GUIDE

regarding the participation of pharmaceutical companies in international congresses

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1. General

The purpose of this guide is to summarize relevant information for the pharmaceutical companies that have joined ENLI as well as their parent companies and other consolidated companies when they participate at international congresses, primarily in Denmark.

If you would like to know more about the rules that have formed the basis for this guide, you can read more about them in ENLI's Promotion Code and the Guidance to the Promotion Code. You can find the rules on ENLI's website: www.enli.dk.

Please note that the rules in this guide only apply for the pharmaceutical companies that have chosen to join ENLI's rules.

If you would like to see which companies have joined ENLI, an updated list can be found on the front page of www.enli.dk.

2. Corporate responsibility

ENLI's rules apply only to the pharmaceutical companies that have joined the agreement regarding ENLI or which are members of The Danish Association of the Pharmaceutical Industry (Lif), The Danish Generic and Biosimilar Medicines Industry Association (IGL) or The Parallel Importers of Pharmaceuticals. It is noted that both ENLI's rules as well as Danish legislation apply to all of the company's employees in their activities in regard to healthcare professionals. Consequently, it is subordinate which department you are employed in, or which title you have - externally you are the company's representative, and it is the *entire* company and thus all employees who are subject to ENLI's rules as well as legislation. Among other things, this means that there is no difference between whether it is a medical adviser or a sales consultant who give a presentation for a group of doctors or who is present at a stand in connection with a congress. The rules regarding **prohibition against prelaunch and off-label reference applies to all employees of the company.** Reference is made to ENLI's Guide on pre-launch, which can be found on www.enli.dk/en.

Other companies, including the company's other consolidated companies locally and abroad are not subject to ENLI's control. Therefore, these companies cannot be subject to sanctions by ENLI as they are not a party to the agreement with ENLI.

Those companies that have joined ENLI cannot be fined/reprimanded either for activities for which they are not party to or are legally liable for. For example, if the company's international consolidated companies have activities that are related to Denmark, without the Danish company being involved in the activity.

It is ENLI's view that a company that is affiliated with ENLI can only be considered as sharing the responsibility for consolidated companies' activities if the affiliated company is considered as co-organiser of the relevant activity. This depends on to which extent the company that is affiliated with ENLI has been involved in the relevant activity.

The company must have demonstrated **clear and direct steps** in the development or execution of the specific activity before it will be considered liable. Thus, an affiliated company can assist the consolidated company with knowledge about the understanding of the Danish rules in order to ensure compliance with the rules. For example, this could be that the Danish company is helpful with a visa application and the like for foreign healthcare professionals. On the other hand, if more active steps are taken in the development or execution of the activity, respectively, the relevant ENLI company could be considered as co-organiser. For instance, this could be that the company assists with the selection of Danish healthcare professionals for participation in a specific professional event, sends invitations or, if the company has influence on the content of a professional programme or the progress of a professional event. Similarly, if the Danish subsidiary participates in the parent company's exhibition stand at a congress, etc.

It is important to note that those companies that are not subject to ENLI's jurisdiction are always obliged to follow Danish legislation, and, in this respect, they are subject to the control of the Danish Medicines Agency. In addition, companies that are members of EFPIA must comply with the national code of the countries in which they operate, cf. EFPIA's Code of Practice.

3. e4ethics

EFPIA member companies are required to comply with evaluations of congress sponsorships, etc., which are assessed in the European platform **e4ethics**. The assessment of international congresses is thus binding on pharmaceutical companies. Thus, if e4ethics has assessed that there are problems with, for example, the scientific program or other matters concerning the congress, pharmaceutical companies will not be able to provide sponsorships for the event. Thus, it is essential to remember to examine e4ethics' assessment of European congresses before committing to supporting them with a sponsorship.

It is noted that e4ethics only applies to

- physical events,
- arranged by 3rd parties,
- where at least 500 people participate, from
- at least 5 different countries

EFPIA has prepared a binding annex to EFPIA's Code of Practice, which can be found on EFPIA's website. The annex can also be found on ENLI's website.

It is noted that national rules and practices must always be followed if these impose stricter requirements on the organisation of an event. An approval from e4ethics thus does not mean that the event also complies with national rules and practices.

4. Advertising rules

Definition of advertising

Advertising of pharmaceuticals is understood as "*any form of door-to-door information, canvassing activity or inducement designed to promote the prescription supply, sale or consumption of medicinal products for humans*". The definition of advertising is the same regardless of whether one is only subject to Danish legislation or ENLI's rules.

It is noted that this is a particularly broad concept in regard to advertising, which means that the main part of the activities the pharmaceutical companies initiate in regard to healthcare professionals, will be considered as advertising activity. Among other things, this means that the companies should generally refer to what their medicinal product is approved for and nothing else given that there is a risk that they will move over into an unlawful advertising situation.

However, please note that the response to verbal questions does not always constitute advertising. Nonetheless, the pharmaceutical company must ensure that a verbal exchange of questions/responses does not entail that the response is given an advertising character and thus covered by the advertising rules. The specific context in which the question is answered must therefore be assessed. For further on this, please refer to the guidance for the Promotion Code's Art. 3(1).

Requirements for advertising in Denmark

Medicinal products that are not approved for the Danish market may not be referred to or in another way used in a medicinal product advertisement in regard to healthcare professionals.

There are two requirements in Denmark that must be met before advertising of a medicinal product may be done:

1. A marketing permit must exist, and
2. The price of the relevant medicinal product must be reported to the Danish Medicines Agency

The assessment of whether a reference to a potential future medicinal product before the date of the marketing approval, is actually advertising (pre-launch), is difficult. A distinction must be made between scientific information and actual advertising.

An advertisement for a medicinal product must also be adequate and factual and may not be misleading or exaggerate the properties of the medicinal product. Information in the advertisement must be in accordance with the medicinal product's approved product summary.

At international events in Denmark, Danish legislation applies, according to which only medicinal products that have a valid marketing authorization in Denmark may be advertised, cf. section 4(1) above. Thus, it is also stated in section 9 of the Danish Medicines Agency's guidelines to the Advertising Order that:

"The rules on advertising of medicinal products also apply to international congresses and conferences in Denmark. This means, among other things, that the prohibition against advertising medicinal products that cannot legally be sold or dispensed in Denmark, cf. section 64(1) of the Danish Medicines Act, and the prohibition against advertising prescription-only medicinal products to the general public, cf. section 66(1)(1) of the Danish Medicines Act, also apply to advertising of medicinal products at international congresses and conferences held in Denmark."

Pre-launch, etc.

As a starting point, ENLI considers any mention of scientific studies and data to healthcare professionals relating to phase I and II of a clinical development programme, for potential, future medicines, as falling 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 mention is considered as scientific if the information is presented in a neutral and non-promotional way (i.e., mention of the potentially, upcoming medicinal product 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 trials 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 the Promotion Code, Art. 7), can therefore 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 after marketing authorization.

When mentioning studies regarding medicinal products, the company must assess whether the mention of the medicinal product occurs on a scientific basis and in a scientific forum (e.g., at an independent international congress) which, according to ENLI's assessment, should not be limited by the Promotion Code, see also the principle in EFPIA's Code of Practice. Thus, in a ruling dated 28 May 2014, the Danish Health 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 a scientific basis and in a scientific forum, e.g. an international congress, that does not have a purpose covered by the definition of advertising for medicines, shall not be considered as a reference to a medicinal product. If the reference relates directly to a medicine and is considered as advertising, the reference must be made in accordance with the rules in the Promotion Code.

In a product's life cycle management, several clinical development programmes are typically included which, for example, could have the intention of studying the medicinal product's effect on other (sub) populations (e.g., pediatric use) or entirely new indications. In a promotional context, the emphasis of such clinical development programmes will, as a basis, be considered as an indication expansion and thus an unlawful advertisement.

For further guidance, see ENLI's Guide on pre-launc (www.enli.dk).

Patient cases/storytelling

As a basis, there is nothing preventing the use of photos of people in medicinal product advertisements. However, it is noted that the use of patient cases/illness stories in pharmaceutical companies' advertising material cannot, in some instances, be considered as being in accordance with the Promotion Code's requirement that advertisements must appear rational, objective and in a factual form. This applies regardless of whether the story is fictitious or true. Consequently, patient cases cannot be used either as documentation basis for the statements a pharmaceutical company provides in connection with an advertising activity.

Generally, patient cases are regarded as a subjective, graphic medicinal claim when used in an advertising context. If the relevant photo/graphic illustration describes an effect at individual person level, the photo/illustration cannot be used to document the 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 with legal references, the documentation requirement for such a claim is not complied with.

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. Accordingly, a photographic image of objective symptoms of a given disease is not regarded as a potential patient case unless viewed in conjunction with a medicinal product, for example by connecting text or by implicitly implying the efficacy of the medicinal product for symptoms or the disease as a whole.

Please take note that 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 color 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, or suggest freedom, holiday and “feel good”. Excessive joy (and childhood joy in adults) is also not considered objective in the context of a medicines advertising. For further on illustrations, including mood-pictures in advertisements, please refer to the guidance for the Promotion Code’s Art. 4(2).

If the information is solely about health/illness, there is nothing to prevent using photos/patient cases as the limitation only applies in relation to medicinal product advertisements. However, it is noted that it is the general impression of the advertisement/material that forms the basis for the overall assessment of whether this is an advertisement, including whether patient cases have been used in conflict with the rules. For further information about patient cases, reference is made to the guide for the Promotion Code, Art. 7 and 13, Sec. 1.

If only the parent company is providing the advertising material and the parent company is not subject to ENLI's rules or a member of EFPIA, only Danish legislation applies (the Advertising Order).

References

References must be made loyally, and references must be included to the extent necessary in order to clarify the overall knowledge in the field. Literature references must be clearly stated. None of these may refer to outdated information or in another way be misleading. More information is available regarding the documentation requirements in the Promotion Code, Art. 7 as well as in ENLI's Guide on Documentation on www.enli.dk/en.

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 coloration of figures in tables is acceptable provided that there is no color loading and thus understanding is not influenced in the direction of product names or degrading a competing product. Color changes can thus only be used to make appearance more "inviting," meaning for example that it would not be acceptable to change the color of a figure or table for the company's own medicinal product to green and the competitors 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.

As **documentation** for a medicinal product's effect, including safety profile, in addition to the product summary, only scientific supporting studies may be used. The studies must have been published in recognized and independent Danish or international works, trade journals, or similar. Prior to publishing, the studies must have been subject to an independent peer review.

For further guidance on specific types of references, please see the Guide for the Promotion Code, Art. 7, Sec. 5, and ENLI's Guide on Documentation.

Comparative advertisement

Comparative advertisement is defined as any advertisement which directly or indirectly refers to another medicinal product.

As a basis, a comparative advertisement is compliant when the advertisement is **correct, relevant** and **loyal** as a whole. The comparison must also be objective and relate to the verifiable information.

A comparative advertisement must be produced on the basis of the information in the product summary for the medicinal products that are part of the comparison. The statements the company expresses in their advertisement must also always be documented with an adequate reference.

According to the Danish Medicines Agency, a medicinal product advertisement which contains a comparison between several medicinal products, must clearly state which medicinal products the comparison covers. The comparison may only cover medicinal products which, when seen objectively, are relevant to compare, i.e., medicinal products with coinciding application area, see the Advertising Order, Sec. 16, item 1. Furthermore, compulsory information must be presented for own medicinal product.

5. Satellite symposiums

A distinction is made between two different types of symposiums:

- Company-sponsored satellite symposiums, which are a part of the official congress programme
- Unofficial symposiums organized by the company, which are not a part of the official congress programme (see the rules for this under the section "Stand-alone")

Symposiums that are **approved and selected by an independent congress committee and which are apparent in the official congress programme** will, as a basis, be considered as a part of the scientific congress programme. The frameworks for what may be included in these symposiums will, therefore, be broader than for the company's own continuing education meetings, which are subject to the advertising rules. If off-label reference to medicines occurs at these symposiums, this will, consequently, not necessarily be in conflict with the advertising rules.

In a ruling dated 28 May 2014, the Danish Health Authority (now The Danish Medicines Agency) has found that two satellite symposiums held at an international congress in Denmark were not unlawful advertisement of medicinal products. It was the Danish Health Authority's view that the speakers' presentations at the satellite symposiums at the congress were of a professional content and they regarded professional presentations to healthcare professionals of scientific data and studies. Likewise, the presentations were presented in a scientific forum. The Danish Health Authority had also noted that

the satellite symposiums were a part of the official scientific programme for the congress and that the external speakers had themselves decided the formulation, content and angle on the subject in the presentations.

In AN-2016-3924 ENLI's Board of Appeal found that two companies' symposium during a medical society´s annual meeting did not constitute a part of the official programme for the annual meeting, as it was not explicitly apparent in the pharmaceutical company's printed programme. This was further emphasized by the symposium being held in the lunch break during the annual meeting. "In accordance with the Danish Health Authority's (now The Danish Medicines Agency) ruling dated 28 May 2014, the symposium must thus be considered as an advertising activity subject to the applicable advertising rules." Consequently, as organizers of the symposium, the companies were responsible for the compliance with these rules. For further also see KO-2018-2255 and AN-2018-3964.

On this background and as a basis, ENLI considers company-sponsored symposiums as scientific if:

- The symposiums are a part of the scientific congress programme
- The content of the symposiums is approved by an impartial congress committee
- It is the external speaker who has compiled the content, the formulation and angle to the subject/subjects in the presentation

Moreover, it may be of importance how the symposium is branded. If (in the programme/invitation) only the pharmaceutical company's name/names appear, this may indicate that this regards a standalone meeting, which would not be considered as a part of the congress programme. (See below regarding stand-alone meetings)

If the symposium is a part of the official scientific congress programme, this means that the relevant company is not considered as obliged to draw attention to the fact, if their medicinal products were to be referred to outside of approved indication/off-label, for example.

6. Stand-alone meetings / symposiums

There is nothing preventing a pharmaceutical company from holding a separate event before or after the official congress programme.

If a pharmaceutical company that is affiliated with ENLI holds a separate meeting which is not part of the set official congress programme, the pharmaceutical company will be responsible for the event as a whole and it would be assessed in the same way as a so-called "Own event" that must be reported to ENLI.

In this way, the company is also responsible for all contributions that are presented at the event, regardless of whether these contributions come from an independent third party that is hired by the pharmaceutical company. See also AN-2016-3924 and AN-2018-3964 from ENLI’s Appeals Board.

Furthermore, it is ENLI's assessment that the company has an obligation to react if a hired speaker refers to their medicines in conflict with the rules, for example, outside of approved indication/off-label or pre-launching of a medicine not yet approved.

If the pharmaceutical company sponsors the participation of healthcare professionals in the remaining congress (in addition to their participation in the stand-alone meeting), actual meals can be offered even though the stand-alone meeting on its own does not have a professional content of minimum two hours.

On the other hand, if there are participants for the stand-alone meeting where the company has not sponsored their congress participation, these people cannot be offered meals unless the stand-alone meeting, when seen in isolation, has a duration and a professional content of at least two hours.

7. Virtual meetings, etc.

General

In principle, the advertising rules apply to both virtual and physical meetings, including congresses. However, there may be special issues to consider at virtual conferences, including live streaming and on-demand solutions.

Commercial Communications

In the EU, the E-Commerce Directive[1], which in Denmark is implemented in the E-Commerce Act[2], applies. The E-Commerce Act governs the choice of law (the laws of which country) for information society services, which is defined as any service that has a commercial purpose and is delivered online at the individual request of a service provider, cf. Section 2 (1) of the E-Commerce Act.

A service recipient is any natural or legal person who receives and uses an information society service, cf. Section 2 (4) of the E-Commerce Act. For example, it is an individual request when a recipient enters the address of the website that the recipient wishes to visit; when the recipient activates a link on the Internet; when the recipient fetches an e-mail in his electronic mailbox; or when the recipient downloads a file from a newsgroup.

It follows from Section 9 (1) of the E-Commerce Act. 1, that all communications that form part of or constitute an information society service must be designed and presented so that it is clear that the communication is commercial, and it must be clearly stated on behalf of which the commercial communication is broadcast. Commercial communication is defined as any form of communication that is intended, directly or indirectly, to promote the sale of goods or services or to establish an image for a business, organization or person engaged in trade, industrial or craft business or a regulated profession, cf. Section 2 (6) of the E-Commerce Act.

[1] DIRECTIVE 2000/31/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market
[2] Law no. 227 af 22/04/2002 on services in information society, including certain aspects of electronic commerce

It is clear from the proposal for the E-Commerce Act that examples of commercial communication, e.g., may include advertising of products and services, including banner advertising, as well as indirect advertising such as promotional measures in the form of reimbursement, discounts, games, contests, sponsorship, etc.

Thus, advertisements for medicines that are communicated online (electronically) are covered by the rules of the E-commerce Act.

Outside the area of the E-Commerce Directive falls information society services, where the service provider is established in a non-EU and EEA country, and where information society services are only targeted to countries which are not members of the EU or the EEA-agreement but where the service provider is established in the EU or EEA area. Thus, a service provider established in Denmark, which only provides the information society service to a country outside the EU and EEA, is not covered by the Directive or the E-Commerce Act.

Which country's laws apply to advertising, including compulsory texts?

In the E-commerce Act (and the directive), a "sender country principle" applies to advertising on the Internet (which may have implications for virtual congresses, among other things). This means that Danish companies (legal entities established in Denmark) must comply with Danish legislation when advertising medicines at a virtual congress, even though most participants are from other EU/EEA countries, and at the same time applies a principle of "mutual recognition", which means, among other things, that a company that is established in another EU/EEA country, and advertising medicines on the Internet are exempt from compliance with Danish rules when the advertisement meets the law of the EU/EEA country where the sender is established, even if the advertisement e.g. targets Denmark.

If a Danish company participates in an international virtual congress and has advertisements in that regard, the Danish company will have to comply with Danish law. If, instead, the advertisement is sent from e.g., a French affiliate, it will be French law and French Code of Conduct (if an EFPIA member) to be complied with when advertising on the Internet.

The sender country principle at virtual congresses is important to note, since Danish established pharmaceutical companies will thus not be able to advertise medicines at a virtual congress if these medicines are not approved for trade in Denmark. Instead, if the congress were physically held outside of Denmark with a physical exhibition stand, the company would have to comply with the legislation in that country (territorial principle).

Which country's ethical codes apply to advertising and events?

EFPIA (European Federation of Pharmaceutical Industries and Associations, IFPMA (International Federation of Pharmaceutical Manufactures and Associations, and PhRMA (the Pharmaceutical Research and Manufacturers of America) has issued a joint guidance regarding Virtual International Medical Congresses Impacted by COVID-19.

The guidance applies to all International Congresses organized by medical associations/societies involving HCPs from multiple countries, and activities organized by Companies at these congresses (e.g., exhibition stands, satellite symposia, poster sessions) that takes place virtually or in a hybrid setting.

The guidance states that companies should consider the code from the region from which the majority of delegates would be expected to come based on past experience. When there is no regional code, the IFPMA code applies. This particular code may be referred to for adjudication purposes, as may the code from where the individual attendees come from. When considering the distribution or display of promotional material at International Congresses and assuming the majority of delegates are expected to be from the US or Europe, Member Companies should consider the US and European label for the products being promoted.

In addition, it is important for companies to clearly state the label by which promotional materials were developed, to avoid any possible confusion. The promotional material must be accompanied by a statement indicating the countries in which the medicinal product is registered, and by an explanatory statement indicating that registration conditions differ internationally. Additionally, the statement should be prominently displayed (e.g., via a pop-up box or alternative display) informing delegates to refer to prescribing information from their home country as information may be different for each country.

The joint guidance emphasizes that if the code of ethics and national law contradict each other, the strictest rule must always apply.

Furthermore, companies should ensure that a process is in place to confirm participants' status as HCPs/Non-HCPs (patient advocates, journalists, industry representatives, etc.). It is expected that they will work with the medical association to ensure that the congress' virtual platforms allow for participant categorization, and to work with the medical association/society (congress owner) to make reasonable efforts to restrict access to promotional material to HCPs only, where required by applicable rules and regulations. Where the medical association's platform does not have a categorization capability, Companies should consider alternative mechanisms to enable attendee classification for their promotional events.

The guidance states that congress attendees should sign a digital consent indicating awareness/acknowledging Virtual Congress terms and conditions, such as specific permission to access different virtual areas (lectures, commercial expositions, social engagement sites, the basis of promotional material development, etc.). Even if this is the responsibility of the medical association/society, Companies need to be aware of the content of these kinds of Explanatory Statements/ Disclaimers.

Please also refer to the joint guidance from EFPIA, IFPMA and PhRMA, which can be found at www.enli.dk.

Live transmission and recorded sessions

It is ENLI's assessment that in connection with the continuation education of healthcare professionals, there is no difference, in principle, between whether the companies sponsor doctors' physical participation at the congresses, or whether they sponsor healthcare professionals' access to follow the scientific presentations via electronic transmissions.

Scientific presentations disseminated at independent (third party) international scientific congresses are, as a basis, not considered as being covered by the advertising rules.

Therefore, the main rule is that companies are allowed to offer doctors access to the scientific presentations via electronic transmissions if it is also in accordance with the rules to sponsor the doctor's participation in the congress.

This means that the pharmaceutical company must check that the congress' professional programme and content cannot be considered as constituting advertising. However, it must be emphasized here that the requirements for this do not differ when compared with the requirements where the company sponsors the doctor's physical participation in the congress.

Pharmaceutical companies are allowed to both live-stream and to offer on-demand solutions (where the professional presentations are uploaded) as the specific context must, however, be assessed.

What is essential is, in which frameworks the web access is made available and that this does not have the nature of an advertisement. This means that a possible company website or similar from which access links are offered, may not contain advertising for medicinal products.

It is recommended that the companies use "neutral" sites for on-demand solutions. Offers of live streaming or on-demand access directly from the congress provider will, likewise, be able to minimize the risk of intermixture with advertising.

If the companies edit in the on-demand "presentation packages" which the congress provider chooses to make available this could, on the whole, be considered as advertising and the relevant company would be responsible for all content that is made available.

Thus, the company should refrain from recommending healthcare professionals to see specific named presentations or similar that have been held (for on-demand solutions) if they are not to be considered as responsible for the content.

Minutes and blogs from congresses

In general, it can be noted that if a company has hired a healthcare professional to prepare minutes, a blog or similar about the congress, the company's responsibility will depend on the following parameters, among other things:

- What the payment consists of; does the healthcare professional's fee reflect the service they are being paid for?
- Is the healthcare professional free to write what he/she personally thinks is relevant to report, or has the company had an influence on the content/framework for the reproduction of the professional content?
- What has the healthcare professional actually written? For example, are there statements making claims about the company's own products?

It must thus be checked whether this is about a matter-of-fact representation/minute of the professional information or whether this could be about an advertisement. Consequently, it would not automatically be a matter of an advertising situation just because the company pays for it. Please note, however, that the definition of advertising is broadly interpreted.

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.

It is noted that EFPIA in their "EFPIA Code of practice: ethical guidance in light of COVID-19", which can be found at www.enli.dk, states that member companies cannot offer catering to healthcare professionals who individually participate in a virtual third-party organized event.

Similarly, Medicines for Europe's Code of Conduct states that companies may not provide or sponsor catering to individual participants in virtual meetings. However, meals can be provided if some of the participants are physically gathered with a representative of the pharmaceutical company while attending a virtual meeting together, cf. Medicines for Europe Code of Conduct art. 5.7.7.

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.

8. Exhibition stands

The advertising rules apply to everyone

ENLI's rules as well as Danish legislation apply to all employees of the company in their activities in regard to healthcare professionals. Consequently, it is immaterial which department you are employed in, or which title you have - on the outside you are the company's representative, and it is the *entire* company and thus all employees who are subject to ENLI's rules as well as legislation if the company is affiliated with ENLI.

Among other things, this means that there is no difference between whether it is a medical adviser or a sales consultant who holds a presentation for a group of doctors or is at a stand in connection with a congress. The rules regarding **prohibition against pre-launching and off-label mention applies to all employees of the company.**

It is noted in general, that exhibition stands are considered as commercial areas where the basis is that all activities that take place here are considered as advertising.

Compulsory information

Compulsory information may be provided in Danish and in English and the compulsory information must be in immediate vicinity of the advertising material, e.g., in the form of an insert in the advertising material. For a roll-up, it is however sufficient that the compulsory information is found freely available at the stand. This must be apparent in the roll-up.

Reprints

The distribution of reprints is not considered as being advertising when the pharmaceutical company, on the basis of an enquiry from a healthcare professional, provides scientific articles (reprints) on clinical trials to healthcare professionals. However, this only applies if the articles are provided without supplementary material/reference.

The articles must have already been published in a recognised and independent Danish or international trade journal or similar. This also applies to non-commented scientific articles, which contain results of comparable studies of various medicinal products.

A distinction is made between whether the distribution of reprints occurs unsolicited or on the company's initiative. An active effort from the company in regard to the distribution of reprints, e.g., if reprints are clearly displayed for free use at an exhibition stand, may be covered by the advertising concept due to the unsolicited conduct.

A company's unsolicited distribution of scientific articles (reprints) is considered as an advertising activity (however, the reprint itself will not be an advertisement) and must therefore attach compulsory information, see Art. 5 of the Promotion Code. The material must be in accordance with the medicine's

product summary (SPC) and must, therefore, not regard dosage or indications, for example, that are not supported by the product summary or include medicines that may not be marketed, see Art. 4 of the Promotion Code.

Regardless of whether the distribution occurs upon enquiry or unsolicited at the exhibition stand, the reprint still constitutes a gift which is why it must be of inconsequential value. For more information, see the Guide to Art. 14 of the Promotion Code.

9. Handing out gifts and practical meeting equipment

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.

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.

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.

10. Entertainment

A prohibition applies against pharmaceutical companies sponsoring or organizing entertainment events.

The following is apparent in ENLI's guide on the understanding of "entertainment":

1. A total prohibition is maintained against organizing/sponsoring entertainment as far as the pharmaceutical companies' own events are concerned (both in Denmark and abroad).

2. In relation to the sponsored third-party events (where the company is not the organizer or coorganiser and therefore does not have any influence on the programme), distinction must be made between different types of entertainment. This means that a distinction must be made between "primary" (prohibited) and "secondary" (permitted) entertainment.

   Primary entertainment is, for example, music or other performance which is included as a separate contribution during a dinner or similar - or by the participants being invited to/getting access to separate entertainment on location, where it applies that based on an overall assessment, it is detrimental to the industry's credibility and image. For example, this could be concerts, opera, theatre, sports events, sports or entertainment activities, stand-up comedy, sightseeing, wine tasting/talk, or similar. Contributions which include people who must generally be considered as "celebrities" - artists, bands, actors, athletes, or similar - constitute a value due to their "celebrity factor" and, as a main rule, will be considered as primary entertainment - even though it does not have the form of a separate contribution.

   Secondary entertainment is activities that do not appear as a separate event, and which are limited in size and/or "celebrity factor" and which do not constitute any entertainment value of significance for the participant. This includes contributions which, under normal circumstances, the participants would not pay for - and which, from an overall assessment, is not detrimental to the industry's credibility and image. Examples of this are background music and similar at a welcome reception or in a lobby.

3. Pharmaceutical companies may provide sponsorships for professional events if any entertainment (see the above definition is considered as "primary" entertainment) in connection with the event is explicitly financed in another way than by the pharmaceutical company's sponsorship, e.g., with selfpayment by the participants or by a sponsorship from a non-pharmaceutical company.

It is noted that in connection with a possible self-payment, the following parameters can add weight in relation to whether a given healthcare professional can receive a sponsorship:

- the company must ensure receipt of payment for the entertainment element,
- the amount must be disclosed by the congress' organizers, and
- the size of the amount must reflect the financial value of the specific entertainment event for the participant.

Among other things, the Investigator panel has approved sponsorships for participation in a professional congress where the participation charge includes activities with elements of entertainment, given that participation assumes **separate registration** by way of check-marking in connection with the registration. In this regard, it must be documented to ENLI that sponsored healthcare professionals will not get access to the social activity.

This will always be based on a specific assessment of the presented documentation whether the sponsored healthcare professionals will be viewed as in conflict with ENLI's regulations when accepting the representation. Including whether the documentation shows, for example, that the healthcare professional only **arrives after the entertainment element**, after the welcome reception for instance. On the other hand, information to the participant that he or she may not participate in the programme item where there is entertainment or invitation to a parallel meeting held by the pharmaceutical company at the time for the entertainment element, is insufficient documentation unless the healthcare professional has **confirmed in writing** beforehand his or her participation in the parallel meeting.

In addition, a pharmaceutical company cannot sponsor parts of a professional event which contains "primary" entertainment just by making it a condition to its sponsorship to pertain to specific payment of speakers or other professionally allowed activity or representation, unless the aforementioned conditions are fulfilled (the entertainment is explicitly paid by the participant or explicitly financed by sponsorship from a non-pharmaceutical company).

Upon request from ENLI, the pharmaceutical company must document that support, if any, is provided - and used - in accordance with this rule.

In principle, it will be sufficient if, as a company, the participating healthcare professionals are requested to sign that they will not participate in a possible social event.

11. The Ethical Committee for the Pharmaceutical Industry's (ENLI) case processing

ENLI consists of the Investigator Panel in the first instance and the Board of Appeal in the second instance. Lawyers and doctors are employed in both bodies.

The Investigator Panel checks that the affiliated pharmaceutical companies comply with the rules that are subject to ENLI's jurisdiction. The Investigator Panel can file a case on the basis of a report, on own initiative or with the starting point in a complaint about an affiliated pharmaceutical company.

Those companies that are affiliated with ENLI are obliged to submit a report to ENLI on the following activities:

- If a pharmaceutical company is organizer or co-organizer of a professional activity and the event is fully or partially aimed at Danish healthcare professionals,
- If a pharmaceutical company provides financial (sponsor) support to a third party's event, which fully or partially is aimed at Danish healthcare professionals or if the pharmaceutical company sponsors Danish healthcare professionals' participation in third party events, e.g.

congresses.
- If a pharmaceutical company purchases an exhibition stand at a congress in Denmark
- All forms of advertising material regarding medicinal products aimed at healthcare professionals on the Danish market.

Reporting must be done on all activities and advertisements which are held/provided in connection with the relevant congress.

The Investigator Panel checks that the pharmaceutical companies comply with the rules via the activities that are reported. For example, the control is conducted by way of random checks where the reported events or advertising are assessed based on whether they comply with the applicable rules.

If a company which is affiliated with ENLI doesn´t comply with ENLI's rules, the company may have a sanction imposed in the form of a reprimand or fine, for example. ENLI has the option to double the fine if the same non-compliance is repeated within a two-year period.

For further information:

ENLI's website: http://www.enli.dk/

The Danish Medicines Agency website: https://laegemiddelstyrelsen.dk/en/

12. Q & A's

Corporate responsibility

1. An international parent company has a Danish subsidiary that is affiliated with ENLI. The parent company purchases a stand in connection with a Danish congress. Should the parent company comply with ENLI's rules?

A: *No, as a basis the parent company are obliged to comply with Danish legislation. If the parent company's Danish subsidiary is affiliated with ENLI, the subsidiary must, therefore, be careful with the following if they are not to be responsible for the content on the stand:*

- *that the subsidiary does not have any employees at the parent company's stand*
- *that the subsidiary does not participate in selecting which advertising material will be displayed at the parent company's stand*
- *that the Danish subsidiary only guides the parent company on which rules apply in Denmark, including how to ensure that ENLI's rules are complied with if the parent company also wants to comply with these.*

Advertising Rules

2. Is an advertisement allowed, which is an illustration of an individual patient in connection with the marketing of a medicinal product?

A: *The basis is that illness symptoms are allowed to be shown by illustration of an individual patient, but that an illustration of an individual patient will not provide a nuanced description of the general effect of the relevant medicinal product. No medicinal product is approved on the basis of a study of the effect on one person. In a trial there will always be some people on which the medicinal product has a good effect and some which the medicinal product may not have equally good effect on. A patient case cannot, therefore, express how all patients will react to/benefit from the medicinal product and, consequently, patient cases as an illustration of the treatment effect, do not meet the requirement for objectivity and rationality, see the Promotion Code, Art. 4, Sec. 2 and Art. 7.*

3. Are happy people allowed to be depicted in advertising material?

A: *There is nothing to prevent using smiling or happy people in medicinal product advertisements. What is essential however, is that the medicinal product advertisement does not use pictures that can give a misleading impression of what the relevant patients are capable of when they consume the medicinal product the advertisement regards.*

4. Are patient cases allowed at the parent company's stand at a congress in Denmark?

A: *This is only allowed if the relevant advertising material complies with Danish legislation (the Advertising Order).*

5. Are patient cases allowed at the subsidiary's stand at a congress in Denmark?

A: *If the subsidiary is affiliated with ENLI, all their advertising material must be in accordance with ENLI's advertising rules, in particular the Promotion Code, Art. 4-8. This means that certain types of patient cases/storytelling, which would not necessarily be in conflict with Danish legislation, may be considered as being in conflict with the requirement in ENLI's Promotion Code, Art. 4, (2).*

Virtual meetings, etc.

6. We would like to hold a continuing education event as a webinar with the opportunity for both live streaming and on demand. However, we have doubts about how we should behave in the event that a presenter mentions our medicine off-label?

A: *You can, as a company, live stream your event. However, the company should review the presentation slides before the meeting as well as inform the presenter that any mention of the company's medicines is only done in accordance with approved SPC. The company should participate in the live streaming and can use the chat function (or similar) to inform the participants if the presenter should nevertheless mention the company's medicine off-label. In the case of an on-demand solution, the company should delete what is not in accordance with the rules of the Promotion Code, including off-label or possibly illegal pre-launch.*

7. Can we send out a "flyer" to the healthcare professionals for whom we have already sponsored congress participation? All the symposiums in the flyer are part of the official congress program. Usually by a physically held congress, these symposia, which are part of the official program, will be placed in the congress folder / bag provided to each participant at the congress.

A: *Congress material can only be sent (electronic mail) if the participants, upon registration to the Congress, have indicated that they wish to receive further information and material regarding the congress. However, be aware that this could be perceived as a condition for accepting an invitation to the total sponsorship for the healthcare professional - e.g., in the form of participation in HQ's symposium or similar.*

8. If in Denmark we send an invitation to Danish doctors, which include a link to attend one or more of our parent company's symposiums at an international virtual congress, will we then be responsible for the symposia we link to?

A: *Despite the fact that the symposium you are linking to is part of the approved program for the congress, you should be aware that when selecting parts of a congress and thus selecting/deselecting certain presentations, it may be considered an advertising activity and you*

will therefore, as a starting point, be responsible for all content. Also, be aware of the regional agreements regarding what can be sent out and to whom.

9. May we give a sponsorship to an organizer (3rd party) who will host a post congress event where two experts at a virtual meeting will talk about what they have heard/seen at a virtual congress?

A: *You should familiarize yourself in advance with the content of the program you are sponsoring. If you know in advance that parts of the program will include off-label advertising for the company's own medicine, you must not support the specific event.*

10. May we invite Danish doctors to our company, where they will be able to follow an international virtual congress with a direct link from the congress? And can we then pay for transport and accommodation for the doctors who come from Jutland? (the company is located in the capitol area)

A: *There are several things that should be considered here. What is the purpose of gathering the doctors in the company's premises if they could just as well attend the congress at home or from their workplace? Although, as a company, you are entitled to pay for transport, accommodation and catering in connection with a continuing education event, you should consider the signal value and purpose in this situation. Thus, it should be necessary to bring together physicians because of the need for networking/ongoing discussions between doctors - and not because of the company's opportunity to influence healthcare professionals.*

If the company extracts the congress onto their own platform and thus also selects which of the many presentations that the doctors get to see, they will be responsible for the content that is being streamed. Therefore, in practice it will be a difficult exercise if the company goes ahead with this planning.

Please also note that regional agreements must be adhered to when inviting hospital-employed healthcare professionals.

11. At the now canceled conference, our HQ should have had a presentation on new studies (part of the scientific program). The Danish company has been contacted, as HQ would like to record the presentation about the new studies, which the Danish company should then send to Danish doctors.

A: *This is no longer a matter of material shared in a scientific forum (i.e., as part of the congress). Thus, this is an advertising activity that must comply with all the rules of the Promotion Code (comparable to the selection of special topics/presentations from a congress). As there is a presumption that off-label/pre-launch will occur, this approach is not recommended.*

12. An organizer has asked how they should behave if they turn one of their big physical meetings into an online webinar. In connection with events, they are used to the companies, in connection with their sponsorships, getting their name and logo printed in the program. This will instead take place online. In addition, companies typically get a booth as well. Now the question is how companies can

get the opportunity to market themselves online. The organizer has suggested that there should be an advertising break between each scientific presentation. Is this possible?

A: *There is nothing to prevent the organizer from having the company logos on the front of the webinar's website.*

In relation to the advertising break, it is optional at the physical meetings whether the participants will enter the commercial area at the exhibition stands. If it is no longer optional and the participants are instructed to view medicine advertising during breaks, it will differ significantly from the physical meetings and there will be a mix of scientific and commercial content.

However, it is legal to make "advertising breaks" between the academic posts if it is clearly marked, e.g., by a speaker voice indicating that what now comes are advertising posts from XX company. Advertising must thus be clearly separated from the scientific part of the congress.

13. May we offer catering for our virtual meeting? The meeting lasts 2 hours and 15 minutes.

A: *In principle, the same rules apply to respectively physical and virtual meetings. However, it should be considered whether there is a real need to offer catering to online meetings as this can send the wrong signals. In addition, it can be difficult to know if the participants are actually attending the virtual meeting. Thus, ENLI does not recommend catering for virtual meetings - and not at all for an on-demand webinar.*

14. Is there anything hindering the healthcare professional to access the company's webinar (which is recorded) afterwards for a limited period of time (e.g., 2 months)? Webinar (continuing education meeting) with external speaker (general information on illness). The webinar is notified to ENLI and recorded. There are no product submissions from a pharma-consultant. Is there anything that we need to be aware of?

A: *There is no immediate obstacle to making the recorded webinar accessible to participants afterwards. If it is the company's own webinar, the Promotion Code must be observed. There is no time limit for on-demand solutions, but like any other promotional material, the company must at all times ensure that all available materials meet the advertising rules.*

15. A healthcare professional has signed up for a webinar that he did not attend as he was not able to (for example, could not log on due to technical difficulties). Is this healthcare professional allowed to view the recorded webinar - without having to re-report the webinar to ENLI?

A: *In this situation it will be ok for them to watch the webinar afterwards and without the company having to re-report the webinar to ENLI. Again, it is pointed out that in the case of the company's own meeting, it is responsible according to the rules of the Promotion Code.*

16. A healthcare professional has *not* signed up for the webinar, but during a pharma consultant visit, he becomes aware that a webinar has been held with a topic that interests him. During the meeting with the pharma consultant, he asks if it is possible to see the lecture. May we make the recording

available to him without reporting the webinar to ENLI? For example, send an email with a link for registration and then the video will be available?

A: *The fact that the inquiry comes at a pharmaceutical consultant meeting, which takes place at the initiative of the pharmaceutical company and for advertising purposes, cannot be regarded as an unsolicited question which may fall under the exception in Art 2 (2)(c) of the Promotion Code. If the company makes the webinar accessible to the person concerned, it will be regarded as an advertising activity which must be notified to ENLI. Please note that in the case of the company's own webinar, it is responsible according to the rules of the Promotion Code.*

17. We will live stream two lectures this fall. The lectures will be available both live and on demand for registered participants for a limited period of time. Is there anything special we need to be aware of?

A: *In the case of the company's own meeting, the rules of the Promotion Code (and the legislation regarding advertising for medicines) must be complied with. And in that regard, the webinar can be streamed live and made available on-demand subsequently. In the case of two lectures selected from a congress, there will also be an advertising activity, since the company made the selection.*

18. Will the answers to the above change if the webinar contains both a product presentation by a pharmaceutical consultant as well as a lecture with external speaker (as above)?

A: *Pharmaceutical companies have the right to offer continuing education, which may contain information on illness and health, as well as on specific medicines. If it is the company's own event, the Promotion Code and the advertising legislation must also be complied with - regardless of whether there is a presentation of specific medicines.*

19. A European medical society is having a virtual congress, where we have been given the opportunity to advertise our medicines on a closed site for healthcare professionals. But which country's rules should we comply with, including which definition of a healthcare professional applies?

A: *If a Danish company participates in an international virtual congress and has advertisements in that regard, the Danish company will have to comply with Danish law. If, instead, the advertisement is sent from e.g., a French affiliate, it will be French law and French Code of Conduct (if an EFPIA member) to be complied with when advertising on the Internet. Thus, within the EU/EEA, a sender country principle applies, so if the company is established in Denmark, the Danish rules must be followed, including the Danish definition of a healthcare professional.*

However, be aware of the joint guidelines from EFPIA, IFPMA and PhRMA.

Exhibition Stands

20. May the personnel from a Danish subsidiary show up at the parent company's stand?

A: *Yes, but the Danish subsidiary will be responsible for what takes place at the stand and will appear as the "owner" of the relevant stand. All the activities/the material that is provided must, in such case, comply with ENLI's advertising rules.*

If only the parent company's own employees are at the stand, they will only be subject to Danish legislation (the Advertising Order).

21. What may a parent company provide at their exhibition stand?

A: *If the parent company is not affiliated with ENLI they are only subject to applicable Danish legislation. Regarding supply of ballpoint pens, food, beverages, etc., reference is made to Sec. 26 of the Advertising Order.*

22. Are patient cases allowed at the exhibition stand?

A: *Yes, but only to the extent they comply with ENLI's rules on rationality, among other things, see Art. 4, Sec. 2 of the Promotion Code. If it is the parent's company's own stand, and they are not affiliated with ENLI, the rules of Danish legislation will apply, see the Advertising Order.*

23. Are videos allowed to be shown at the exhibition stand?

A: *Yes, if the video complies with the advertising rules in the Promotion Code.*

24. Are there special rules for medical booths?

A: A medical booth, which is placed in the exhibition stand, will be considered as being a part of a commercial area. Regardless of who from the company mans a medical booth, they are subject to ENLI's rules and Danish legislation. This means that the material that is provided at such a stand and the medicines, including the use of medicines that are referred to, must be in accordance with the advertising rules.

25. Are you allowed to serve coffee and sweets at an exhibition stand?

A: For companies that are subject to ENLI's (or EFPIA's) rules, food and beverages may not be served at an exhibition stand. However, ENLI operates with a triviality limit, the basis of which is that coffee or water is permitted for free use. For example, the same applies to individually packaged sweets/chocolates.

Importance is placed especially on the signal value of whether this regards a form of items (beverages) that are of a trivial nature and which are intended to be consumed at the stand area and not to be taken from the stand.

26. Are pens or notepads allowed to be provided at an exhibition stand?

A: *No, pens, notepads, etc. are not allowed to be provided at exhibition stands. These may only be provided in connection with professional continuing education. This rule originates from EFPIA and thus applies to companies that are affiliated with ENLI as well as their parent companies if they are members of EFPIA.*

27. Are competitions allowed in the stand area?

A: *No, the companies may not assist in participating in competitions. If, on the part of the congress organiser, there are competitions in the stand area, these must be kept separate from the companies' exhibition stands.*

Handing out gifts and practical meeting equipment

28. What is the pharmaceutical company's responsibility if a third party provides gifts to healthcare professionals in conflict with the Promotion Code at a professional event where the company has sponsored a healthcare professional's participation?

A: *Pharmaceutical companies that sponsor healthcare professionals' participation in a third party's professional events, such as professional scientific conferences/congresses, are not responsible if the organiser or other parties/sponsors at the location provide gifts in conflict with the rules without the company's prior knowledge. However, if the company becomes aware beforehand that, in connection with an event (e.g. that it is apparent in the invitation or programme or is known to take place from a previous year's congress), a congress organiser or similar will hand out gifts in conflict with the rules, the company must ensure documented reservations that this will either not be given to the healthcare professionals the participation of whom the company has sponsored - or alternatively, will not be accepted by the same healthcare professionals.*

29. What is the pharmaceutical company's responsibility if a congress organiser provides gifts to healthcare professionals at a professional event where the company has provided a sponsorship directly to the congress organiser?

A: *Congress organisers may not provide gifts to healthcare professionals, which are in conflict with the rules in the Promotion Code, where the congress organiser has received a sponsorship from a pharmaceutical company. However, pharmaceutical companies will not be held responsible for this if they have explicitly clarified in the associated sponsorship contract that gifts may not be given.*

If the company becomes aware beforehand that, in connection with an event (e.g. that it is apparent in the invitation or it has happened at a previous year's congress), a congress organiser

will hand out gifts contrary to the rules, the company must ensure documented reservations that this will either not be given to the healthcare professionals, the participation of whom the company has sponsored - or alternatively, will not be accepted by the same healthcare professionals.

30. Is it permitted to have practical meeting equipment such as ballpoint pens, notepads or similar at congresses, etc.?

A: *Having relevant practical meeting equipment is allowed such as ballpoint pens, notepads or similar at professional symposiums, congresses, etc., both one's own and third party's events. However, this is under the condition that this equipment lives up to the insignificant value requirement.*

For third party events, it applies that the meeting equipment must be entirely without branding for the pharmaceutical company. This means that the company's or product's brand, name or logo may not appear anywhere. The use of a common name is also covered by the prohibition against product branding. However, there is nothing preventing having the hotel or congress name printed on the meeting equipment as this is not considered as branding.

For those events which the companies have organized themselves, it applies that the meeting equipment is allowed with company brand (name and/or logo) but still without product brands, i.e. no trade or common names. Adding a therapeutic area, e.g. oncology, diabetes, cardiology or similar is allowed.

Ballpoint pens and notepads that are provided in conference bags may not be branded with the company brand or product brand, just as the prohibition against providing meeting equipment at the exhibition stands is absolute.

Entertainment

31. Can we invite any doctors to a congress that states on the congress website that a gala dinner with entertainment is planned on the last night?

A: *As a company, one should first examine what kind of entertainment is planned. In the case of primary (illegal) entertainment, it will be permissible to invite doctors to the congress in question if the gala dinner with entertainment is financed by the participants themselves (or by others than pharmaceutical companies), or if the company prior to departure have asked the participating healthcare professionals to sign a form stating that they are not participating in the social event in question.*

32. We have invited three doctors to a congress in Paris. The congress program states in connection with the opening ceremony that there will be a beautiful French opera performance, and the

description on the website states "you will be pleasantly surprised by the light entertainment program". How do we ensure that we comply with the rules and that our participants do not have access to the entertainment?

A: *There are more options. Either you can choose to arrive at the congress only after the opening ceremony has been held, or you can choose to have a parallel meeting where the participants have confirmed in writing their participation in the parallel meeting. It will not suffice merely to inform the participants that they may not participate in the program item involving entertainment.*

ENLI's case processing

33. If in Denmark we send an invitation to Danish doctors, which includes a link to participate in one or more of the company's symposiums that are part of the official scientific program, do we have a notification obligation on the invitation?

A: *Yes*