



enli

GUIDE

regarding the participation of pharmaceutical companies in international congresses in Denmark

NB! You can search in the guide in PDF form by pressing "Ctrl+ F" and enter your search word.

Contents

1. General	2		
2. Coporate responsibility	2	- Live transmissions and recorded sessions	
3. Advertising rules	3		
- Definition of advertising			
- Requirements for advertising in DK			
- Pre-launc, etc.			
- Patient cases/storytelling			
- References			
- Comparable advertisement			
4. Satellite symposiums	8		
5. Stand-alone meetings	9		
6. Live and recorded sessions	10		
- General			
		7. Exhibition stands	11
		- The advertising rules apply to everyone	
		- Compulsory information	
		- Reprints	
		- What is permitted on a stand?	
		8. Handing out gifts and practical meeting equipment	14
		9. Entertainment	15
		10. The Ethical Committee for the Pharmaceutical Industry's	17

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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 that are held 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 brochure only apply to the pharmaceutical companies that have voluntarily chosen to join ENLI's rules. In several instances, ENLI's set of rules is stricter than the rules that follow from the Danish legislation.

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.

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.**

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.

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 coorganiser of the relevant activity. This depends on to which extent the company that is affiliated with ENLI has been involved in the relevant activity.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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.

Examples:

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?

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

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". 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

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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.

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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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 HCP Code regarding access to "non-promotional medical, scientific or factual information". 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-launch (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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

If this is solely about health/illness information, 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, only Danish legislation applies (the Advertising Order) and not necessarily the rules outlined above.

Examples

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

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.

Are happy people allowed to be depicted in advertising material?

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.

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

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

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

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

Unauthorised translation

In case of doubt the Danish version is always applicable and official

cases/storytelling, which would not necessarily be in conflict with Danish legislation, may be considered as being in conflict with the rationality requirement in ENLI's Promotion Code, Art. 4, (2).

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.

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 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.

As **documentation** for information about a medicinal product, in addition to the product summary, only scientific supporting studies may be used. The studies must have been published in recognised and

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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.

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. Thus, 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,

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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 organisers of the symposium, the companies were responsible for the compliance with these rules.

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 are 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.

Stand-alone meetings / individual meetings

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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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/offlabel 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.

Live and recorded sessions from a congress

General

It is the Investigator Panel's view that both live streaming and recorded sessions are covered by the rules of the Promotion Code if a pharmaceutical company wants to offer these to healthcare professionals.

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/minutes 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.

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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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

[Unauthorised translation](#)

[In case of doubt the Danish version is always applicable and official](#)

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.

Which advertising rules apply to the exhibition stands?

Reference is made to the section "Advertising rules" above.

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

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).

What may a parent company provide at their exhibition stand?

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.

Are patient cases allowed at the exhibition stand?

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.

Are videos allowed to be shown at the exhibition stand?

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

Are there special rules for medical booths?

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.

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, the reprint still constitutes a gift which is why it must be of inconsequential value.

What is permitted at an exhibition stand?

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

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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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

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.

Are competitions allowed in the stand area?

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

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?

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.

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?

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

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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

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

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

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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 ad 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

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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.

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 cases 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.

Unauthorised translation

In case of doubt the Danish version is always applicable and official

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/>