation will not be met. In that case, the press release must comply with the advertising rules, including requirements for documentation, etc.

It should be noted that answering questions from the journalist on the basis of a press release is not covered by the exception. Oral statements can thus be advertising, regardless of whether the statements can be documented and regardless of whether the media has published similar articles prior to this.

If statements are put forward to a journalist who is not a healthcare professional, ENLI cannot process the case. Pharmaceutical companies' actions against the public are dealt with by the Danish Medicines Agency.

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.

It is therefore important to make a distinction between, if the reprints are distributed on the company's or healthcare professional's initiative in relation to the definition of advertising, cf. sec. 2.2 of the guideline to the Advertising Order. An active effort on the part of the company regarding distribution of reprints, e.g. reprints made available free of charge at an exhibition booth, can be covered by the definition of advertising due to the outreaching behavior.

A company's unsolicited distribution of scientific articles (reprints) is considered a promotional activity, and must therefore be enclosed with the compulsory text, cf. Art. 5. The reprint must be in accordance with the summary of product characteristics (SPC), and must therefore not concern dosages or indications, which are not supported by the product characteristics, or include the medicines, which may not be placed on the market, cf. Art. 4.

Regardless of whether the distribution is effected on request or unsolicited, the reprint still constitutes a gift, why the value thereof must be clarified; see further details under Sec. 14.3.

*Re: Sec. 2.2 (d):* It is important to note that in Denmark, the clinical area is controlled by the Danish Medicines Agency and the Biomedical Research Ethics Committee system. Cases relating to clinical research notified to the Biomedical Research Ethics Committee system and/or the Danish Medicines Agency 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

### *Definition of advertising*

#### 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 Medicines Agency'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. For further on the broad definition of advertising, including the use of social media, please see ENLI's Guide on use of Digital Media in advertising activities.

- 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 digital 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 access 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. 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. See further details in ENLI's guide on digital media.

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. 6. 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 Medicines Agency, ENLI regards the healthcare professional concerned as an employee of the pharmaceutical company and correspondence with the healthcare professional concerned is not regarded as advertising.

Conversely, the opinions of an employee of a pharmaceutical company, including an employed healthcare professional – no matter where in the company one is employed – is regarded as statements by a representative of the company, thus the Promotion Code must be complied with. This

means, among other things, that it is subordinate, whether it is e.g. a medical adviser, a sales person or a market access manager, which refers to a phase 3 study to healthcare professionals –their mentions of the study can be advertising (see more about this at Art. 4.1). For further, please see ENLI's Guide on Pre-launch.

The Danish Medicines Agency 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 Medicines Agency 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 Medicines Agency in a specific case 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 Appeals 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. If an invitation mentions generic or invented names, the compulsory information must be an integral part of the invitation. If there is no mention of specific generic or invented names, one can choose to attach to the compulsory information; however, there is no requirement for this to be integrated.

### *The company's responsibility for presentations*

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. By virtue of its responsibility for the event as a whole, the company is always 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**).

The Appeals Board has in AN-2016-3924 stated *“the companies have in their agreement with the lecturer clarified that the lecture should be held in accordance with the applicable rules and legislation. The agreement, however, does not exempt the companies for the overall responsibility for being compliant with the advertising rules. It is therefore for companies to establish a regime that adequately ensures control of, that the rules are complied with, see the Appeals Board's comments on this in case AN-2014-0917 of 28 April 2014. As noted by the Investigators Panel it is the usual practice of the majority of phar-*

*maceutical companies that presentations are reviewed in advance with this responsibility in mind. The Appeals Board is not aware that this practice should have given rise to practical problems or fundamental concerns, taking that this is merely about an overall verification of compliance with the formal rules in this area."* For further please refer to KO-2018-2255 and AN-2018-3964.

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. 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. However, the company has the overall responsibility, see above.

If it is a wish from the podium, the company can assist with practicals such as handing out slides, so they are ready with the participants at the start of the meeting. This can be carried out without the slides thereby is considered as an advertisement from the company, which shall be notified to ENLI. Slides can also be made available via apps, if it is clear that when downloading the app, you get access to all the material from the event. It is thus up to the individual participant to assess whether one will "request" about the whole thing via the app. If you only want to receive slides from a single presentation during the event, you as a participant must request the company/speaker for the specific slides instead of downloading the app. Thus, if the content of the app is clearly stated before download, the material does not have to be reported to ENLI.

It will also be compliant to distribute slides to participants after the meeting, where these have been requested. If distribution of slides is unsolicited, e.g. in connection with a consulting visit, the distribution of slides will, as always, be regarded as an advertising activity.

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 Sec. 21.

**Reply to oral questions** will not always constitute advertising. The pharmaceutical company must, however ensure that an oral exchange of question/answer does not lead to an advertising situation, and thus fall within the scope of the rules on advertising. The specific context in which the question is answered in, must thus be assessed.

It is the starting point, that an oral answer to a specific question about a particular medicinal product is not advertising, if a pharmaceutical company stick to answering the specific question. It is provided that the pharmaceutical company did not take the opportunity to orally advertise the drug, e.g. by going further than to answering the question, with positive publicity/claim of the medicinal product or

claim of off-label use. It is also provided that the reply is addressed to the persons who have asked specific questions about the company's medicinal product.

If a pharmaceutical company answers a specific question with factual information, and the company stick to answering the question without using e.g. subjective claims of the medicinal product, it is ENLI's immediate perception that this will not be perceived as outreach information activity, canvassing or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (advertising concept).

However, it must be based on a specific assessment of the company's activities, whether it is advertising of a medicinal product. There will, among other things be seen on the issue, the contents of the reply and the context in which the reply is included. If a pharmaceutical company disseminates the answering of the question for people who did not ask the question, it is ENLI's immediate presumption that it is a promotional activity from the company's side. Similarly, there will be a presumption of advertising if the company approaches healthcare professionals to see if they are interested in a meeting with representatives of the company to get information about the medicinal product.

It is in this regard, allowed to respond (objectively and factually) on an individual, unsolicited and concrete question asked by a healthcare professional, also where this is taking place on behalf of a group of healthcare professionals. This means that the answer may well be disseminated to the entire group e.g. in connection with a meeting to be held on the initiative of the healthcare professionals. It must however be kept in mind that the meeting must not take on the character of advertising, e.g. by means of a general review and supplementary information in relation to the asked question. If there are concrete follow-up/clarifying questions on the unsolicited meeting the company must make sure that these are questions which the whole group wants to get answered. If this is not the case, the company can answer the questions verbally and individually after the meeting or answer the question in writing and individually after the meeting. The company must continue to ensure that the reply sticks to this particular question and that the answer does not take on the character of e.g. claims of off-label use or advertising for a medicinal product.

It is important that the company can demonstrate that the meeting is held at the request of the healthcare professionals based on a concrete invitation, and that it can be demonstrated that the company has stuck to the issues from the healthcare professionals in its reply. It can be beneficial to receive the specific questions in writing prior to the meeting, together with a written invitation, and ENLI recommends that companies should prepare a note/a summary of the meeting (with accompanying documentation provided for answering questions – e.g. in the form of talking paper and PowerPoint presentation).

It should be noted that pharmaceutical companies' training sessions and individual consultancy meetings remains in the field of the Promotion Code, which in connection with questions during such meetings – as here are held at the company's initiative – answers must be in accordance with the rules on advertising and therefore the answer must stay within what the company's drug is approved for.

### *Definition of Healthcare professionals*

**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 Medicines Agency, a healthcare professional should be taken literally and formally as any person educated/in education in one of these professions. It thus makes no difference whether or not a given healthcare professional is actually working in his/her profession.

It should be noted that the legislator by deciding which occupational groups should be included in the definition, places emphasis on whether or not there is a well-defined training, which enables the occupational group to understand, assess and see through advertising of prescription medicines, as well as to if the occupational group has a professional interest in prescription drugs, see. inter alia, the comments to the proposal for a modification of the Pharmaceutical Act, etc., tabled in Parliament on 5 December 2013.

### *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. 39.1 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 The Danish Association of Parallel Distributors of Medicines. There is a list of all associated companies at [www.enli.dk](http://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 Institute (SSI) or the National Veterinary Institute at the Technical University of Denmark in accordance with Sec. 30 of the Medicines Act.

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.

The provisions of Sec. 4.1 of the Code are based on EFPIA's Code of Practice 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 Medicines Agency at least 14 days in advance of the price becoming effective. Notification may be done previously to the Danish Medicines Agency, which simply must be done via mail ([medicinpriser@dkma.dk](mailto:medicinpriser@dkma.dk)), where the expected price and when it should apply from are reported.

Advertising activities may start from the date that the price has been notified, when a marketing authorization has been obtained. If the price has not been published on [medicinpriser.dk](http://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 Medicines Agency. For radioactive medicinal products, documentation must be provided to ENLI that the price has been notified to the Danish Medicines Agency at least 14 days in advance of the effective date of the price.

The assessment of whether mentioning of a potential future specific drug before the time of marketing approval, is advertising (pre-launch), can be difficult. A distinction must be drawn between scientific information and actual advertising, which is especially difficult when the presentation of information is assessed in a specific context with many shades (pre-launch):

- ENLI considers as a starting point, any mentioning, towards healthcare professionals, of scientific studies and data related to phase I and II of a clinic development program for potential future medicines, to fall outside the scope of the Promotion Code, as it is not a given that a specific project ends with a marketing authorization for a specific medicinal product. Such mentioning is considered as scientific if the information is presented in a neutral and non-promotional way (i.e. mention of the potentially upcoming drug may not be laudatory). When mentioning information from phase III studies, one must consider in particular whether it can be considered as advertising, especially if an application for a marketing authorization or publishing of the study is imminent. Mention of results from phase III trial after its publication in a scientific journal (i.e. after e-publishing with DOI number or print in a recognized journal with unbiased review, see. Promotion Code Art. 7) can therefore be, and will, most often, be considered as pre-launch when this is carried out in a specific commercial marketing context, as it must be assumed that from this date, the company is working determinedly on a marketing authorization.
- When mentioning of studies on medicinal products the company must 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 to ENLI's assessment should not be limited by the Promotion Code, cf. also the principle in EFPIA's Code of Practice 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 (now the Danish Medicines Agency) stated that teaching, a professional presentation of scientific data or a professional review of studies which take place 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 considered 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, the reference must be made in accordance with the rules of the Promotion Code, including this clause.
- In a medicine's life cycle management, several clinical development programs are typically included which, for example, could have intended to examine the medicine's effect on other (sub) populations (e.g. pediatric use) or entirely new indications/uses. In a promotional context, the emphasis of such clinical development programs will, as a basis, be considered as an expansion of indication and thus an unlawful advertisement.
- For further guidance, see ENLI's Guide on pre-launch.

#### Re: Sec. 4.2

See also sec. 63 of the Medicines Act, EFPIA's Code of Practice 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. 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 require-

ments 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.

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.

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.

Reference is also made to ENLI's Guide on Information Material and Documentation, in which documentation sources and requirements for comprehensive information in advertisements are reviewed.

### *Illustrations/images in advertisements*

It is stated in Article 87 (2) of Directive 2001/83/EC of the European Parliament and of the Council that: "*All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics*". The European Court of Justice cites in Case C-249/09 that in an advertisement for medicines, no statements must be made that are inconsistent with the information contained in the SPC of the medicinal product. It is noted in the judgment that "*Specifically, no part of an advertisement for medicinal products may ever suggest, inter alia, therapeutic indications, pharmacological properties, or other characteristics that conflict with the summary of the product characteristics [...]*".

Pictures are part of the advertisement and often put in context of the information in the advertisement. When an advertisement is evaluated by ENLI, the overall impression of image and text will therefore be assessed.

Illustrations/images typically represent a natural part of the advertising of medicines, particularly in order to enhance understanding of the nature, effect and appearance of the medicine. However, the illustrations must not have a suggestive character (induce a strong emotional influence), cf. the prohibition in the Promotion Code Art. 4 (2), regarding consumer-stimulating marketing. Illustrations/images that, for example, in a romantic colour scheme and setup gives the impression of freedom, youth and prosperity without relevant connection with the medicine being advertised, is therefore not acceptable.

Images must not signal improved quality of life or be too aggressive. It is thus not in accordance with Art. 4 (2) of the Promotion Code, to signal that a good life is waiting ahead, after taking the medicine, or to signal an activity level that cannot be expected in connection with the disease in question and its treatment, see, inter alia, AN-2019-1358.

Pictures that suggest freedom, holiday and “feel good”, and could just as well be included in an advertisement for a holiday destination, are therefore not legal to use in a medicines advertising. Excessive joy (and childhood joy in adults) is also not considered objective in the context of a medicines advertising.

It is also not in accordance with Art. 4 (2) of the Promotion Code, using images that put a melancholy theme for medicines advertising or through images, plays on fear and signals that there is danger ahead. It is thus not objective to intimidate with images that signal that you are in (serious) danger if you do not take the medicine or that you will otherwise suffer from harm if the medicine is not taken.

Illustrations/images are generally very expressive and may in some cases express more than you can immediately write in words. Illustrations/images can be value-laden and make a great impression on the recipient. Therefore, it must always be considered whether it is ethical and objective to use a concrete image in connection with the marketing of the company's medicine. It should be noted that it will always depend on a specific assessment of the individual advertising whether the requirements for objectivity have been complied with. However, in general, pharmaceutical companies must exercise considerable restraint on the use of mood images.

Images of people in medicines advertising may constitute a patient case/medical history, which is not in accordance with the Promotion Code requirement that advertisements appear proper, ethical and factual. This applies regardless of whether the story is fictitious or true. Patient cases can also not be used as a documentation basis for statements made by a pharmaceutical company as part of its promotional activity.

Patient cases are regarded as a subjective, graphical medicinal claim when used in a promotional context. A graphic illustration describing an individual effect can, thus, not be used to document its effect, which clinical studies that are based on effect measurements at population level, can document. A claim at individual person level is therefore not 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.

An example could be an illustration of a single patient in connection with the marketing of a medicinal product. Such an illustration will not nuanced describe the effect of the medicine based on a study of e.g. 100 patients. No medicinal product has been approved based on the study of the effect on just one person. In a trial there will always be some people on which the medicine has a good effect and some which the medical product may not have equally good effect on.

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. The Appeals Board thus stated in AN-2018-1262 that the key to using images of a patient in an advertisement is whether it reflects a realistic or expected appearance, reaction or action in relation to the use of the medicine.

Patient cases are construed as claim-making direct or indirect product-individual relations based on an image, a series of images or in a video. Thus, a photographic image of objective symptoms of a given illness is not regarded as a patient case unless viewed in relation with a medicinal product, for exam-

ple, with coherent text or by implicitly implying the efficacy of the medicinal product for symptoms or the illness as a whole.

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.

It is noted that distribution of promotional material (for the same medicine) with time offset, for example a "before" image in the first distribution and an "after" picture in the next distribution will be perceived as an illegal patient case, unless it is clear that each distribution is an independent advertisement.

#### Re: Sec. 4.3

The clause corresponds to EFPIA's Code of Practice Art. 8 and is not replicated in the Advertising Order.

For advertising materials used on exhibition stands or distributed to participants of such international events outside Denmark, it is ENLI's view that these, as a minimum, should comply with sec. 2.01 in EFPIA's Code of Practice, which prescribes a set of minimum information to accompany the advertisement. Thus, there is no requirement that the compulsory information according to Art. 5 accompany the advertisement, even if the event also is considered to be fully or partially targeted Danish healthcare professionals and therefor falls within the scope of the Promotion Code.

However, one must also make sure to observe the national rules in the country, where the international event takes place.

At international events in Denmark, the Danish legislation continues to apply, which means that only drugs that have a valid marketing authorization in Denmark must be advertised, see. above ad Art. 4, (1).

## COMMENTARY ON CHAPTER 3 – ADVERTISEMENTS

### Re. Article 5 Compulsory information

The rule is regulated in EFPIA's Code of Practice Sec. 2.01 and the IFPMA Code of Practise Art. 5 and corresponds by and large to Sec. 11 of the Advertising Order.

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](http://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 latest 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.

The Danish Medicines Agency 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 Medicines Agency 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 if the invented name and generic name are mentioned in the overall promotional material.

### 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 if 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.

In AN-2017-2394 the Appeal Board states that the provision in Art. 5 (1)(3), "*stresses that mentioning of the therapeutic indications of a medicinal product is key in advertising of medicinal products. The SPC of the medicinal product must be an integral and eye-catching part of the advertisement, which the typical reader (HCPs) cannot avoid taking a position on and which is a part of the overall message. Therefore, the requirement that the full indication (SPC) must be clearly stated where the disease area is mentioned first.*" However, the Appeal Board states, that if the promotional materials constitute one sheet (possibly with writing both on front and back), there are no requirements to where on the sheet the full indication appears, cf. AN-2017-2394.

It should be noted that, in any promotional material, the full indication should appear from the promotional part of the advertisement if there is a risk that the advertisement may be perceived as misleading or incomplete in relation to the other statements in the advertisement and the advertisement's setup. Essential and necessary information relevant to adequate and accurate advertising can therefore not be separated from the specific promotional part of the advertisement. Therefore, if it is not possible, for spatial reasons, that the entire medicine's therapeutic indication appears in the promotional material, it will not be possible to use the relevant advertising format, e.g. a banner ad where space is limited.

The indication of a medicinal product should be the pharmaceutical advertisement's main message and the medicinal product's indication must under no circumstances be reworded e.g. to promote other medical remedy effects than the medicinal products approved indication. The use of disclaimers does not make laudatory statements of a medicinal product, outside the approved indication, legal. Other positive effects of the medicinal product that are not covered by the legal indication can thus only be specified neutrally with reference to valid source manual. For furthermore, please see the guidance to Sec. 4.2.

#### 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 Medicines Agency 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.

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 63 of 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.”*

The same applies for an advertisement containing a price comparison on a pharmaceutical company’s own medicinal product seen over a period, with an indication of a savings percentage. This is legal, if it contains information about the concrete prices covered by the price comparison. It is sufficient that a note in the advertisement shows the prices. It must clearly appear which price is the current price, and which prices are old prices.

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](http://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](http://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](http://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.

Early advertising for a medicinal product, where the price do not appear yet in the "rate" ([medicinpriser.dk](http://medicinpriser.dk)) (but this is notified to the Danish Medicines Agency, see. Promotion Code, Art. 4, (1)), the Danish Medicines Agency has stated that they will not demand that there is a reference to [medicinpriser.dk](http://medicinpriser.dk) in the compulsory text, but that e.g. one can write that the medicinal product is expected in the market for the price (the reported price) x DKK.

For more on advertisements containing price comparisons, please see the guidance on Art. 8.2.

### 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 date, month and year, and dating should normally relate to the date of the preparation or modification of the advertising material. Separate dating in magazines, etc. is unnecessary in advertisements, if the magazine clearly gives a date, month and year.

It is noted that the compulsory information is a part of the advertisement, which means that changes in the compulsory information will require a revised date in the actual compulsory text.

### Re: Sec. 5.2

The clause corresponds to Sec. 11.4 of the Advertising Order, and partly EFPIA's Code of Practice Sec. 2.01.

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. It must say "Read the compulsory information here" or the like, so it clearly appears, where to find the compulsory text. It is thus not accepted to link to the compulsory text and only write "See more here" or the like.
- In a video, the compulsory text must, as a starting point, be an integral part of the video, i.e. that the compulsory text should appear at the beginning or end of the video. However, this can be waived in the following cases:
  - The video is not "owned" by the company, i.e. that the company does not have the opportunity to edit the video - for example, because the video comes from the company's foreign headquarters. In this case, the compulsory text can be placed max. one click away.
  - In the case of a video displayed on an exhibition stand, there is no certainty that the recipient will watch the entire video from start to finish. Thus, the following visible information is allowed: "Compulsory text is freely available on the exhibition stand".
- In PowerPoint presentations it is accepted that the compulsory text appears e.g. initially or finally as last slide.
- The compulsory text may in an e-mail message be replaced by a direct link to it. The link must state clearly that this is where you find the compulsory text.

The advertisement must however, regardless of whether it is on a roll-up, poster or the like, comply with the Promotion Code.

When changes occur in an SPC (e.g. in connection with updates), the compulsory text must be changed at the same time. This means that the company is obliged to update the existing marketing material with a new compulsory text. The amendment of the compulsory text (as a result of amended SPC) must take place immediately, regardless of whether it is a significant or minor change in the SPC.

*Promotional materials in Danish:* The compulsory text must as a starting point be printed in the material. In the case of e.g. a brochure, there must be a special justification if the compulsory information is not integrated (= printed) in the material itself. A reason could e.g. be that the company wants to have the compulsory information as inserts, because they regularly will revise the wording of the compulsory information. In that case, the company must prove what the justification is for not having printed the compulsory information.

*Promotional material in languages other than Danish, e.g. English:* In the case of material that the company have drafted in English, or material, which the company has received from the headquarter in a foreign language, it will be sufficient as a starting point, that the compulsory information is added as inserts in the promotional materials, or behind the material/brochure. This could for example be the case on exhibition stands or in other conditions where promotional material in languages other than Danish are handed out. What matters is that the advertising and the compulsory text actually will be distributed together.

**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 Code of Practice 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.*"

It should be noted, that the provision must be interpreted very narrowly, which means that if there is information other than name and common name, as well as possibly company name, this will result in a requirement for compulsory text.

Logos can 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 are significantly minimised.

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's Code of Practice 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 of the medicinal product on an individual patient 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 product characteristics (although reference is required to the summary of product characteristics). It should be noted that a reference to the Summary of Product Characteristics on [www.produktresume.dk](http://www.produktresume.dk) is sufficient if there is no doubt about which summary of product characteristics appears, including the risk of misleading. There is thus no requirement to refer to a dated summary of product characteristics.
- 2) Regarded as generally known by professionals. Therefore, no information is required about issues that are available in standard textbooks.

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 claim.

- 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. See, among other things, AN-2018-2631 concerning the term "simple and flexible", where three subsequent sub-items primarily had the character of a subjective assessment by the company and not an actual documentation of the claim that the treatment with the medicine was "simple and flexible".
  - 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 and AN-2018-2220.
  - Claims to be "first" and the like must be documented to ENLI in case of inquiry, e.g. by submitting documentation that you have searched for all medicines with the same indication and can prove that you are the "first" with the stated condition.
- b) Claims that a product is effective within a given timescale must also be accompanied by documentation. If it is wished for example to emphasize that a medicinal product works within 1 hour, the statement must be scientifically supported and documented from the SPC or by reference to another compliant source.
- 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.

#### Re: Sec. 7.2

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

#### Re: Sec. 7.3

This clause corresponds to Sec. 13.2 of the Advertising Order. The clause further implements EFPIA's Code of Practice Sec. 3.01 and 3.04, and 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 must be stated unambiguously. None of these may refer to obsolete information or be misleading in some other way.

The references can in principle be placed e.g. along with the compulsory text. In certain situations, this can be done on a separate page, cf. Art. 5(2). However, essential and necessary information that is important for proper and fair advertising cannot be separated from the promotion part of the advertisement. Thus, in such situations, the references must be placed directly in the advertising section.

In connection with references to relevant studies, it is noted that one should not select one single study that indicates positive results for the company's medicine, if it appears misleading in relation to the overall knowledge in the field. Thus, exhaustive new/relevant references must be provided, which must be published in recognized journals, indexed on a par with Pub-Med and Embase.

If there are errata/erratum for a given publication, the corrected data which an advertisement refers to must be stated in the reference statement together with the article. Thus, in order for the advertisement to be regarded as adequate both the article and its erratum must be stated.

If a video is used, a dynamic reference view is recommended, where the references are continuously displayed in the video in conjunction with the statements to which the references relate. It may also be considered to make a reference collection at the end of the video with clear and concise reference to which segment of the video the reference applies, for example by setting the time stamp. An aggregate indication of references in the end without clearly indicating which segment the reference relates to is not in accordance with the rules.

#### Re: Sec. 7.4

This clause derives from the EFPIA's Code of Practice 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. A precise reference must also be given to the source.

Depending on the circumstances, companies can accordingly customize by rephrasing the content from the source, as long as this it without significant professional important omissions or distortions, and the message overall is reproduced faithfully. 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. It is also allowed to change the units to the units used in Denmark, for example, from mg/dl to mmol/l, as well as statistical recognized values can be inserted into figures, if these are included in the reference and will not be highlighted laudatory in the figure.

Companies may draw up their own figures, graphs and tables of results or messages in source material if such graphical reproductions are not found in the source material, or if there e.g. is a wish of another type of shape.

- In such cases, a figure, graph or table can be drawn up if this precisely reproduces the results from the reference without essential omissions or distortions. It is therefore important for figures, graphs or tables to faithfully reflect the message in the source material.

- It is acceptable to remove information from a figure/graph/table, if it is irrelevant for the advertisement if e.g. the shape of the reference shows figures for both COPD and Asthma, but the advertisement only concerns asthma – here it will be legal to omit information about COPD in the figure/table.

The above mentioned is provided that it is clearly indicated that the graph/figure/table is prepared by the company, and that the final result is reproduced faithfully and cannot be considered to mislead/distort the message in relation to the reference. There must not be excluded data, which is relevant in order to consider the figure, etc. as a loyal version that is not misleading.

Reference is made in this context also to AN-2017-2394, where the Appeals Board found that the change in the sequence of data from a table from RADS was misleading and unfair, since the emphasis of the company's own medicine as the first in the sequence, distorted the message. This was therefore a breach of both Art. 4, sec. 2, and Art. 7, sec. 4.

#### 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 (indexed on level of PubMed and Embase). Similarly, peer-reviewed textbooks used for teaching purposes in universities in Denmark.
- 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 or economic interest cf. in this connection also how 'independent' above is construed, i.e. a referee.

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.

Even though a study is peer-reviewed and published in a journal, which formally comply with Art. 7 (5), this does not mean that the reference can be used completely indiscriminately. If the reference e.g. contains information about conditions that are contrary to the SPC, the reference cannot be used, even though it complies with Art. 7 (5) since, at the same time, it is contrary to the other provisions of the rules on advertising. Furthermore, see the decision of the Appeals Board in AN-2017-1490.

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.

With reference to the Promotion Code Art. 7 (5), scientifically sound studies can, in addition to the summary of product characteristics, be used as documentation for information about a medicine.

Randomized, controlled studies published in a recognized and independent journal and subject to an independent review (see above), is in fact considered the primary supplementary source for the lawful and approved summary of product characteristics.

For further information on the use of different types of documentation (studies, guidelines, the Medicines Council's recommendations, etc.), see the ENLI Guide to Information material and Documentation.

#### Re: Sec. 7.6

Sec. 7.6 implements EFPIA's Code of Practice 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

Art. 8 implements EFPIA's Code of Practice sec. 3.05. and sec. 16 in the Advertising Order.

Comparative advertising is 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 Promotion 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.

Reference is also made to the ENLI Guide to Information Material and Documentation.

### 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 medicinal products are being used for comparison. This also applies when the company compares medicinal products that are only sold by the company itself.
  - It will be a comparative advertisement to indicate that the medicine "does better" or the drug "works the fastest". In that case full documentation must be available in relation to all relevant medicinal products on the market, cf. the rules for documentation in Art. 7. More indefinite declarations such as "other" or "competing products" are not acceptable. Comparison with a group of medicines where this is of a more indefinable nature cannot be accepted.

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. However, ENLI's practice is after a 1-year trial period changed, so the requirement for a comparison chart lapse, after which ENLI thus accommodates the Danish Medicines Agency's rules in the Advertising Order and associated guidance. However, be aware that the Promotion Codes other rules regarding pharmaceutical advertisements still must be met, including the requirement of completeness, which may have an influence on the assessment of the comparison.

According to the Danish Medicines Agency it should clearly appear of a pharmaceutical advertising that contains a comparison between multiple medicinal products, what medicines the comparison includes. The comparison must be limited to medicinal products, which it is objectively appropriate to compare, e.g. medicines with coincident scope, cf. the Advertising Order on sec. 16.1. There is also an obligation to present the compulsory text. See also AN-2018-3964, which states: "*The Appeals Board can agree that during the presentation - especially when using slide 30 - an unfair comparison of medicinal products has been made in violation of Section 8 (1) of the Promotion Code. This slide compares the efficacy and safety endpoints of [X] and [Y], regardless that [...] drug [X] is not approved for the indication, thus, it is an off-label comparison contrary to the advertising rules.*"

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 pharmaceuti-

cal form or strength or differ significantly in pack size. Medicines with an insignificant market share (2-3%) may however be omitted from a comparison.

In AN-2015-2944 the Board of Appeals decided, that if one compare one's medicinal product with a clear limited group of medicinal products, there must be identification of the specific medicines in the comparative advertisement, just as there must be full documentation in relation to all the medicinal products, which are subject to the comparative pharmaceutical advertisement.

Full documentation on the comparative medicinal products can be done by reference to their SPC's.

In connection with references to relevant studies, it is noted that one must not pick out one single study indicating positive results for the company's medicine, if it will appear misleading in relation to the collective knowledge in the field, cf. also Art. 7.3. One must specify an exhaustive list of newer/relevant references, which should be published in recognized journals, indexed at level with PubMed and Embase.

The Appeals Board has in AN-2017-1564 also stated "*The overall requirements of factual and adequate advertising has central importance in relation to comparative advertising, in particular because this form of advertising is an essential differentiation and positioning tool [...]. Regardless of accordance with other rules of the Promotion Code, advertising of medicinal products must comply with the Promotion Code Art. 4(2)...* "

Documentation of "absence" of parameters with the comparative medicinal products should be presented to ENLI upon request. This can be e.g. SPC's or studies.

If a company wants to continue to use a comparison chart, it must be true and fair for the comparison.

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

#### 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 medicinal products to which the comparison relates. This applies insofar as the product summary contains information about the subject covered by the comparison.

The Appeals Board has in AN-2017-1564 stated, "*Although the general documentation is compliant with the Promotion Code Art. 7 (5), and regardless of the fact that the statement is reproduced unchanged in the advertisement - in Danish translation - from a schema of the general documentation, the Appeals Board agrees, that the concrete use of the statement must be considered as misleading and contrary to the Promotion Code Art. 4 (2) and Art. 8 (2). Comparative advertising is to be drawn up on the basis of the information contained in the summaries of product characteristics of the medicinal products that are included in the comparison.* "

There must be no comparison with medicinal products that cannot be legally traded in Denmark, cf. Sec. 4.1, so information about such medicinal 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.

Add-on medicinal products are regarded as all other comparative advertising.

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](http://medicinpriser.dk). In **price comparisons**, the current price must be given.

A price-comparing advertisement for medicines must contain all medicines with the same indication. One cannot therefore choose to compare only on price with one selected competitor. It follows from the guide for the Advertising Order, cf. 3.2 that a comparison is basically sufficient only if it includes all synonymous (as well as any parallel imported) medicines that do not differ in either pharmaceutical form or strength or differ significantly in package size. However, pharmaceuticals with a negligible market share (2-3%) may be omitted from the comparison.

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 medicine. Price comparisons in which analogue or synonymous products are included must only be based on the dosage approved by the Danish Medicines Agency. 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 all prices have not been calculated, they must be based on relevant, common pack sizes, which give the lowest price for the competitor.
- 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.

In an advertising with price comparison sent to hospital clinics/hospitals, tender prices which pharmaceutical companies are obliged to use when selling medicines to the hospitals, can be used.

**Prices** should only be given in a comparative advertisement if price claims are being made in the advertisement. In comparative advertisements, prices must be current and correct at the point at which the advertising matter is being used.

**Re: Sec. 8.3**

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

All information must be 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 Code of Practice and supplements the rules set forth in the Marketing Act, *inter alia* on SPAM mail and the rules on registers in the Data Protection Regulation to which reference is also made.

### **Re: Article 10 – Transparency of sales promotional measures**

The clause corresponds to EFPIA's Code of Practice Art. 7. Reference is further made to the provisions of the Marketing Act.

It is noted in the IFPMA Code of Practice that all research, including clinical trials and observational studies, must have a scientific purpose and must not be covert marketing, see IFPMA Art. 9.2.

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

The clause corresponds to EFPIA's Code of Practice Art. 9.

## 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 Sec. 22.1 of the Advertising Order (although there is no reference to the exceptions with respect to public meetings, etc.), EFPIA's Code of Practice Art. 11 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.8, so that the most stringent rule apply.

Accordingly, pharmaceutical companies must not give or offer financial benefits to healthcare professionals in any kind, direct or indirect (prohibition against gifts). This also applies to personal services that are any kind of service that is not associated with the profession and which gives the recipient a personal benefit. This could, for example, be helping a pharmacist with setting up goods and moving around inventory, goods, etc.

Interpretation of the prohibition against gifts is based on relevant official practice and FAQ's from EFPIA and Lif thereon. EFPIA's FAQ's 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 Code of Practice (as incorporated in the Promotion Code Art. 13-15) 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, including the Advertising Order.

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), in the EFPIA Code of Practice and in EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.8, 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 contracts, etc.

**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 for how long it is borrowed. For example, loaning IT equipment such as a tablet may be permitted at a medical congress for a limited period 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.) to comply with the professionalism requirement (Lif's FAQs/ Q 16).

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 medicines, 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 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 professional. 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 or 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. 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, EFPIA have provided 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 key cards, etc.

It is the Investigator panel's opinion that it is allowed to provide folders at the pharmaceutical companies' own meetings, if there is a need to do so. This means there is no need, if nothing is handed out during the meeting. "Own meetings" is continuing educational meetings – and not individual medical representatives' meetings. It will thus not be allowed to distribute a reprint carrier or the equivalent at individual medical representatives' meetings

It should be noted in this context that practical meeting equipment must not be branded with product names (either invented or generic names). At own events it is thus only acceptable with company name/logo as well as possibly disease area. By 3-party events, it is only allowed to brand the practical meeting equipment with the hotel or conference name.

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 depends on their involvement in the event:

- 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 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 make a difference, whether this is part of marketing a specific medicinal product or as part of the company's "image care". It states in the guidance to the Advertising Order 5.6.1. that: *"It is irrelevant whether or not the competition held by a pharmaceutical company is linked directly to the promotion of a certain medicine. A competition launched at health professionals as part of a company's »image management« activities must be assumed to come from intentions to promote not only the company but also its products. Therefore, the competition must be assumed to have been conducted for advertising purposes in breach of the provision."*

Pharmaceutical companies are not allowed to participate in competitions in exhibition areas, including activities to get participants around the exhibition area. This means, among other things, that companies should not contribute with questions/answers for the competition, and that questions/answers must not be positioned as a part of the company exhibition. However, the questions/answers may be

placed around the room itself. Thus, the organizer should not involve companies in the competition, and it should be clearly noted in the program for the event, that it is the organizer's competition.

It is noted that, e.g. an interactive display at an exhibition with questions about the pharmaceutical company's medicine is not in itself a competition, because the purpose in itself will be a more engaging form of knowledge sharing of scientific information. This is of course assuming no prizes are awarded.

## **Re: Article 13 Professional events, sponsorships and hospitality**

The clause corresponds to a compilation of the provisions of EFPIA's Code of Practice 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 Code of Practice, 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.

#### **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.

The **concept of professionalism** has been 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 dis-

ease, with the focus on health economic, political and general consequences for society and management mechanisms.

On the other hand, ENLI's basically does not accept 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 (e.g. 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 to conflict with this requirement, as emphasis had been on ensuring that no current safety issue problem was involved, cf. AN-2012-2584.

#### *Patient cases as teaching method*

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 if 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. Therefore, such a presentation may have, in certain circumstances, the character of a more general exchange of experience (cf. below under sponsorship)

#### *Patients as speakers*

So far, it has been the practice of ENLI that patients could not in principle be used as presenters in a professional event, since they are not considered to have the necessary scientific background to be able to present a professional presentation pursuant to Art. 13 (1). However, at the request of Lif's Ethics and Compliance Committee, ENLI has reassessed the applicable restrictions on the use of patients as speakers, cf. Art. 13(1).

After discussing the scenarios and purposes of having patients as presenters, ENLI has decided to allow the use of patients as presenters in a **one-year trial scheme from June 1, 2020 - May 31, 2021**.

During the trial, ENLI will accept the involvement of patients as speakers. In this connection, please pay particular attention to the following:

- Patients as speakers may only talk about illness, and conditions during the illness, that do not relate to treatment with specific medicines. Thus, patients' presentations should not be used as a "live patient case" to illustrate the effect of a medicine;
- Patients should not be included as part of an advertisement for specific medicines;
- Patients' presentations must form part of a comprehensive event on the disease in question, and must not stand alone as the sole or most important purpose of organizing the continuing education event;
- The selection of patients must be done in collaboration with relevant patient organizations;
- Pharmaceutical companies are, as usual, responsible for the content of presentations on their continuing education events and are therefore also responsible for the individual presentations not taking an unforeseen turn along the way, for example where a patient as a speaker is asked to relate to the use of specific medicines.

As far as the selection of patients to be used as presenters is concerned, the selection must be documentable to ENLI on request.

If patients are used as presenters in a disease area where no actual patient organization exist, e.g. for certain rare diseases, the selection can be done in collaboration with a healthcare professional who is either hired to give lectures under the same continuing education event or who is part of a planning committee in connection with the continuing education event.

For example, as speakers, patients will be able to shed light on certain points in the dialogue between the healthcare professional and the patient. The following are a number of *examples* of patients as presenters who will be accepted by ENLI during the trial period:

- The patient's path through the health system:
  - In a disease area where the disease is particularly aggressive and the survival after the diagnosis is quite few years, the purpose of a patient's presentation will be to tell how important it is for these patients to be diagnosed as soon as possible. As part of a comprehensive program on the disease, a patient presentation is requested, in which the patient will only tell what doctors/departments and examinations he/she has been through.
- Improving dialogue with patients for better disease management:
  - The presentation is based on a dialogue between a healthcare professional and a patient. The patient's perspective is necessary to gain an understanding of how knowledge is translated into information that can be understood by the patient. The purpose of the

use of live interaction with patients is thus to see what challenges and opportunities exist in the dynamic communication between doctor and patient, thereby improving the dialogue.

- There will be no discussion of medicines and there will be no sharing of the patients own medical history.
- The speaker facilitates/guides the dialogue and any questions from the meeting participants (specialists in the therapeutic area) are evaluated by the speaker before the patient is given the opportunity to answer. The speaker will thereby ensure that questions fall in line with the relevant academic topic being discussed.
- Patients' experience of the transition from young to adult and declining adherence/compliance;
  - The continuing education meeting deals with the results of a study on adherence in young patients in a therapeutic area. The study has focused on identifying factors that can inhibit and promote the adherence of young patients in the transition phase from parent-based to self-care and from treatment in the paediatric to adult ward.
  - The purpose of live patient presenters will be an interactive dialogue between healthcare professionals and two patients at different stages. The focus of the meeting will be the patients' needs and experience of the transition from young to adult and the declining adherence/compliance in this particular phase.
- The importance of "joint decision-making" - involving the patient in consideration regarding, among other things, risk taking concerning treatment:
  - Joint decision making is about helping patients when faced with difficult choices about their treatment. Here, the patient and the HCP work together to make the decision by taking into account both professional, scientific knowledge and the patient's lifestyle and personal preferences.
  - The patient presentation is touching on considerations about his risk appetite regarding the opportunity for milder preventive treatment that allowed the patient to work as opposed to a more intensive course of treatment.

### **Company 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 responsible for all presentations made at the event, irrespective of whether they come from an independent third party, hired by the pharmaceutical company. ENLI assess that companies have a duty to react if a speaker makes 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 (now the Danish Medicines Agency) 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 (now the Danish Medicines Agency) 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 (now the Danish Medicines Agency) 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: Art. 4.1).

In AN-2016-3924 the Appeals Board thus found that the two companies' symposium during a medical society's annual meeting did not constitute a part of the official program for the annual meeting, since it did not appear clearly from the medical society's printed program, which was further underlined by the fact that the symposium was placed in the lunch break during the annual meeting. *"In accordance with the Danish Medicines Agency decision of 28 May 2014, the symposium must thus be regarded as a commercial activity subject to the applicable advertising rules."* The companies were, as organizers of the symposium, thus responsible for compliance with these rules.

The Board of Appeal noted that the companies according to the reported agreement with the professional speaker had clarified that the lecture should be held in accordance with the applicable rules and legislation. This agreement, however, does not exempt the companies for the overall responsibility for complying with the advertising rules. *"It is therefore incumbent on companies to establish a regime that adequately ensures that the rules are complied with, cf. the Appeals Board's comments on this in case AN-2014-0917 of 28. April 2014. As noted by the Investigator's Panel, it is the usual practice of the majority of pharmaceutical companies that presentations is reviewed in advance with this responsibility in mind. The Appeals Board is not aware that this practice should have given rise to practical problems or principle concerns, taking that this alone concerns an overall verification of compliance with the formal rules in this area."*

### *Presentations/slides*

There is no requirement to report slides drawn up by a third party unless the company has been influential in preparing them. It should be noted that, as a starting point, the company can look through the presenter's slides with a view to ensuring that the presentation meets ENLI's advertising rules. What matters is that the company is not actively trying to influence the professional content or the angle of the topics that the presentation deals with, cf. the above about the Appeal Board's decision.

If it is a wish from the podium, the company can assist with the practical as to hand out slides, so they are ready with the participants at the start of the meeting, without the presentation thereby is considered as an advertisement from the company.

The company can also distribute slides to participants after the meeting, where these have requested this. If the distribution of slides is unsolicited, e.g. in connection with a consulting visit, the distribution of the presentation, will, as always, be regarded as an advertising activity, after which the content must be in accordance with the SPC and the Promotion Code.

### *Scientific meetings/communication of scientific data*

ENLI has been asked, whether it is possible to hold meetings/inform via portals without it being subject to the Promotion Code, if you e.g. set up an external expert committee which determines the scientific content of the meeting/portal, just like at international congresses, where there is also an external committee, who determine the contents of the congress, and where scientific discussions (including any off-label, etc.) can take place. It is ENLI's view that this cannot be done outside the scope of the advertising rules, including both the Advertising Order and the Promotion Code, as it is the company who initiate the meeting/portal and the company that pays the external expert committee.

Article 16 of the EFPIA Code of Practice states that member companies may offer scientific continuing education, but that such activities may not constitute advertising and are thus not subject to the advertising rules, within special requirements. However, the provision of Article 16 of the EFPIA Code does not change ENLI's view that the advertising rules must be complied with if a pharmaceutical company is the initiator, and thus organizer or co-organizer of continuing education activities. This is also in accordance with the broad definition of the "advertising" concept for medicines, cf. hereof Art. 3(1) of the Promotion Code.

Of course, there is the option of an advisory board, where more is possible with regard to discussing science, as otherwise would collide with the rules on advertising.

### **Transmission/streaming of professional activities**

It is ENLI's immediate assessment that online transmissions, etc. is covered by the Promotion Code's Art. 13 (1), and that the professional content in such events, just as much as at other events, must be in accordance with the Promotion Code, including covered by the requirement to notify, cf. Art. 21.

### *Scientific content or advertising*

When a pharmaceutical company disseminates scientific data at an international scientific congress, it is ENLI's view that such information as a starting point is not considered as advertisement for a medicinal product, since the presentation is done in a scientific forum. On the other hand, if a company selects parts of a scientific congress program, such as e.g. one symposium, and targeted offers just the selected program/symposium for healthcare professionals, invited e.g. via web-broadcast, the company will, after ENLI's opinion, be responsible for the contents according to the Promotion Code. The scientific context in which the symposium is presented in at the International congress, for instance will not be present at the selection. This makes the presentation of selected parts from a scientific congress comparable to one of the company's own events.

It must therefore be based on a specific assessment, whether a professional congress contains presentations including advertising, or if a pharmaceutical company e.g. subsequent uses footage from an academic congress in advertising. The last can for example be the case if a pharmaceutical

company selects posts containing positive publicity/claims by one of the company's drugs, and then invite healthcare professionals to view the post on its website.

For example, if a company chooses to sponsor a link that provides direct access to Congressional content, and the relevant healthcare professionals themselves can make the selection of relevant posts from Congress, the sponsoring company as a starting point, will not be responsible for the content of what is being streamed.

It is ENLI's view that professional presentations that take place in a scientific forum at an international Congress as part of the official scientific program, as a starting point is not advertising. A pharmaceutical company that wants to offer a healthcare professional access/link to posts from a scientific Congress, however, must assess beforehand whether the program and admission (if it is available on demand), contain illegal advertising of the company's drugs.

ENLI is aware that although many healthcare professionals are happy to be able to digitally keep up with the congress, it is often an expressed desire to sit with other healthcare professionals and see the sessions, and subsequently interact/discuss news/updates with colleagues. In such cases, companies will be able to offer a physical meeting where the recorded sessions have become available. Based on the congress program, the invited healthcare professionals can select the sessions they would most like to see (to be managed by an external moderator). It is ENLI's assessment that such a meeting concept can generally be regarded as a scientific arrangement, since the company has no influence on the selection of sessions. However, the company is obliged to ensure that the selected sessions (and the congressional professional program as a whole) cannot be considered as advertising. It should be emphasized here that the requirements for this are not different compared to the requirements in which the company sponsors the physician's physical participation in the congress.

### *Live transmission and recorded sessions*

In the case of live transmissions, these can be equated with a professional meeting, where one are physically present. Thus, if a company chooses to provide live access to the full congress, it will not be considered as advertising, but would be considered as purely scientific content (though please see below). However, this applies only for those presentations, which is part of the official congress program. (See Appeal Board's decision above, AN-2016-3924).

If a company via its own website, or via a hired third party wants to live stream posts from a congress, the company must familiarize themselves with the program prior to livestreaming, including assessing whether there are posts which may include mention of the company's drugs, which could constitute advertising.

For material that a company places on its website and make available on demand, it will also be the company's responsibility to ensure that there is no material, which may constitute illegal advertising for the company's medicines, including pre-launch and off-label. It will depend on a specific assessment, whether or not the given material may be considered advertising for the company's medicines, when it is placed/will be livestreamed from a platform/website, owned by the company or one of those hired third party.

Whether the content of any post can be considered as advertising, will, among other things depend on whether it is the company that select which presentations to be streamed or possibly be included, or whether it e.g. is the congress, which as independent third party, who's making the footage and offers streaming of congressional posts.

As a company, one should therefore be aware of the fact that it may be considered advertising, if the company selects individual presentations for (live) transmission, and if selection is not based on objective criteria, e.g. access to a particular day's full program, or a certain number of up-load that is chosen on the basis of the topic. The fact that the company and not the congress, has selected, may be an argument that it is advertising. Whether or not this is the case requires, however, that the content of the specific program is known, why it will always depend on a specific assessment, if the contents of the relevant documents, will be considered advertising. The assessment should take the contents of the selected post, the background of the selection of posts and possibly additional presentation from the company's side, into consideration.

A session that is recorded, and that a given healthcare professional will be shown, or have option to see or revisit (possibly on optional time) can be regarded as promotional material, depending on the specific content.

The pharmaceutical company should also consider the placement of a link to the transmission/recordings from professional congresses. In this context, it should be considered to place the link on a separate website that does not contain advertising for the company's medicines. If a link to the post from a professional congress is included as part of e.g. a business website with advertising for medicines, ENLI could, after concrete assessment, asses that the professional presentations (depending on content) from congress, is used by the company for advertising purposes. Another solution may be that healthcare professionals gets a password and can log on the congress organizer's website, where live transmission/recordings from congress are accessible.

### **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. A pharmaceutical company may only offer medical information and training to healthcare professionals, regardless of whether this is for events that health professionals attend or organize themselves.

The following on Public meetings is included in the guidance to the Advertising Act, point 5.8.: *“Pharmaceutical companies are permitted to sponsor meetings that provide professional information about medicinal products to the public hosted by health professionals and pharmacies, cf. section 29(1) of the Advertising Order. Such events may also include information about health and disease. The amount paid in sponsorship must not exceed the direct expenses related to the hosting of the event in question, cf. section 29(2) of the Advertising Order. A proprietor pharmacist, who holds a professional information meeting at his own premises, can neither have his own fee nor the rental fee sponsored. However, the fee paya-*

*ble to an external speaker, costs for announcing the meeting, costs for printing the information material for the participants and any additional costs for cleaning the premises can be sponsored legitimately.”*

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, if 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.

#### *Generally, on sponsorships to third-parties:*

When a third party/organizer applies a pharmaceutical company for financial support, this should be done in writing. There should, therefore, always be a written contract, when a company commits to a sponsorship.

If a professional activity, for example, an annual meeting for a medical society, are sponsored by one or more pharmaceutical companies, the purpose of the event, and whether there has been granted sponsorship from pharmaceutical companies to the event, must always appear in the attendee invitation.

The revenue, which the organizer receives from sponsors, may only be used to cover the actual, documented and reasonable direct costs, which are an integral part of the professional event. Examples of such costs can be fee for conference speakers, venue rental, catering in relation to that event, etc. Pharmaceutical companies may not sponsor activities, where expenditure on meals represents the only cost. It should be specified what the company is sponsoring, including whether parts on one's sponsorship e.g. is for purchasing an exhibition booth, purchase of advertising space, etc.

When applying for sponsorships, the event organizer must provide an adequate **budget** for the current activity, so that any sponsors have the opportunity to assess whether the rules in ENLI's Promotion Code can be complied with. If the income from the sponsors give profits to the organizer and the organizer is an association of healthcare professionals, the surplus shall be refunded to the respective sponsors, since there must not be granted general sponsorships to individual healthcare professionals. This is to ensure that the organizer, e.g. an association of healthcare professionals, does not receive more money than what the educational professional activity requires, which might otherwise be considered a financial gift in violation of the code of conduct Art. 12.

In connection with the conclusion of contracts for sponsorships, the pharmaceutical company are called upon to ask the organizer for subsequent evidence, for example, in the form of accounts after the conclusion of the event, in which the activity's income and expenditure is accounted for.

Since some companies provide commitment of a sponsorship up to one year prior to the event, ENLI will not require that information on e.g. representation (food/drinks/hotel/transport) must be an exact name, address and price for hotel, flight and departure time. ENLI accepts that the company in connection with the report of sponsorships simply sets the framework for the representation, e.g. that the hotel will be maximum 4-star and maximum costs 1,500 DKK per night, or that flights are booked on economy class with arrival and departure so close to the start and end time of the event as possible.

Pharmaceutical companies must not provide general sponsorships (economic benefits) to healthcare professionals, including healthcare associations such as societies. Sponsorships for medical societies may only be given in connection with healthcare professionals' educational training. Thus, it will not be possible to support the general operation of a medical society, such as planning meetings or tasks such as preparation of patient information material.

#### *Purchase of advertising space*

A pharmaceutical company can purchase advertising space, as long as the purchase is proportionate, including reflecting the market price compared to the exposure option. The companies may therefore advertise towards healthcare professionals, and there are no immediate limits in relation to where the company can purchase advertising space. These cases will thus not be regarded as a sponsorship but purchasing of ad space.

In this context, it should be noted that there is no differentiation between the purchase of advertising space in medical magazines, newsletters or websites, etc.

#### *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 to ensure patients get the best medical treatment, in accordance also with the Appeals Board's ruling above.

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 Ph.D. 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 programme/event is otherwise predominantly professional. 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 noted 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?**

- 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. (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 the Promotion Code Art. 13.

### **Save-the-date:**

If a company wishes to invite healthcare professionals to a professional event before a program is available with sufficient information to be able to make 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 "Save-the-date" 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.

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 Code of Practice 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 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 Code of Practice Sec. 10.02 and Sec. 26.4 of the Advertising Order, although it is not possible, as in the Advertising Order, to consider financial issues. In contrast, the requirement for 'significance' does not follow from the EFPIA Code of Practice, 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 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 Code of Practice 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 Code of Practice 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 Danish Medicines Agency ruled in a consultation dated 7 January 2011 that: "*It is permitted to provide **hospitality** for a healthcare professional provided even for 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 offering Danish healthcare professional attendees, 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 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 kilometers 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 the remarks to Sec. 13.7 below. If a healthcare professional wants to have a holiday before or after participation in a professional event, and therefore don't have to travel either outbound or home in immediate connection with the professional event, companies may not pay for travel expenses to or from the professional activity in question, if the change of travel time is grounded in personal reasons. Pharmaceutical companies must only offer economic benefits, which are justified by the professional context.

**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 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 Code of Practice Sec. 10.06 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.4. A comparable provision is not stated 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 pharma-

ceutical 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.

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 of the Advertising Order's Sec. 26.2, EFPIA's Code of Practice Sec. 10.07 and EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.3 and 4.4.

An assessment of the extent and level of hospitality with respect to the professional event must be made. Hospitality must 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 make its sponsorship conditional upon only covering expenses for the professional program, for example payment for speakers or venue, and thus avoid being subject to these provisions (otherwise Sec. 13.10 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. If 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 Code of Practice Art. 10.07. The wording should 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 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 and also compliant with the rules on meals (see below). See more on medical representative visits in re: Sec. 20.2.

It should be noted that whether or not the company should provide hospitality depend 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 choosing 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 a requirement that for a phar-

maceutical 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

**Transport** must be at a reasonable level, which has to take into account the circumstances surrounding travel by healthcare professionals. Reasonableness should therefore be assessed based on 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:

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 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. See also AN-2020-0248, where the Appeals Board when using Business Class e.g. emphasized an overall assessment of the trip's temporal extent, the time difference, length of stay and subsequent recovery time before the person in question had to return to work (the day after returning home).
5. 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.
6. Further, the use of **Business Class** is acceptable at all levels if the traveller is in a wheelchair, etc.
7. 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 based on Sec. 13.8. It has thus been determined that dinner or similar meals can only be offered at events consisting of **at least two hours of professional content** - cake, fruit, coffee/tea/soft drinks, or the like excepted. 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. Thus, this also applies to medical representative's visits with HCP's.

It is ENLI's opinion that pharmaceutical companies should be careful about serving sandwiches or other lunch-like for a shorter meeting held around lunchtime. If the invitation states that sandwiches or the like are served, it may send the signal that lunch is being offered at the meeting, even though the length of the meeting does not justify a meal offer for the participating healthcare professionals.

Business symposia held in conjunction with a scientific congress – e.g. two symposiums of 1 hour each, but not following each other in time and thus not coherent, will be considered as separate events, whereby the condition of a minimum of two hours of academic content has not been complied with, if the company wishes to invite the participants for dinner after the last symposium.

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 and there should never be any doubt as to whether attendees only come for the professional content or for a free meal, cf. Art. 1 of the Promotion Code. Furthermore, see Aa-2015-1796.

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, cf. sec. 8.

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."

### *Catering for virtual meetings*

The signal value should be considered at online meetings/virtual meetings. In principle, the rules of promotion for physical and virtual meetings are the same. However, it is ENLI's recommendation that companies should carefully consider whether to provide refreshments to the participants when, for example, the rep.-meeting takes place virtually instead of the usual personal attendance, where, for example, fruit, cake, etc. is provided. In particular, the purpose provision in Art. 1 of the Promotion Code also refers to the fact that companies must at all times maintain high ethical standards and not behave in a way that brings discredit upon or reduce confidence in the pharmaceutical industry or anything else that may cause offence.

ENLI therefore encourages pharmaceutical companies to consider whether refreshments are required for a virtual meeting and the signal value thereof. Sending catering - especially if participants are sitting on their home addresses, can send the wrong signals. ENLI is aware that several pharmaceutical companies have already decided internally that no catering is offered for virtual meetings.

For on-demand meetings, it is ENLI's assessment that catering cannot be provided, as it cannot be ensured in these cases that the healthcare professional will actually attend the continuing education meeting or when this will happen.

Therefore, the considerations for catering are based solely on the live-streamed virtual meetings, and ENLI generally recommends that no catering be offered, cf. Art 1 of the Promotion Code.

**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 Code of Practice 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](http://www.enli.dk). 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. Therefore, the Danish spending cap will be the starting point.

Remember that it must be possible for the maximum amounts to be checked by ENLI. 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. Thus, meeting packages must also be specified, so ENLI is able to see what the price for breakfast, lunch and dinner is, as well as other catering during the day.

**Re: Sec. 13.9.**

This clause corresponds to EFPIA's Code of Practice 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.

The starting point is a total prohibition against organizing/sponsoring entertainment with respect to pharmaceutical companies' own events (both in Denmark and abroad).

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.

It should generally be specified that the Appeals Board's interpretation that pharmaceutical companies are permitted to provide sponsorship for professional events, if any entertainment (in accordance with the above regarded as primary entertainment) associated with the event takes place under the condition that the entertainment 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

With respect to any **self-payment** from healthcare professionals, 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 Code of Practice Art. 10.01 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.

As part of dealing with two principle cases on 21 September 2011, and as most recently held in AN-2014-5624 (the ruling has not been published since it is based on an appeal of 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 manor houses, 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.*

In relation to the above-mentioned circumstances regarding castles and manor houses, ENLI considers that the use of a mansion or estates as a venue signals luxury and extravagance on an equal level with castles and mansions. Thus, the term "mansion" and "estate" adds something extra that signals something unique, luxurious and cultural-historical, and goes far beyond what is considered necessary for a professional event. Pharmaceutical companies should therefore avoid using these estates as a venue unless there are logistical circumstances or lack of alternative venues that points to choosing this particular venue.

With respect to the above classification issues, ENLI is aware that it is possible to use **booking sites** as Trivago.com, Booking.com and on VisitDenmark's website, 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. Therefore, it is also the overall assessment of the meeting venue's reputation, which is essential for hotels who have chosen to remain outside the classification/rating system and thereby refers to itself as "non-rated"/"non-classified" hotels. It is recommended to conduct a broad search on the internet at the intended venue and thus see how this is described and appear in common reputation.

Venues that are "known" for their entertainment facilities or for being extravagant /luxurious can be used under the following conditions:

- 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; 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.*

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.

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 a reprimand for the first breach. The first breach means that no company has previously been sanctioned (reprimand or fine) for using the venue (since these are published on ENLI's website).

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 based on the venue's own marketing. There will be no decisive weight laid on subjective assessments, even though these are publicly available, e.g. websites like TripAdvisor.com.

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 Art. 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 mostly 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 would 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 later 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.

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 the like.

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

In summary, it follows that Art. 13 (10), is strictly interpreted and that, as a basic rule, 5-star hotels etc. cannot be used see the Opinion of the Board of Appeal above. By way of exception, meeting venues that, in principle, violate ENLI's rules, may be used if there are specific circumstances that can substantiate the use in specific cases - for example, accommodation/special meeting room facilities, no other alternative venues, safety reasons and the like. In this connection, it is important, with regard to reporting to ENLI, to always provide documentation as to why the company/organizer has chosen that venue.

#### Re: Secs. 13.11-12

The provisions correspond to Art. 13 of the EFPIA Code of Practice, since the last clause on Danish and other relevant legislation was inserted to supplement the EFPIA Code of Practice, as it was suspected that such rules would often be invariable in the host country. Clarification should therefore be sought from the Danish Medicines Agency as to whether payments for foreign attendees at international congresses, etc., held in Denmark should be solely in accordance with the rules of the healthcare professional's own country or whether Danish legislation 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 Medicines Agency 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 Medicines Agency when they are paid for their expenses for attending professional activities abroad. Notifications must be submitted digitally using a form posted on the Danish Medicines Agency'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 Medicines Agency'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 Code of Practice Art. 17.01 and 17.03 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.

According to EFPIA's FAQs from April 2015, **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 patient support programme.

The clause also applies to online materials and materials may be supplied on a **USB stick**. When distributing on a USB stick 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).

Lif's supplementary FAQs of 20 January 2015 (available at [www.enli.dk](http://www.enli.dk)) specify (Q1) that the Danish Medicines Agency'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.

Q4 specifies that supplying **medical textbooks and 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.

### *Medical textbook or advertisement?*

A "Medical textbook" only contains technical editorial regarding health/disease informative nature as well as on disease treatment. A medical textbook contains no laudatory claims of medicinal products. Medicinal products may, however, be mentioned in the book – as long as it does not appear as laudatory claims.

Advertising and informational material must not be mixed. If the book contains laudatory claims about medicinal products, an assessment has to be made on what the overall purpose/signal with the book is; advertising or information?

If a medical textbook in general is of informative nature, but laudatory claims of concrete medicinal products appears or if one chooses to insert an advertisement e.g. on the cover of the book, the book can no longer be considered to be a medical textbook, which may be supplied pursuant to Sec. 14.1. Also, the book cannot be distributed as advertising, since the purpose of the book is to be informational material and not an advertisement. So one cannot get around the gift ban in Art. 12 by e.g. inserting advertisement in the “medical textbook” and then hand over the book as an advertisement cf. Promotion Code Art. 4-8.

If the entire purpose/signal with the book is an advertisement with laudatory claims about a medicine, then the book is not considered a “medical textbook”, but rather an advertisement, and then the Promotion Code must be complied with.

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 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.

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 Code of Practice Art. 17.02 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](http://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 as 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 permitted. However, anatomical models must amount to insignificant value for the healthcare professional, i.e. their value must not exceed a total amount of DKK 300 p.a. for the healthcare professional.

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 based on 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 possible proceedings at ENLI, to document to ENLI the total value (of items) from the company to a healthcare professional.

It follows from the guidance to the Advertising Order sec. 5.6, that value is not assessed by what the entity - as maybe due to great shopping can achieve significant discounts – has paid for the gift, but from what the receiver should have given for an equivalent product if he or she should have purchased it in the normal way. This means that e.g. reprint is valued at DKK 0 (zero) when distribution to a doctor with free access to that journal e.g. through the employer. Conversely, valorization by distributing to a doctor without free access should be estimated as the price he or she would have to pay online. Thus, the market value is taken into account for the assessment of the gift's value. It is ENLI's view that one needs to look at the individual concrete healthcare professional, who receives the gift, and not healthcare professionals in general.

It should be noted that there are some exemptions that apply where insignificant value is determined based on 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.

It is noted that the rule applies to Danish soil for all healthcare professionals. With regard to foreign parent companies' handing over of reprints, etc. in connection with international congresses in Denmark, they must ensure that the reprint is of insignificant value. The parent company's disclosure of reprints - also to Danish healthcare professionals - is not included in the Danish subsidiary's "accounts" regarding, "insignificant value per years per year healthcare professional".

#### Re: Sec. 14.4

The provision implements EFPIA's Code of Practice Sec. 17.4.

It is noted, that branding on informational material must be interpreted by analogy with Lif's FAQ regarding branding, according to which:

- Invented and generic name is prohibited (unless patient safety issues)
- Company name/logo is permitted as long as it does not appear promotional
- It is thus possible to use logo and write "Distributed by [company name]" on medical textbooks

**Branding** with the product name or product logo is 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, is 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.

#### Re: Article 15 Use of consultants/professional services

This clause is based mainly on Art. 15 of the EFPIA Code of Practice, 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 a limited assignment or for a restricted number of hours. Healthcare professionals are 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 Code of Practice Sec. 15.01 and 15.02, 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 Code of Practice, which thus goes slightly further than Danish legislation. In contrast, (g) is not in the EFPIA Code of Practice 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 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 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, 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 Medicines Agency 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 Code of Practice 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 Medicines Agency, both the payer 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.

It is stated in section 15(1)(g) of the Promotion Code as well as in the guidance to the Advertising Order item no. 5.6.2 that remuneration to healthcare professionals may only be granted in the form of actual payment. In this regard, it is subordinate whether it is the pharmaceutical company itself or a partner who provides the healthcare professional with benefits. It is the Investigator Panel's assessment that sponsorship support to cover remuneration to healthcare professionals in the form of wine or other natural property is to be considered a gift that does not comply with Art. 12 (1) of the Promotion Code, nor is it subject to the exceptions to the prohibition in Art. 12 (1).

**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 Medicines Agency, cf. Sec. 202(a) of the Health Act. Pharmaceutical companies are required to brief healthcare professionals on this and to notify the Danish Medicines Agency 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 Medicines Agency'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 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 Code of Practice Sec. 15.04. 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. Market surveys must be notified to ENLI as they are regarded as advertising.

For further please refer to ENLI's Guide on Market surveys.

#### Re: Sec. 15.5

The clause comes from Sec. 15.05 of the EFPIA Code of Practice and states that the rules in EFPIA's Code of Practice Art. 10 (Promotion Code Art. 13) also applies in regard to consultants.

Following applies to flights for consultants providing professional services to the company:

- a) Air travel should primarily be either in the economy class or in economy plus, such as "Economy Flex" or "Premium Economy". See also AN-2020-0248, where the Appeals Board when using Business Class e.g. emphasized an overall assessment of the trip's temporal extent, the time difference, length of stay and subsequent recovery time before the person in question had to return to work (the day after returning home).
- b) If justified by special logistical issues, the based on a specific assessment of logistics, price, class and any alternative solutions, flights in a higher class than stated above can be accepted.
- c) Further, the use of Business Class is acceptable at all levels if the traveller is in a wheelchair, etc.
- d) 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 EFPIA's Disclosure Code, which is binding on Lif and Lif's members. This code is now implemented in EFPIA's Code of Practice, chapter 5.

Those EFPIA states that have no national legislation on the area are required to implement the provisions of EFPIA's Code of Practice, chapter 5 directly into their international code. EFPIA's Code of Practice, chapter 5 does however provide for the possibility of implementation by way of rules that differ from the specific rules in EFPIA's Code of Practice, chapter 5, where dictated by national legislation and regulation.

This 'flexibility provision' has significance in Denmark since Lif implemented the requirements of EFPIA's Code of Practice, chapter 5 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.

In the autumn of 2014, **ENLI's steering committee** stated that ENLI is not required to exercise controls and sanctions on obligations specifically imposed on pharmaceutical companies in accordance with the 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 ON 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 Code of Practice art. 18. 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 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 Code of Practice'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 [now the Danish Medicines Agency]. 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 [now the Danish Medicines Agency] are exempted from this, they are still subject to the rules of the Personal Data Act.

*LF, LVS and Lif further agree to:*

- o Recommend their members to make use of the Danish Health and Medicines Authority's [now the Danish Medicines Agency] offer of guidance. In responding to a request, the Danish Health and Medicines Authority [now the Danish Medicines Agency] may provide guidance on whether a trial is, or is not, an intervention trial. The Danish Health and Medicines Authority [now the Danish Medicines Agency] may also in the event of a specific request provide guidance on the advertising rules and their interpretation in connection with non-intervention trials.*
- o 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. 18.02 (d) of the EFPIA Code of Practice.

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 Code of Practice but is an extension of Art. 9 of the previous "Collaboration Agreement" for the previous ethical board, 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. the Promotion Codes Sec. 13.1, and 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 public are not regulated by ENLI but by the Danish Medicines Agency. It is noted that stands at an event specifically aimed at healthcare professionals may also include stands from non-pharmaceutical companies such as banks, etc., as it is assumed that the staff at the exhibition stand is not the target group for the other stands' advertising for prescription drugs. However, in this situation, it is recommended that exhibition stands for e.g. Banks or other non-pharmaceutical companies are placed at the forefront of the exhibition area, so that staff on these stands should not be unnecessarily exposed to advertising of prescription medicines.

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 event, exhibitions can only be permitted if the content of the event 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 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 of thumb, it can be reckoned that a square metre price of DKK 2,000 for a whole-day event in a 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 Medicines Agency 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 EFPIA's Code of Practice Art. 19 and the EGA's Code of Conduct on Interactions with the Healthcare Community, Sec. 4.9.

**Re: Sec. 19.1**

Here the Danish legislation is more restrictive than EFPIA's Code of Practice. 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 the Promotion Code's 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 Medicines Agency. According to the Order, only one me-

dicinal 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, where reference is made.

ENLI has been notified by the Danish Medicines Agency 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 Code of Practice Art. 20.1. 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 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.

According to the Danish Medicines Agency's guide, section. 9.1. pharmaceutical consultants are defined as "*persons who, on behalf of pharmaceutical companies and the like. presents, informs and advertises drugs to healthcare professionals and traders who are entitled to sell medicines.*"

According to Art. 20 (1)(litra c) in the Promotion Code (which is a partial reproduction of the Advertising Act Sec. 18 (2)), a summary of product characteristics shall be given to the healthcare professional or made available for their disposition. The purpose of this provision is that the healthcare professional can read the product characteristics during the meeting, so that there is a case for a good professional discussion. A summary of product characteristics must therefore be handed out, if it is demanded by the healthcare professional, or otherwise be ensured that the healthcare professional get this for its disposition during the meeting. To send the summary of product characteristics following the meeting is therefore not sufficient for compliance with this provision.

According to section 20 (1)(f) of the Promotion Code, visits to hospitals must not take place unannounced. ENLI refers pharmaceutical companies to orientate themselves in existing agreements with the Regions on continuing education, and notes that there may be guidelines for company visits to hospitals in the individual regions that must be observed.

## COMMENTARY ON CHAPTER 9 – ENFORCEMENT, REPORTING REQUIREMENT AND PRE-APPROVAL

### Re: Article 21 Reporting requirement

*General:* According to the EFPIA Code of Practice Art. 25, 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 Medicines Agency.

The notification requirement 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 because 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. During the period 2014-2018, there have been random checks for approx. 35-45% of all notified cases.

The notification requirement in accordance with these rules are restricted to **continuity training events** (including sponsorships) and **exhibition stands** and **printed advertising matter** (apart from tender documentation) and must as noted below be regarded as a supplement to the Danish Medicines Agency'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 "**Save the date**" 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. For an overview please also refer to ENLI's checklists for the different event types available at [www.enli.dk](http://www.enli.dk).

Upon notification of the above sponsorships, the following must be uploaded:

- Sufficient detailed program
- Sufficient detailed budget
- Documentation (including date) for sending of invitation to sponsorship or binding consent, and
- If sponsorship to a third-party event - contract or similar, indicating which elements of the event is covered by the sponsorship (if the entire event is not covered)

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 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, if 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.

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 be 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**. All relevant material must thus be enclosed in the notification to ENLI. It could lead to an administrative reprimand.

mand if ENLI is to request documentation to carry out the sampling check and thereby assess adherence to the Promotion Code. 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 to avoid sanctions. The Appeals Board confirmed this position on 23 November 2011 with its rulings in AN-2011-1927 and AN-2011-1480.

The understanding is also confirmed by the Board of Appeal in AN-2018-0650: *"The Board of Appeal agrees that it is the reported matters that are subject to review. This is a basic element of ENLI's self-justice system, cf. the Appeals Board's decisions in the AN-2011-1927 and AN-2011-1480, and the express comments on this in the Guidance to the Promotion Code Art. 21 (4), as further inscribed in the Newsletter of 21 December 2016."* However, in the same case, the Board of Appeal stated that *"pharmaceutical companies should be able to correct typographical errors in ENLI reports during the course of the Working day where the notification is made without imposing sanctions. The access to correct typing errors on the notification date shall apply without the need for documentation of the typing error."*

The pharmaceutical companies therefore have the opportunity to change errors in their notification to ENLI, by changing the notification information within the same day as the notification has been made. Changes to reports/notifications can always be sent to sekretariat@enli.dk with reference to the relevant case. The day after notification has been made, the information is thus binding on the event of the case in a randomized sample check and any error can only be accepted if it can be documented that it is a fault entry, etc.

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 stating the file reference number. This might for example be a change of venue for a medical event. If an activity notified to ENLI is cancelled, this should also be reported to ENLI, stating the 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 be re-notified to ENLI.

It is only the conditions that can be documented that are assessed by ENLI. Reference is made in this connection to AN-2018-3964.

#### 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.

Notification of sponsorship must be made within 10 working days after a binding promise to provide financial aid is delivered. By submitting a binding promise of financial support, means the day on which the company indicates that they want to grant the sponsorship. This can for example be at the company's invitation of the sponsorship recipient, mail with confirmation of sponsorship or transmission of contract to support receiver, as the company at this point have assessed that they can vouch for the conditions.

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 based on the documents submitted with the application. If changes are made due 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 based on specific information and conditions. If these changes, 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.

**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. This applies to both physical as well as virtual events.

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. 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.

### Abbreviations

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
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 and Biosimilar Medicines Industry Association
Lif	Danish Association of the Pharmaceutical Industry
Medicines Act	Medicines Act
Marketing Act	Order on the Marketing Act
NSL	The Danish Legal Board of Self-Regulation concerning Pharmaceuticals (Nævnet for Selvjustits i Lægemiddelindustrien)
Personal Data Regulation	Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such information, etc.
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