Version 3.0 June 2022

GUIDANCE

to

”Ethical Rules for dialogue and negotiations with decision-makers“(Lobbying Code)

The Code of Ethical Rules for dialogue and negotiations with decision-makers (Lobbying Code) will continuously be updated as practices develop or change. The guidance is therefore dated, and it has a version number. All abbreviations used are explained in the last part of the guidance.

NB! You can search the guidance by pressing ”Ctrl + F” and entering your keyword

Purpose

Art. 1

The purpose of these rules is to provide a framework for the ongoing dialogue and negotiations between pharmaceutical companies and politicians/regulatory authorities, so as to ensure the independence between the parties. There must be no doubt that the collaboration between the parties takes place on an ethically sound level.

It must be ensured that:

a) The dialogue between pharmaceutical industry and decision-makers, cf. Sec. 2 (c), must never be such as to bring discredit upon, or reduce confidence in the pharmaceutical industry.
b) The ethical rules entail that the possibility of pressurization and dependency between the parties are excluded.
c) The ethical rules entail openness and transparency regarding the dialogue and negotiations between the pharmaceutical industry and decision-makers, cf. Sec. 2(c).

Re: Article 1

The pharmaceutical companies agreeing to ENLI's rules and controls have chosen to supplement the existing legislation with a number of voluntary ethics rules.

The Lobbying Code specifies a set of minimum standards to be complied with, in addition to the current legislation. In selected areas, the Lobbying Code supplements and strengthens the provisions of the Advertising Order regarding the medicinal companies' dialogue with decision-makers.

The purpose of the Lobbying Code is to increase the ethical profile of the industry, and enhancing the image of the industry by:

- Showing the outside world that the industry's lobbying activities take place in an open, honest, fair and trustworthy manner
- Ensuring that the industry's dialogue with the political/administrative level is free and independent
- Being a good example - being first movers, and one of the first industries to introduce a Lobbying Code in Denmark.

The Lobbying Code does not only obligate the companies on their own lobbying activities, but the companies also have the responsibility to ensure that the ethical rules are fully respected by pharmaceutical companies' partners, for example PR and communications agency.

The purpose of the Lobbying Code is to provide greater transparency of the rules for contact between the pharmaceutical companies and the decision-makers in Denmark and abroad.

As a starting point, it is not required that dialogue and negotiation covered by the Lobbying Code is reported to ENLI.

The Appeals Board has in several cases in 2021 highlighted the purpose of the Lobbying Code and has in that context also highlighted the prohibition of financial support. Thus, in a case of pre-approval from December 2022 the Appeals Board stated that:

"The overall purpose of the Lobbying Code is to raise the ethical profile of the industry and thus strengthen the industry's image. The ethical rules must ensure a framework for the dialogue between pharmaceutical companies and politicians/authorities, so that the dialogue always takes place in an open, honest, fair and credible way. The rules of the Lobbying Code contribute to ensuring that pharmaceutical companies and politicians/authorities are financially independent of each other, thus cooperation and dialogue always takes place excluding pressure opportunities between the parties, cf. the Lobbying Code Sec. 1. The provision in Sec. 13 of the Lobbying Code, according to which company representatives may not in any way provide financial support to decision-makers, is of central importance in the efforts to achieve this purpose. The prohibition is absolute in the sense that any violation - regardless of the amount of financial support - entails penalties, cf. the ruling by the Appeals Board of May 7th 2021 in case AN-2021-1468 and the ruling of August 24th 2021 in case AN-2021-2757."

Definitions

Art. 2

a) "Politicians" refers to persons who are members of (or are candidates for) the Folketing (Danish Parliament), Regional Councils, Municipal Council (or Town Council) and European Parliament, etc.

b) "Officials" refers to all those, whose primary occupation is as employees of a public authority that has regulatory powers or the like. These would for example be employees of:

1. *Ministerial departments, national agencies, directorates as well as institutes, councils and boards, etc., associated with the above,*
2. *Regional and municipal administrations,*
3. *A number of private associations and companies, etc., where members or owners are part of the public sector. This would apply for example to employees of the Danish Regions and Local Government Denmark, or*
4. *The European Commission or other EU administrative body.*

c) "Decision-maker" refers to a politician or other official person, cf. Secs. a) and b) above.

d) "Pharmaceutical company" refers to ENLI's affiliated companies or their representatives.

e) "External consultant" refers to a third party working on behalf of the pharmaceutical company, cf. Sec. d) above, with dialogue and negotiating with decision-makers. This may for example be a PR or communication agency, legal counsel, etc.

f) "Company representative" refers to an employee of a pharmaceutical company or an external consultant working for the company, cf. Secs. d) and e) above.

g) "Healthcare professional" refers to doctors, dentists, pharmacists, nurses, pharmaeconomists, midwives, bioanalysts, clinical dietitians, radiographers, social- and healthcare assistants, and students of these professions.

h) "Dialogue" refers to all types of verbal and written communication that company representatives engage in with decision-makers.

i) "Negotiation" refers to a situation in which the company representative is in dialogue with a decision-maker to reach agreement on or to gain support for one of the company's wishes or proposals.

Re: Article 2

Re: Pharmaceutical company

Pharmaceutical companies are defined in Section 1, subsection 4, of the Advertising Order, as "companies that have a license pursuant to section 7, subsection 1, or section 39, subsection 1, of the Danish Medicines Act., except for public hospitals."

"Pharmaceutical companies" are in relation to this code defined on the basis of the definition in section 1, subsection 4, of the Executive Order on Advertising of Medicinal Products, and means members of:

a) The Danish Association of the Pharmaceutical Industry (Lif),

b) The Danish Generic Medicines Industry Association (IGL)

c) The Danish Association of Parallel Importers of Medicines (FPM) and

d) Affiliated companies and associations, i.e., companies and associations, which are not members of the above-mentioned associations, but have decided to be bound by these ethical rules, and

e) Consultancy service companies, etc., acting on behalf of the companies and associations mentioned in litra a) to d). Please refer to the definition of external consultant below.

A list of all affiliated companies can be found at www.enli.dk.

Re: External consultant

The definition of "external consultant", cf. Article 2, litra e) of the Lobbying Code, is limited to a third party who, on behalf of the company, works with dialogue and negotiation with decision-makers for a company-specific/product-specific case. For example, consultants may be hired by a single company to perform a specific task, as defined in a contract between the company and the relevant consultancy firm.

Trade associations, for instance, are not included in the definition, since a trade association does not work for a single company but the industry as a whole.

Re: Healthcare professional

All persons who are not trained in the fields listed in the Article 2, litra g), of the Lobbying Code are regarded as the public.

Example:

Are members of the Health Committee in Parliament healthcare professionals?

> *- It depends on whether they are trained in one of the fields listed in the definition of "healthcare professional" in Article 2, litra g), of the Lobbying Code.*
>
> *- The determining factor of which rules applies, is which occupation the member primarily has.*
>
> *- If the members primary occupation is a doctor (= healthcare professional) and you are attending a meeting as a healthcare professional, the Promotion Code applies.*
>
> *- If the member, while being a healthcare professional, is also a "decision-maker", cf. Article 2, litra c), of the Lobbying Code, and attending a meeting in the capacity as a decision-maker, it is only the rules of the Lobbying Code that apply.*

Scope

Art. 3

The ethical rules constitute a minimum set of rules, which are mandatory for ENLI's affiliated companies. The pharmaceutical companies may therefore have their own ethical rules that go further than this set of rules.

Re: Article 3

The Lobbying Code applies to all ENLI's affiliated companies. In general, all pharmaceutical companies in Denmark are subject to Danish legislation, as a minimum.

A list of all affiliated companies can be found at www.enli.dk.

Art. 4

The ethical rules shall apply for company representatives' dialogue and negotiations with decision-makers at a European or national level.

Re: Article 4

The Lobbying Code applies to both the companies' dialogue with decision-makers in Denmark and in the European institutions such as the European Parliament and the European Commission.

When it comes to the terms "dialogue" and "negotiation" please refer to the definitions in Article 2, litra h) and j) of the Lobbying Code.

Art. 5

If an external consultant is engaged to enter into dialogue or negotiations with decision-makers, it shall be the responsibility of the pharmaceutical company to ensure full compliance with the ethical rules by the external consultant.

Re: Article 5

The Lobbying Code applies not only to ENLI's affiliated companies, but also to third parties acting on behalf of pharmaceutical companies. This means, for example, that consulting firms, including advertising agencies, public relations and communications agencies, are required to comply with the rules of the Lobbying Code if they work in this area on behalf of a pharmaceutical company.

The pharmaceutical company is always responsible for ensuring that the external consultant is aware of and complies with the rules of the Lobbying Code.

When it comes to the term "external consultant" please refer to Article 2, litra e) of the Lobbying Code.

Transparency

Art. 6

There must be full transparency on whom and what interests the company representative represents. Company representatives shall therefore initially, and without request, introduce themselves clearly by name and by giving the name of the pharmaceutical company for whom they are working. This also applies in cases where an external consultant is used to represent the interests of several companies.

Re: Article 6

Currently there is no guidance for this provision.

Art. 7

The pharmaceutical company is obliged to demonstrate and ensure full transparency in instances, in which the company remunerates a decision-maker, cf. the exemption provisions in Art. 14.

Re: Article 7

Currently there is no guidance for this provision.

Art. 8

Every pharmaceutical company is obliged to publish a schedule on their website with the names of the PR or communication agencies, legal counsel or similar external consultancies acting on behalf of the pharmaceutical company to engage in dialogue and negotiations with decision-makers.

a) Disclosure shall be made by stating the name of the external consultant concerned.

b) closure must take place without undue delay after concluding an agreement with the external consultant and must be publicly available, while the agreement/project is in progress and at least for three months.

c) pharmaceutical company's schedule on its website shall further explicitly state that the pharmaceutical company has made the external agency or consultancy aware of the present set of rules and that the pharmaceutical company accepts responsibility for ensuring third party compliance therewith.

Re: Article 8

ENLI's affiliated companies are obliged, on their website, to publish a list of names of the external consultancy companies who work on behalf of the pharmaceutical company on dialogue and negotiation with decision-makers. It does not have to be the name of the specific external consultant, which is to be published.

It is noted that it is always the responsibility of the pharmaceutical company to ensure that the external consultant is aware of and complies with the rules in the Lobbying Code.

Please note that the formal requirements listed in Article 8 of the Lobbying Code must be complied with in connection with the publication.

Re: Article 8, litra c)

It is required that the pharmaceutical company must have made the external agency/consultant familiar with the rules of the Lobbying Code, and the requirement can be fulfilled by incorporating or attaching the Lobbying Code to the contract concluded between the pharmaceutical company and the external agency.

Requirement for information

Art. 9

Information passed to decision-makers must be up to date and complete, and must not contain incorrect or misleading information.

Re: Article 9

The information provided by the pharmaceutical companies to decision-makers must be in accordance with the applicable legislation. This means that the rules on advertising to the public must be respected, cf. Article 4-5 of the Advertising Order. This means that the companies are not allowed to advertise prescription medicines to the public. In this connection, it should be noted that the promotion concept is very broad and also includes image-creating promotion activities.

It is noted that the rules in the legislation and the Lobbying Code apply to all employees in the pharmaceutical company, but the rules also apply to those consultants who have contracted with a pharmaceutical company when these (consultants) are in contact with the decision-makers.

Proper conduct

Art. 10

In dialogue and negotiations with decision-makers, proper conduct shall be observed, which shall include, among other things:

a) A decision-maker's integrity must never be maligned by the company representative.

b) No misleading, false, injurious or discriminatory reference shall be made to other parties.

c) Irrelevant personal information must never be used in an intimidating manner or as to exert pressure.

Re: Article 10

In dialogue and negotiations between pharmaceutical companies and decision-makers decent behavior must be demonstrated. This means that if an agenda has been agreed on before a meeting, the company must comply with the agreed agenda.

Decent behavior means that pharmaceutical companies or their representatives are not allowed to mention competitors in a discouraging way, or to mention specific medicines in a misleading manner, at any time.

Confidential information

Art. 11

The company representative must always act with discretion and must fully respect in-formation obtained in confidence from a decision-maker, unless this would be unlawful. This must also be respected in cases where confidential information is acquired by a coincidence or error. Confidential information must not be obtained in a dishonest manner.

Re: Article 11

Currently there is no guidance for this provision.

Independence

Art. 12

There must never be any kind of financial dependency between pharmaceutical companies or their representative, on the one hand, and the decision-maker on the other. Similarly, the company representative must not act in a way that may cause suspicion of bribery.

Re: Article 12

Please refer to the wording of Article 1 of the Lobbying Code and the Guidance of the Lobbying Code regarding Article 1.

Art. 13

Company representatives must not in any way provide financial support or sponsorships to decision-makers, either individually or through organisations/associations (e.g., political parties, election funding, etc.).

a) Pharmaceutical companies may however sponsor specific professional activities, campaigns and similar events organised and held by a public authority.

Re: Article 13

According to this provision, company representatives may not in any way give financial support or sponsorship to decision-makers, either on an individual level or through organisations/associations (e.g., political parties, electoral funds, etc.). This prohibits both direct and indirect financial support. This has been established by the Appeals Board, which in 2021 decided in two cases concerning direct and indirect economic support, respectively.

In AN-2021-1468, the Appeals Board has decided on the *direct* financial support, and justifies the decision in the case as follows:

> *"Compliance with the rules of the Lobbying Code is of central importance to the image of the pharmaceutical industry. The rules of the Lobbying Code contribute to ensuring that pharmaceutical companies and politicians/authorities are financially independent of each other, thus cooperation and dialogue always takes place excluding pressure opportunities between the parties, cf. the Lobbying Code Sec. 1.*
>
> *A cornerstone of the effort to achieve this purpose is the provision in Sec. 13 of the Lobbying Code, according to which company representatives may not in any way provide financial support to decision makers. The ban is absolute in the sense that any violation - regardless of the extend of financial support - entails penalties. The determination of penalties in the individual case is based on an assessment of the specific circumstances of the case, cf. the Sanctions- and fees regulations of ENLI Sec. 1 subsec. 3. As a consequence of the central importance of the ban on financial support to decision-makers for the image of the pharmaceutical company, it is the overall opinion of the Appeals Board that any violation of section 13 of the Lobbying Code as a starting point should be sanctioned with a fine.*
>
> *In the specific case, where the [company] has provided financial support to two parliamentary candidates with DKK 20,000 each, the Appeals Board finds that a fine of DKK 70,000 would be appropriate, cf. the Sanctions- and fees regulations of ENLI Sec. 1 subsect. 3 and Sec. 6, litra e), no. 2.*
>
> *In making the decision, the Appeals Board has not attached significance to the fact that the two parliamentary candidates have repaid the support they received, nor that the publicity of the case after [the company's] information has seriously damaged the company's reputation."*

In AN-2021-2757, the Appeals Board decided on the *indirect* financial support in a case where a pharmaceutical company was a member of a political network established by a political party, and where the profit from the network went to the political party. In this instance, the Appeals Board emphasized, among other things, that there is a stricter duty of inquiry when you are part of constellations that are associated with a political party. The Appeals Board justifies the decision in the case as follows:

> *"That [networks] are closely linked to [political party] is and has long been well known to the public, just as neither [network] nor [political party] at any time has hidden this. This must also have been clear to the [pharmaceutical company], at least after the first meetings of the [network]. Therefore, [the pharmaceutical company] is subject to a stricter duty of investigation, cf. the Lobbying code Secs. 1 and 13, in regard to the economics of the [network], including how the membership fee is used. For example, through inter-network postings, [the pharmaceutical company] could have reviewed [the political party's] annual reports for the preceding years and found that the [network] is mentioned among the top 8 contributors to the party (year 2016). The stricter duty of investigation is further accentuated by the fact that [the pharmaceutical company's] enrollment in the [network] took place a few months after [the political party's] formation of a one-party government in 2019.*
>
> *It should be noted that the stricter duty of investigation is the sole responsibility of the pharmaceutical companies, that are subject to ENLI's rules. As a trade association, Lif is not covered by these rules.*
>
> *The Appeals Board agrees that [the pharmaceutical company] has violated the Lobbying Code Sec. 13, cf. Sec. 1."*

Non-financial support:

On the other hand, The Appeals Board in an appeal case at the end of 2021, concluded that the facilitation of a podcast platform for political debate was not to be regarded as financial support for decision-makers.

A company had requested a pre-approval for a project, which would result in a series of podcasts in which candidates for the regional council elections in November 2021 and a health economist were to talk about the future of health care. The company would finance the production of podcasts and distribution to radio stations, etc.

The Investigator's Panel could not approve the request for a pre-approval, as it was, among other things, the Investigator's Panel's assessment that the participating politicians would gain a financial advantage as the company would bear the costs of production and distribution in violation of the prohibition of financial support in of the Lobbying Code Section 13.

Furthermore, the Investigator's Panel assessed that the amount itself (in particular the cost of production/distribution and the value to the politicians) was subordinate.

The Appeals Board did not believe that the support for the project was a financial support within the scope of Section 13 of the Lobbying Code, and thereby reversed the Investigator's Panel's refusal of pre-approval. The Appeals Board justifies the decision as follows:

> *"The overall purpose of the Lobbying Code is to raise the ethical profile of the industry and thus strengthen the industry's image. The ethical rules must ensure a framework for the dialogue between pharmaceutical companies and politicians/authorities, so that the dialogue always takes place in an open, honest, fair and faithful manner. The rules of the Lobbying Code contribute to ensuring that pharmaceutical companies and police/authorities are financially independent of each other, thus cooperation and dialogue always takes place excluding pressure opportunities between the parties, cf. the Lobbying Code Sec. 1. The provision in Section 13 of the Lobbying Code, according to which company representatives may not in any way provide financial support to decision-makers, is of central importance in the efforts to achieve this purpose. The prohibition is absolute in the sense that any violation - regardless of the amount of financial support - entails penalties, cf. the ruling by the Appeals Board of May 7th 2021 in case AN-2021-1468 and the ruling of August 24th 2021 in case AN-2021-2757.*
>
> *According to [the pharmaceutical company's] information, the podcast project will consist of 7 podcast episodes, the content of which relates to the topic "Health Care Anno 2041" and consists of the discussions of the participants on this. The participating persons vary from episode to episode and are constituted for each episode by the relevant regional chairman, his or her primary counterpart in that region, as well as a representative from an additional political party and a health economist. Participants will not receive any form of payment. The podcast episodes will be available on one or more podcast platforms and are offered to one or more radio stations. The discussions must be broadly embraced within the topic of the podcasts so as not to promote or accommodate partisan views. The participants must have equal time on air and consist of a wider range of decision-makers and thus not only of representatives from one or two political parties. [The pharmaceutical company's] contribution to the podcast project consists of paying the costs of producing the podcast episodes, which will be stated in the individual podcast episodes (both in the description of and in the introduction of the podcast*

episodes themselves), and all the parties involved in the podcast project will be informed about this in advance.

The Appeals Board agrees that the podcast project in the form described in a relevant way can contribute to the general health policy debate. The project takes transparency and political balance into account in the representation of participants, so that there should be no risk that [the company] can promote certain health policy views. In this context, the payment of production costs does not amount to financial support to decision-makers, cf. Sec. 13 of the Lobbying Code. It is therefore the opinion of the Appeals Board that, with the podcast project, the [pharmaceutical company] is carrying out a legitimate goal without the risk of the participating politicians becoming financially dependent on the company. Based on an overall assessment of the specific circumstances, the Appeals Board does not find that [the pharmaceutical company's] podcast project violates the Lobbying Code and therefore there has not been adequate reason to reject the request for pre-approval.

By the decision, the Appeals Board has not attributed significance to the fact that municipal and regional elections were imminent at the time of the request for pre-approval. Furthermore, the special nature of the podcast-format as a forum for debate and dissemination of political messages has been irrelevant to the decision."

Art. 14

Pharmaceutical companies or their representatives must not in any way remunerate decisions-makers performing their duties, which the company may have a direct interest in influencing. However, this is permitted exceptionally in the case of:

a) A decision-maker whose primary occupation is as a permanent employee of a pharmaceutical company and whose remuneration exclusively relates to this main occupation. If a company has employed a decision-maker who is required as part of his/her main occupation/area of responsibility to conduct dialogue and negotiations with decision-makers on behalf of the pharmaceutical company (e.g., employees responsible for public and external affairs), the company is especially responsible for ensuring:

1. *That the rules and principles on conflicts of interest in the Public Administration Act are always complied with at the very least.*
2. *That the person engaged in dialogue and negotiations with other decision-makers is always, and without exception, fully transparent about the nature of his employment, cf. Art. 6 and 7, so there can be no doubts as to conflicts of interest.*

b) A decision-maker who also acts as a healthcare professional and who, in his duties as such, exclusively undertakes professional services for the pharmaceutical company, cf. Sec. 24 in the Executive Order on Advertising of Medicinal Products. Remuneration must only be provided in relation to such professional services and shall otherwise be reasonable, compared to the services provided.

c) A decision-maker who provides a specific, limited service for the pharmaceutical company relating to teaching, lectures, etc. Remuneration must only be provided in relation to such teaching/lecturing services and must otherwise be reasonable compared to the services provided.

Re: Article 14

The provision concerns the possibility of remuneration of the decision makers.

Example:

If a person participates in an advisory board and this person is both a doctor (healthcare professional) and a politician (decision-maker), are the pharmaceutical company allowed to pay him?

- Yes, if the person in the specific situation participates due to his capacity as a healthcare professional. Any remuneration must be in accordance with the service provided by the decision maker.

- If, on the other hand, the person was only a decision-maker, he/she cannot get paid for participating, cf. Article 14 of the Lobbying Code.

Example:

If a pharmaceutical company collaborates with an employee from the CEPOS policy institute and wishes to pay him for his time and advice, will this employee be considered a decision-maker?

- No, employees in various policy institutes will not be considered politicians or government officials (decision-makers).

Art. 15

Pharmaceutical companies or their representatives must not in any way offer or provide gifts, etc., to decision-makers that have a financial value for the recipient, and which have no professional purpose: for example, private gifts, tickets to sporting, cultural or entertainment events, travel, vacation, extravagant visits to restaurants or the like shall not be provided.

a) However, company representatives may provide professional information material (reports, books, analyses, films) which are intended by the company to provide relevant information, and which are included as a natural, open part of the company's dialogue with decision-makers.

Re: Article 15

This provision regulates whether pharmaceutical companies are allowed to offer gifts, information materials or the like to the decision-makers.

Example:

A pharmaceutical company has just had a meeting with a decision-maker, and the company would like to give him two bottles of wine for his time. Is the company allowed to do so?

- No, pharmaceutical companies are not allowed to give decision-makers economic benefits without a professional purpose, in any way.

Art. 16

The company representative may provide relevant hospitality at direct meetings between the company representative and the decision-maker, or when attending theme days, conferences, etc., organized and funded by the company. As part of the above meetings, the company representative may cover decision-makers' travel expenses and accommodation:

a) The above expenditure for hospitality, travel expenses or accommodation must be reasonable and not extravagant.

b) The permitted level of the above expenditure must follow the same strict framework for hospitality, accommodation and travel which applies for the pharmaceutical companies' relations with healthcare professionals, cf. The Danish Ethical Rules for Promotion of Medicinal Products towards Healthcare Professionals (Promotion Code).

Re: Article 16

The provision relates to the payment of representation, travel, catering etc. for the decision-makers. For further information regarding these rules, please refer to Article 13 of the Promotion Code, as well as the Guidance to the Promotion Code regarding Article 13.

Catering

If a pharmaceutical company fully or partly helps to cover the cost of catering, the company must ensure that lunch does not exceed DKK 450, and dinner does not exceed DKK 850 for events in Denmark. In addition, there is a general maximum amount for participating in full day meetings totaling DKK 1,400 in Denmark. Prices are incl. VAT and beverages.

The maximum amounts mentioned above applies to meals in Denmark. For meals in other European countries, the maximum amount stipulated by the pharmaceutical industry organizations in these countries apply. For further information, please refer to EFPIA dining card on ENLI's website.

A company is not allowed to pay for part of a meal if the *total* amount of catering will exceed the allowable amount, for instance if the participant himself pays for the remaining amount. A company cannot pay DKK 600 for a dinner if the participant additionally pays 300 DKK, for instance. In that case, the total price for the dinner (DKK 900) will exceed the maximum amount of DKK 850.

Hospitality

Pharmaceutical companies must, in support of the decision-makers' activities, only offer representation in the form of travel, meals and hotel expenses. All forms of representation must be at a reasonable level

and may not be extravagant or luxurious. At the same time, the representation must be limited to the main purpose of the event and must be temporally subordinate to the professional activity. What matters is the attraction of the activity: is it the catering or the professional information? Therefore, it is not acceptable to serve a sandwich for a meeting that only lasts 15 minutes.

A pharmaceutical company can only sponsor hotel expenses if the extent of the event requires accommodation in a hotel. If an event is less than six hours, it should be possible to attend without the need for a hotel accommodation. If a hotel accommodation is required, there must be professional activities the day before and the day after the hotel stay.

A pharmaceutical company is not allowed to provide any representation to the participant's companion. If a pharmaceutical company has supported a decision-maker's participation in an event, the invitation cannot include companions, even if the companion pays his or her own costs associated with the event. This means that the pharmaceutical company is not allowed to act as a "travel agent" for accompanying spouses/partners. It also means that a pharmaceutical company cannot book tickets etc. to accompanying spouses/partners, regardless of the fact that the pharmaceutical company does not pay the cost of the ticket itself.

Venues

Events must take place at venues suitable for the main purpose of the activity. This means that venues need to provide suitable settings for the given meeting. So-called 'non-industry' venues, such as boat trips, visits to museums, etc., are not allowed unless these facilities have separate, suitable meeting facilities.

Apart from that, the venue must not be known for its entertainment facilities or be considered extravagant or luxurious. ENLI's rules prohibit the use of 5-star hotels, gourmet restaurants, castles and manor houses, golf hotels, ski and bath hotels (in the season), boat trips, etc.

It is irrelevant if the participants at the event actually have access to the offered leisure and entertainment activities or, in addition, receive luxury meals. But it is crucial if the planned venue in common reputation is "known" for its entertainment facilities, is extravagant and/or luxurious.

However, it is always a concrete assessment of the legitimacy of the meeting place in relation to the individual meeting, which includes the meeting's logistics and facilities requirements.

If you wish to see if there has been a decision regarding the use of specific venues, please check ENLI's website.

Advertising Order

Article 20 of the Advertising Order states that:

> *"In connection with the promotion of medicinal products, the public must not be given or offered representation in form of payment of expenses for dining, travel, stay, etc."*

This means that the public (including decision-makers) cannot be offered representation at the promotion of medicinal products. However, this does not apply if the decision-maker is also a healthcare professional.

Legislation

Art. 17

All activities pertaining to dialogue and negotiations with decision-makers shall comply with applicable legislation. If an opposing party makes proposals on activities or a quid pro quo that is contrary to the legislation, these shall always be refused.

a) The company representative shall always take the initiative to act against a breach of the legislation when having become aware that this is happening or is being planned by a third party.

Re: Article 17

Currently there is no guidance for this provision.

Enforcement

Art. 18

The rules are sanctioned as outlined in the Sanctions- and fees regulations of ENLI, please refer thereto.

Re: Article 18

Please refer to the Sanction- and Fee regulation of ENLI at www.enli.dk.

Entry into force

Art. 19

This code shall enter into force on 15 June 2022 and replaces the latest published code of 1 June 2017.

Re: Article 19

Currently there is no guidance for this provision.

Questions and answers

Section 1 - Scope

1. Does the Lobbying Code always apply to dialogue with decision-makers?

   Answer: *Yes.*

2. Is there a difference between what a Medical Advisor or a Key Account Manager can inform a decision maker about?

   Answer: *No, the Danish legislation and the Lobbying Code apply to all company employees and their representatives. ENLI is aware that internally there may be guidelines within the companies as to who can answer questions from healthcare professionals or inform about specific medicines, but ENLI still considers it important to state that all ENLI rules (and Danish legislation in general) apply to all the company's employees in their actions towards decision-makers. Thus, it is subordinate to which department you are employed in or what title you have - externally you are the company's representative, and the company is subject to ENLI's rules as well as legislation, including the Advertising Order.*

3. May a pharmaceutical company provide financial support to a decision-maker's party?

   Answer: *No, but the company is allowed to provide sponsorships for specific professional activities and campaigns held by a public authority.*

Section 2 - Definitions

4. Is the president of the Danish Medical Association a decision-maker?

   Answer: *No, as he is neither a politician nor a public official, cf. Section 2 litra a) and b) of the Lobbying Code. The chairman is a healthcare professional and the contact with him is therefore subject to the rules of the Promotion Code.*

5. Is an employee of Danish Regions a decision-maker?

   Answer: *Yes, as the members of Danish Regions are part of the public sector, cf. Lobbying Code Section 2, litra a) to c).*

6. Is an employee of AMGROS a government official?

   Answer: *Yes, cf. Section 1 of the Lobbying Code Section 2, litra b).*

7. Is the Director of CEPOS a decision-maker?

Answer: *No. CEPOS is an independent private organisation, that are not affiliated with the public sector or the like, cf. Section 2, litra a) to c) of the Lobbying Code contradictory.*

8. Is the head of department at a hospital included in the definition decision-maker, cf. Article 2, litra c) of the Lobbying Code?

Answer: *No, since this person is not part of the Executive Board at the hospital and therefore does not have the authority to make decisions at the Executive Board level.*

Abbreviations

The Lobbying Code	Ethical Rules for dialogue and negotiations with decision-makers
ENLI	The Ethical Committee of the Pharmaceutical Industry in Denmark
IGL	The Danish Generic and Biosimilar Medicines Industry Association
Lif	The Danish Association of the Pharmaceutical Industry
PFL	The Danish Association of Parallel Distributors of Medicines
Advertising Order	Order on Advertising, etc., for Medicinal Products (Bekendtgørelse nr. 849 af 29/04/2021 om reklame mv. for lægemidler, som ændret ved BEK nr. 134 af 25/01/2022.)
Guidance to the Advertising Order	Guidance to Advertising, etc. for Medicinal Products (Vejledning om reklame mv. for lægemidler nr. 9400 af 20. april 2022)
The Promotion Code	The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals
Guidance to the Promotion Code	Guidance on "The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals"