



GUIDE

for events at Folkemødet

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1. Purpose

The objective of this guide is to provide a comprehensive summary of relevant information for pharmaceutical companies involved in organizing or supporting events at Folkemødet.

Folkemødet is a political event held annually in Allinge on Bornholm since 2011 and takes place every mid-June.

As the events at Folkemødet may be directed at a diverse audience, including healthcare professionals, politicians, patient organisations, and the general public, this guide will address relevant provisions from the Promotion Code, the Patient Organisation Code, and the Lobbying Code. In addition, there will be events that do not fall under ENLI's jurisdiction as they are targeted at the general public.

For a complete overview of ENLI's rules and guidance, please visit our website at www.enli.dk.

It is important to note that the regulations outlined in this guide are applicable only to pharmaceutical companies that have voluntarily chosen to adhere to ENLI's guidelines. A list of companies that have joined ENLI is available on the website: www.enli.dk.

2. Definitions

Patient Organisations and Their Representatives

The Patient Organisation Code governs collaboration between pharmaceutical companies and patient organisations etc.

Section 2(1) of the Patient Organisation Code states, that: *“Patient Organisations” is defined as in Article 1, section 7 of the Advertising Order: “By Patient Organisations means organisations of patients and relatives, whose purpose is to protect the interests of patient groups, cf. Article 71 d of the Danish Medicines Act.”*

Section 2(2) of the Patient Organization Code states that: *“Patient Organisations, etc.” in relation to this code means: a) Patient Organisations, cf. section 2.01 and, b) Other organisations working for: 1. Patient related issues, 2. Health related issues or, 3. Consumer interests with a focus on health issues.”*

Decision-maker

The Lobbying Code applies to company representatives' dialogue and negotiations with decision-makers at European or national level. Decision-makers are *“a politician or official person, cf. points a) and b)”*, cf. section 2(c) of the Lobbying Code.

Section 2(a) of the Lobbying Code states that: *“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.”*

Section 2(b) of the Lobbying Code states that *“Officials” refers to all those, whose primary occupation is as employees of a public authority*

1. Ministerial departments, national agencies and 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."

For further information on definitions and dialogue with decision-makers, please refer to the Lobbying Code and the associated guidelines.

The concept of promotion

According to section 1(1) of the Advertising Order, advertising for medicinal products for human use means "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products to humans." All activities, regardless of the medium, are covered by the concept of advertising, which means that events, videos, banners, roll-ups, podcasts, etc. may be considered advertising depending on the specific content.

It appears from the Danish Medicines Agency's guidelines to the Advertising Order that the definition of advertising for medicinal products is interpreted broadly in accordance with the wording of the provision and the main purpose of the advertising rules, which is the protection of public health, among other things. The Danish Medicines Agency's guidelines section 2.1. also state that:

"

It depends on a concrete assessment of the present circumstances, including the nature of the activity carried out and the content of the message, whether it is advertising for medicines.

The definition of advertising for medicinal products is not limited to specific senders or media. It is not a requirement that a message about a medicinal product must be disseminated in connection with a commercial activity in order to be considered advertising, or that the person who disseminates the message about a medicinal product must be associated with the pharmaceutical company / marketing authorization holder. It can be both pharmaceutical companies and others who are senders of advertising for medicines.

[...]

It is not a condition that it is an advertisement for a medicinal product that the material appears in form as a typical advertisement, e.g., an advert, as the concept of advertising is not limited to certain forms, but it will in that case be included as a factor together with other relevant factors in the assessment. [...]

It is not a criterion in the definition of advertising that the person advertising a medicinal product must have a special, typically financial, interest in promoting the sale of the medicinal product. If, for example, a person or company through public statements unequivocally strives to influence others to buy a particular medicine, and the statements appear in the

form of an advertisement, it will be a medicines advertisement, even if the person or company acts on its own initiative and both legally and in fact is completely independent of the marketing authorization holder of the medicinal product.."

The concept of advertising, as established in Directive 2001/83 of the European Parliament and Council, is subject to ongoing interpretation by the European Court of Justice, which typically interprets the concept broadly. to adopt an expansive understanding of the term. A notable example of this is the 'Damgaard case' (C-421/07), in which the Court ruled that the dissemination of information about a medicinal product by a third party may be classified as advertising, even if the third-party acts independently and is legally and actually separate from the manufacturer or seller of the product.

Healthcare Professionals

Section 3(5) of the Promotion Code states that *"Healthcare professionals" is defined as in the Advertising Executive Order Section 1 (3): "Healthcare professionals means doctors, dentists, pharmacists, nurses, pharmaconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and health assistants and students in these disciplines". "Danish healthcare professionals" means healthcare professionals employed in Denmark, or healthcare professionals with independent business in Denmark, e.g., general practitioners with a clinic in Denmark.*

The provisions of the Promotion Code apply to the advertising activities of pharmaceutical companies affiliated with ENLI, targeting healthcare professionals. Given the broad scope of the term "advertising," any events organized by pharmaceutical companies that are intended, either in whole or in part, for healthcare professionals will fall under the scope of the Promotion Code, even in the absence of references to medicines or treatments.

The General Public

Section 3(6) of the Promotion Code states that: *"The general public" is defined as in Sec. 1, section 2 of the Executive Order on Advertising of Medicinal Products and by this is meant anyone who is not covered by the definition of a healthcare professional, cf. section 3.(5)."*

3. Overview of the Ethical Codes

The Patient Organisation Code

Purpose:

The primary objective of the Patient Organisation Code is to establish a structured framework for interactions between pharmaceutical companies and patient organisations, among other entities. It is essential that any collaboration between these parties occurs within an ethically sound framework. The principles outlined in the Patient Organisation Code are also applicable during events such as Folkemødet, where pharmaceutical companies engage with patient organisations or their representatives.

Support:

According to Section 2(4) of the Patient Organisation Code, *"Support" is defined as any kind of financial support and non-financial support.'*

It follows from the guidance to Section 2(4) of the Patient Organisation Code that: *"Benefits" are also covered by article 2, section 4, re. "Support". For example, it would be considered a benefit for a Patient Organisation if the Patient Organisation receives information about illness and / or health from a pharmaceutical company.'*

Collaboration:

Section 2(5) of the Patient Organisation Code defines *"collaboration" as any kind of contact between pharmaceutical companies and one or more patient organisations.'*

This definition is further clarified in the guidelines to Section 2(5), which state that *"collaborations that entails a value for a Patient Organisation is covered by the Patient Organisation Code."*

Additionally, it is important to note that the Patient Organisation Code extends to third-party events directed at patient organizations if the funding is wholly or partially provided by the pharmaceutical industry. A comparable provision is found in the Advertising Order, specifically in Section 5.4 of the accompanying guidelines, which clarifies: *"The provision [Article 21 of the Advertising Order, ed.] applies when a Patient Organisation has received a financial benefit directly from a pharmaceutical company, but also applies when a Patient Organisation has received a financial benefit, provided through a third party, from a pharmaceutical company. A financial benefit that is substantially financed by a pharmaceutical company will in principle also be covered by Article 21 of the Advertising Order, even if it is provided by a third party, if it must be clear to the Patient Organisation that the company's participation is a crucial and necessary condition for the transfer of the financial benefit to the organisation.."*

Written Agreement on Support:

In accordance with the Patient Organisation Code, a written agreement is mandated when a pharmaceutical company provides financial support, substantial non-financial support and/or indirect support (including both financial and non-financial support) through a third party to a Patient Organisation, as well as consultancy services. The agreement must be explicit and include the following elements, as applicable, in accordance with Section 6 of the Patient Organisation Code:

1. *"Name of the collaboration project,*
2. *Name of the parties who have entered into the agreement (pharmaceutical companies, Patient Organisations, etc., and any third parties),*
3. *Types of projects,*
4. *Purpose of the agreement,*
5. *Roles of the parties in the project,*
6. *Timeframe of the project,*
7. *Size of the financial support given and what it is used for,*
8. *Scope and content of non-financial support."*

It is important to note that the Patient Organisation Code does not prescribe requirements for the drafting of a written agreement. Consequently, the parties involved have the discretion to determine whether the agreement should take the form of a formal document or, alternatively, be conveyed through less formal means, such as an email confirming the terms of an oral agreement or a similar arrangement.

Consultancy Agreements:

With regard to consultancy agreements between pharmaceutical companies and representatives of patient organisations, Section 8(2) of the Patient Organisation Code mandates the creation of a **written contract** prior to the initiation of any services, which clearly outlines the **nature of the service** and the **payment terms**. Furthermore, the criteria set forth in Section 8(2), points 2-10 of the Patient Organisation Code must be adhered to, as applicable:

- “2. A legitimate need for the services must be clearly identified and documented in advance of the company requesting the services and entering into arrangements.*
- 3. The company’s criteria for selecting services must be directly related to the identified needs of the company. The person in the company who is responsible for selecting a specific service must have the expertise necessary to evaluate, whether the particular experts or advisors from the desired organisation meets these criteria.*
- 4. The extent of the service and the retained number of representatives must not exceed what is necessary to achieve the identified needs.*
- 5. The company must maintain records, and make appropriate use, of the service .*
- 6. The arrangement with the Patient Organisations, etc., must not include any obligation or inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.*
- 7. The compensation for the services must be reasonable and must not exceed the fair market value of the services provided. In this regard, contracted services must not be used as general financial support for the Patient Organisations, etc.*
- 8. Remuneration may only be made in the form of direct payment, and thus not by set-off, transfer of fees or other indirect means .*
- 9. In their written contracts with Patient Organisations, etc., companies are encouraged to incorporate provisions, which obliges the Patient Organisation, etc., to openly declare that they have provided paid services to the company whenever they communicate in public on any matter that is related to the service or other issues related to the company.*
- 10. Companies must annually publish a list of the Patient Organisations, etc., that they have engaged to provide paid-for services in accordance with Article 7, cf. Article 6.”*

ENLI does not impose further requirements regarding the content or format of written contracts for consultancy services provided by representatives of patient organisations. The parties involved may determine whether the agreement should be documented formally or communicated via email. The decisive factor is that the agreement complies with Section 8 of the Patient Organisation Code - specifically, that it must be in writing, detail the nature of the service, and include information regarding any associated payment. Items outlined in points 2 -10 should be regarded as providing a general framework for the agreement, but they are not mandatory elements that must be explicitly included in the contract.

Prohibition of Gifts:

In accordance with Section 10 of the Patient Organisation Code, it is strictly prohibited to provide, offer, or promise any form of gifts or financial advantages to representatives of patient organisations. This includes, but is not limited to, cash, cash equivalents, personal favors or in-kind services, cf. section 10 of the Patient Organisation Code.

Venues:

The professional event must be held at a venue that is appropriate in relation to the main purpose of the activity, cf. Section 5(3) of the Patient Organisation Code. This means that the venue must constitute an appropriate setting for the specific meeting. Non-appropriate venues, such as boat trips, museums, etc. cannot be used unless these venues have separate, suitable meeting facilities. In addition, the venue must not be known for its entertainment facilities or be extravagant or luxurious. In accordance with ENLI's rules, 5-star hotels, gourmet restaurants, castles and manor houses, golf hotels, ski- and beach hotels (in season), boat trips etc. are prohibited. It is not crucial in this connection whether the participants in the professional event actually have access to the leisure and entertainment activities in question or are otherwise provided with luxurious catering. The decisive factor is whether the planned venue is "known" by common reputation for its entertainment facilities or for being extravagant and/or luxurious.

Catering:

Pharmaceutical companies may offer meals to representatives of patient organisations in connection with company-hosted events, provided the cost does not exceed specified limits. These limits are as follows: DKK 100 for professional meetings lasting up to two hours; for other meeting activities, DKK 450 for lunch, DKK 850 for dinner, and DKK 1,400 for meals provided at full-day meetings/conferences etc. in accordance with section 5(7) of the Patient Organisation Code. The maximum amounts must also be observed when a pharmaceutical company's sponsorship of a patient association is used for catering.

Entertainment:

In connection with events, pharmaceutical companies must not sponsor or organise any form of entertainment activities (e.g. sports, cultural, music or leisure activities), cf. section 5(5) of the Patient Organisation Code.

Publication:

In connection with financial support, significant non-financial support and/or indirect support (both financial and non-financial support) via third parties and consultancy agreements, pharmaceutical companies are obliged to publish an overview on their website containing the information mentioned in section 6 of the Patients' Organisation Code to prevent the perception of unethical or similar links between the pharmaceutical industry and patient organisations etc. The publication must take place from the conclusion of the agreement and must be available on the website for at least two years thereafter and for at least six months after the end of the collaboration project, cf. section 7(1) of the Patient Organisation Code. The collaboration must also be reported to ENLI at the end of the year, cf. section 7(3) of the Patient Organisation Code.

For further information on collaboration with patient organisations, please refer to the Patient Organisation Code and the associated guidelines.

The Lobbying Code

Purpose:

The purpose of the Lobbying Code is to raise the ethical profile of the industry and thereby strengthen its image by:

- Demonstrating to external stakeholders that the industry's Lobbying activities are conducted in an open, honest, fair, and credible manner.
- Ensuring that interactions between industry and political or administrative bodies is based on independence.
- Setting a good example – and take the lead as one of the first industries to introduce a Lobbying Code in Denmark.

The Lobbying Code seeks to promote greater transparency regarding the regulations governing pharmaceutical companies' engagement with decision-makers, both within Denmark and internationally.

The Lobbying Code establishes a set of minimum standards that must be adhered to in all interactions between pharmaceutical companies and public officials. The rules of the Lobbying Code also apply to "Folkemødet".

Gift Ban:

The Lobbying Code, under section 15 stipulates that "*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.*"

Consultancy Service:

According to section 14 of the Lobbying Code, pharmaceutical companies may not remunerate decision-makers who perform a task that the company has a direct interest in influencing. However, this is exceptionally permitted in cases where:

- 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.

Agreement with Decision-Makers

The Lobbying Code does not contain specific rules on how an agreement with a decision-maker should be formulated or which elements that should be included. However, it is important to emphasise that the integrity of the decision-maker must never be compromised.

Venue:

The professional event must be held at a venue that is appropriate for the main purpose of the activity. This means that the venue must provide a suitable setting for the specific meeting. Non-professional venues, such as boat trips, museums, etc. can therefore not be used unless these places have adequate, suitable meeting facilities. In addition, the venue must not be known for its entertainment facilities or be extravagant or luxurious. The starting point in ENLI's rules is that 5-star hotels, gourmet restaurants, castles and manor houses, golf hotels, ski and beach hotels (in season), boat trips, etc. are prohibited. In this context, it is not crucial whether the participants in the professional event actually have access to the leisure and entertainment activities in question or otherwise receive luxurious catering. The decisive factor is whether the planned venue is "known" in general reputation for its entertainment facilities, is extravagant and/or luxurious, cf. Section 16 of the Lobbying Code.

Catering:

Pharmaceutical companies may provide relevant catering for decision-makers in connection with the company's events. If a pharmaceutical company partially or fully finances the catering, it is required to ensure that the cost of lunch does not exceed DKK 450 and that the cost of dinner does not exceed DKK 850 for events held in Denmark. For professional meetings up to 2 hours, catering must not exceed DKK 100. Furthermore, there is a general limit of DKK 1,400 for total catering costs for full-day meetings in Denmark. These amounts include VAT and beverages, as stipulated in Section 16 of the Lobbying Code.

Dialogue with decision-makers does not typically need to be reported to ENLI.

For additional details regarding collaboration with decision-makers, please refer to the Lobbying Code and the accompanying guide.

The Promotion Code

Purpose:

The purpose of the Promotion Code is to establish a framework for the necessary and professionally sound cooperation between the pharmaceutical industry and healthcare professionals, so that professionalism and ethics are paramount, and opportunities for pressure and dependence between the parties are excluded. It outlines essential minimum standards that must be adhered to, alongside relevant legislation.

Events targeting healthcare professionals, either in whole or in part, must comply with the regulations set forth in the Promotion Code. This also includes events organised by pharmaceutical companies at the Folkemødet.

Gift Ban:

According to section 12 (1) of the Promotion Code, it is not permitted to supply, offer or promise healthcare professionals gifts or financial benefits, either in the form of cash, cash equivalents, personal services or benefits, except as listed in Art. 13 - 15.

However, companies may hold events that are wholly or partially targeted at healthcare professionals if the programme meets the professional criteria in the Promotion Code Art. 13 (1) (and complies with the remaining provisions in Art. 13 of the Promotion Code).

If other than healthcare professionals participate in the meeting, the Investigator Panel must note that prescription medicines may not be advertised to the general public, cf. section 66 (1)(1) of the Danish Medicines Act.

The Professionalism Criterion:

Pharmaceutical companies may provide or offer professional information and training to a healthcare professional if it meets the professionalism criterion. The professionalism criterion covers the concept of “professional information and training” and, according to ENLI's established practice, is understood to mean that events must have a specific health professional content and further education for healthcare professionals, including professional presentations on diseases, disease areas, products and treatment methods.

The concept of professionalism has been nuanced by the Appeals Board and is now understood in the light of ENLI's various ethical rules in a broader perspective and also includes more general topics, including health policy and health economics topics and areas that do not directly enhance a physician's clinical capabilities, but which address developments in a disease area, or examine the quality of a given treatment, or otherwise have a more long-term treatment-oriented aim. ENLI considers such content to be in compliance with Section 13(1) of the Promotion Code, provided the focus remains on treating a disease area with the aim of ensuring the best medical treatment for patients..

Conversely, ENLI generally does not approve offers of, or support for, non-health-related courses that are also offered to other professional groups, such as financial management, organisational development, leadership training, computer skills, collaboration training, planning meetings, coaching, practice management (e.g., accountancy assistance), entertainment or comedy, political speeches, communication, teaching how to teach, etc.

Courses addressing topics such as health economics may be accepted, provided that the primary focus pertains to specific treatment-related or medication-oriented issues, rather than constituting a general political discussion of the subject matter.

In 2023, the Appeals Board further broadened the interpretation of professional relevance to encompass the environmental impact of pharmaceutical use, as *“Focus on sustainability and climate-friendly solutions must be expected to become a necessary and integral part of the daily life of healthcare professionals in line with the ever-growing global climate crisis [...]. The concept of professionalism for health professionals must reflect this development.”*

Refer to the guidance of the Promotion Code, Art. 13(1) for more detailed information on the criteria for content related to climate/environment and sustainability.

Venue:

Professional events must be conducted at venues that are appropriate and consistent with the primary objective of the activity, in accordance with Section 13(3) of the Promotion Code. This implies that the selected location should provide a suitable and professional setting for the specific nature of the meeting. Venues not typically associated with professional gatherings - such as boat excursions, museums, or similar establishments - are generally deemed inappropriate unless they offer distinct and adequate meeting facilities. Furthermore, the venue must not be associated with entertainment amenities or perceived as extravagant or luxurious. As stipulated in Section 13(10) of the Promotion Code, ENLI regulations prohibit the use of five-star hotels, gourmet restaurants, castles, manor houses, golf resorts, ski or beach hotels during peak seasons, and boat excursions, among others. Importantly, the assessment of a venue's appropriateness does not depend on whether participants actually engage in leisure or entertainment activities or receive lavish hospitality. Rather, the key consideration is whether the venue is commonly recognised for its entertainment features or is considered extravagant and/or luxurious by general perception.

Catering:

In relation to corporate events, catering may be provided to healthcare professionals, provided the value does not exceed the following specified limits: DKK 100 for professional meetings of up to two hours, for other meeting activities, the maximum allowable amounts are DKK 450 for lunch, DKK 850 for dinner, and DKK 1,400 for full-day meetings or conferences, in accordance with Section 13(8) of the Promotion Code.

Consultancy Services:

Pharmaceutical companies are permitted to engage healthcare professionals for consultancy services, such as serving as speakers or panel debaters. A written agreement outlining the terms of the engagement must be concluded prior to the commencement of the consultancy service, in compliance with Section 15 (1) of the Promotion Code. Remuneration for such services is permissible; however, it must be provided exclusively as direct monetary payment. Remuneration via set-off, payment in kind, or other indirect methods is not allowed, as stipulated in Article 15(1)(g) of the Promotion Code.

Competitions/Entertainment

Pharmaceutical companies are prohibited from organising competitions or awarding prizes to healthcare professionals at meetings that are wholly or partially directed at healthcare professionals, pursuant to Section 12(2) of the Promotion Code. Furthermore, organising or sponsoring entertainment events—such as sport- or leisure events are not permitted, in accordance with Section 13(9) of the Promotion Code.

Reporting:

Pharmaceutical companies affiliated with ENLI are obligated to notify ENLI of any events, including those involving sponsorships, that are wholly or partially directed toward healthcare professionals, in accordance with Section 21 of the Promotion Code. For further information on collaboration between healthcare professionals and pharmaceutical companies refer to the Promotion Code and its accompanying guidelines.

4. Open Events

Events that are accessible to the general public and where the pharmaceutical company has not issued invitations to healthcare professionals, patient organisations etc., and decision-makers, are referred to in this context as "open events."

If a pharmaceutical company has a stage at Folkemødet that is open to everyone, and a healthcare professional happens to pass by the stage and chooses to participate in the event as an audience member, it is ENLI's assessment that the event is not fully or partially aimed at healthcare professionals, and the event thus does not fall under ENLI's competence, including the regulations of the Promotion Code, which is why the event agenda does not have to fulfil the professional requirement or be notified to ENLI. An open event will generally not be subject to ENLI's jurisdiction, as the event will be aimed at the general public.

The same assessment is made if a representative from a patient organisation or a decision-maker passes by the stage and chooses to participate in the event as an audience member. This does not mean that the Patient Organisation Code or the Lobbying Code applies.

However, it should be noted that if a representative from a pharmaceutical company talks to a decision-maker at an open event, the Lobbying Code must be complied with, including that the pharmaceutical company representative must disclose the name and the company the representative works for without being asked, so that the decision-maker is aware that they are talking to a representative from a pharmaceutical company, cf. section 6 of the Lobbying Code.

5. Closed Events

The pharmaceutical companies' activities that are not open to everyone and where the pharmaceutical company selects participants by invitation are referred to in this guide as a "closed event".

Activities that are wholly or partially aimed at healthcare professionals will be subject to the rules of the Promotion Code, as the pharmaceutical company chooses that such an event must be wholly or partially aimed at healthcare professionals.

Activities that are wholly or partly directed towards decision-makers will be subject to the rules of the Lobbying Code.

Activities that are wholly or partially aimed at patient organisations will be subject to the rules of the Patient Organisation Code. As a starting point, closed meetings at Folkemødet are considered to be subject to the requirements for written agreement and disclosure (cf. sections 6 and 7 of the Patient

Organisation Code), as such meetings often represent a significant non-financial value for a patient organisation.

In order for closed meetings at Folkemødet to be considered to represent an insignificant non-financial value, and thus not subject to the requirements for written agreement and disclosure in the Patient Organisation Code, it requires, among other things, that:

- There is no agreement/demand/expressed expectation that the patient organisation must deliver something active before, during or after the event
- The event is not otherwise an integral part of an overall collaboration project with the pharmaceutical company
- No fee has been paid to an external speaker in connection with the event
- the pharmaceutical company has not paid for services provided by an external agency/consultant in connection with the event
- the pharmaceutical company does not, in connection with the event, provide healthcare material, educational material, etc., to the patient organisation which the company has paid for and which represents a significant value
- the pharmaceutical company does not cover expenses for an external venue that represents a significant value, and/or
- the pharmaceutical company does not cover expenses for catering that represent a significant value

6. Regional Agreements

LIF (The Danish Association of the Pharmaceutical Industry) has established formal agreements with each of the five Danish regions concerning collaboration between the pharmaceutical industry and hospital-employed healthcare professionals within the respective regions. These are commonly referred to as 'regional agreements'.

The scope of the regional agreements is limited to activities related to continuing education and professional skills development.

According to Lif, these agreements generally do not apply to pharmaceutical company events held at Folkemødet, as debates and similar activities conducted during Folkemødet are not typically classified as continuing education or skills development. However, should pharmaceutical companies organise events at Folkemødet that qualify as continuing education or skills development, and are wholly or partly directed towards hospital-employed healthcare professionals, the regional agreements shall apply, including specific obligations such as the requirement to send invitations to hospital management. Additional details regarding the regional agreements are available on the website of the Ethical Committee for the Pharmaceutical Industry (ENLI).

7. Affiliation

As a result of the affiliation rules in Danish legislation, pharmaceutical companies must report information to the Danish Medicines Agency about doctors, dentists, nurses, midwives, pharmacists and

clinical pharmacists who are affiliated with the pharmaceutical company. The aforementioned healthcare professionals have a prior obligation to notify or apply to the Danish Medicines Agency for affiliation with pharmaceutical companies. For use at the Folkemødet, the Danish Medicines Agency has prepared the guidelines: “*Rules for affiliation in connection with participation in panel discussions*”, which can be found on the Danish Medicines Agency’s website.

Rules concerning affiliation at the Folkemødet apply when:

- a doctor, dentist, nurse, midwife, pharmacist, or clinical pharmacist participates in a public panel debate organized by a pharmaceutical company
- a doctor, dentist, nurse, midwife, pharmacist, or clinical pharmacist participates in a panel debate closed for the public, organized by a pharmaceutical company
- a doctor, dentist, nurse, midwife, pharmacist, or clinical pharmacist receives a personal fee from a pharmaceutical company in exchange for participation in a debate

In the case of a public event:

- the doctor, dentist, nurse, midwife, pharmacist, or clinical pharmacist is required to notify the Danish Medicines Agency of any collaboration prior to the event, categorising it as participation as a "panel debater with public access."
- the doctor/dentist/nurse/midwife/pharmacist/clinical pharmacist must notify the Danish Medicines Agency prior to the event if the healthcare professional receives a personal fee from a pharmaceutical company for participation in a public debate
- the pharmaceutical company must inform the doctor/dentist/nurse/midwife/pharmacist/clinical pharmacist of the prior obligation to notify the Danish Medicines Agency
- the pharmaceutical company must report the affiliation to the Danish Medicines Agency - the report must be made digitally once a year no later than January 31st

In the case of a closed event that is not open to the public,

- the doctor/dentist/nurse/midwife/pharmacist/clinical pharmacist must apply to the Danish Medicines Agency before the event for permission to participate as a “panel debater without public access”
- the doctor/dentist/nurse/midwife/pharmacist/clinical pharmacist must apply for permission from the Danish Medicines Agency before the event if the healthcare professional receives a personal fee from a pharmaceutical company for participation in a debate without public debate
- the affiliation requires prior authorisation from the Danish Medicines Agency, which means that the doctor/dentist/nurse/nurse practitioner/midwife/pharmacist/clinical pharmacist may not participate in the closed event until authorisation has been received
- the pharmaceutical company must inform the doctor/dentist/nurse/midwife/pharmacist/clinical pharmacist about the prior obligation to apply to the Danish Medicines Agency and the authorization from the Danish Medicines Agency
- the pharmaceutical company must report the affiliation to the Danish Medicines Agency - the report must be submitted digitally once a year no later than January 31st

As compliance with the affiliation rules is monitored by the Danish Medicines Agency through its publication of the information, it has been decided by the parties behind ENLI that ENLI will not control or sanction the pharmaceutical companies' compliance herewith. For questions about the affiliation rules, please contact the Danish Medicines Agency: www.laegemiddelstyrelsen.dk or by e-mail: tilknytning@dkma.dk.

In connection with the preparation of this guide, ENLI has asked the Danish Medicines Agency about the specific questions in the following Q&A regarding affiliation.

8. Q & A's

Open events

Healthcare professionals

1. Via a third party, five pharmaceutical companies organise a debate event at Folkemødet that is open to all and where three healthcare professionals are invited as panel debaters. The panel debaters will each receive DKK 5,000 for their participation.
 - a. Must all five pharmaceutical companies enter into a contract with the panel debaters (according to section 15 of the Promotion Code)?
 - b. Must the collaboration with the healthcare professionals be notified to the Danish Medicines Agency? If yes, with which company?
 - c. Must the collaboration be authorised by the Danish Medicines Agency before the event?

A:

- a. *It can be decided that only one of the five companies will enter into a written agreement with each healthcare professional. It can also be decided that three different pharmaceutical companies enter into a written agreement with each 'their' healthcare professional. It may also be the third party that enters into a written agreement with the healthcare professionals on behalf of the pharmaceutical company.*
 - b. *Yes, if the healthcare professionals are either doctors, dentists, nurses, midwives, pharmacists or clinical pharmacists, the affiliation must be reported to the Danish Medicines Agency. If payment of fees only comes from one pharmaceutical company, it is sufficient for this pharmaceutical company to report the affiliation of the three healthcare professionals to the Danish Medicines Agency. Similarly, this pharmaceutical company must remember to inform the healthcare professionals about the prior notification to the Danish Medicines Agency. The duty to inform can be delegated to a third party, but it is still the responsibility of the pharmaceutical company to ensure compliance with the duty to inform. If the fee comes from all five pharmaceutical companies, the healthcare professionals must report affiliation with all five companies - and all five companies must inform the healthcare professionals of the notification obligation and report the affiliation to the Danish Medicines Agency themselves - e.g. that each healthcare professional (doctor, dentist, nurse, midwife, pharmacist or clinical pharmacist) reports having received DKK 1,000 from each of the five pharmaceutical companies (DKK 5,000 (fee)/5 pharmaceutical companies)*
 - c. *No, the affiliation does not require prior authorisation from the Danish Medicines Agency before the arrangement, but only notification.*
2. A pharmaceutical company organises an open event at Folkemødet where they will invite two healthcare professionals as panel debaters. The healthcare professionals do not receive a fee for their panel participation.
 - a. Does the company have to enter into a contract with the panel debaters according to Section 15 of the Promotion Code, or is it voluntary whether a written agreement is entered into?
 - b. Must the consultancy agreement be notified to ENLI?

- c. Must the collaboration with the healthcare professionals be notified to the Danish Medicines Agency?
- d. Must the collaboration be approved by the Danish Medicines Agency before the event is held?
- e. Is the entire event subject to the Promotion Code as a result of two healthcare professionals sitting on the debate panel? In other words, for example, must the agenda thus fulfil the professionalism criterion in Section 13(1) of the Promotion Code?
- f. Is the event subject to the Promotion Code if a healthcare professional (as an audience member, but without a separate invitation) participates in the event?

A:

- a. *Yes, the company must enter into a contract with the panel debaters according to Section 15 of the Promotion Code, even if the panel debaters do not receive a fee*
 - b. *No, consultancy agreements do not need to be notified to ENLI, cf. Section 21(2) of the Promotion Code*
 - c. *Yes, if the healthcare professionals are either doctors, dentists, nurses, midwives, pharmacists or clinical pharmacists, they must notify the Danish Medicines Agency as a 'panel debater with public access', as it is a pharmaceutical company that organises and hosts the event. This means that, in addition to the healthcare professionals mentioned above having to report the affiliation to the Danish Medicines Agency, the pharmaceutical company must inform the healthcare professionals of the prior notification and report the affiliation to the Danish Medicines Agency itself. As no fee is paid, the healthcare professionals must simply state '0' DKK in fees in connection with their notification*
 - d. *No, the affiliation does not require prior authorisation from the Danish Medicines Agency before the event, but must only be notified*
 - e. *No, the entire event is not subject to the Promotion Code because of two healthcare professionals sitting on the debate panel*
 - f. *No, the entire event is not subject to the Promotion Code if a healthcare professional (as audience, but without separate invitation) participates in the event*
- 3.** A pharmaceutical company organises an open event at Folkemødet. No invitations are sent, so the event does not fall under ENLI's jurisdiction. However, the company wishes to provide information about the event but is in doubt as to whether an information letter will mean that the event falls under ENLI's competence. The information letter/teaser only contains information about the time, place and agenda, and there is no registration option. Will an information letter about the event on the following platforms be considered an invitation, which means that the event falls under ENLI's jurisdiction?
- a. Posting on X or other social media
 - b. Advertisement in Medical Journals
 - c. Posting on the company's closed website for healthcare professionals
 - d. The pharmaceutical company's newsletter for healthcare professionals

A: *Regarding points a to d: No, distributing an informational letter (without an option for registration) about an open event at the Folkemødet does not place the event within the scope of ENLI's jurisdiction, and therefore ENLI's rules do not apply.*

4. Do healthcare professionals who are invited to participate as an audience in a pharmaceutical company's event at Folkemødet have to report the affiliation to the Danish Medicines Agency, and must the pharmaceutical companies inform the healthcare professionals of this reporting obligation?
- A:** *No, healthcare professionals who participate solely as audience members and do not perform a task - or receive a personal remuneration - are not required to report their participation as audience members to the Danish Medicines Agency. This means that the pharmaceutical company is not required to inform or report any affiliation to the healthcare professional(s) participating as audience members.*

Patient Organisations

5. A pharmaceutical company organises an event at Folkemødet that is open to everyone and where the company has invited a representative of a patient organisation as a panel debater. Neither the patient organisation nor representatives receive a fee for their participation.
- Does the company need to enter into a written agreement with the patient organisation?
 - Must the collaboration be disclosed on the company's website and reported to ENLI?
 - Will the entire event be subject to the Patient Organisation Code as a result of a representative of a patient organisation sitting on the debate panel?
 - Is the event subject to the Patient Organisation Code if a representative of a patient organisation (as an audience member, but without invitation) participates in the event?

A:

- Yes, for pharmaceutical companies' consultancy agreements with patient organisations, section 8(2) of the Patient Organisation Code states that a **written** agreement must be drawn up in advance, which specifies **the service** and **states the amount for any payment of fees**. In addition, the criteria mentioned in section 8(2), points 2-10 of the Patient Organisation Code must, to the extent relevant, be fulfilled.*
It is irrelevant whether the panel debaters receive remuneration, as the decisive factor is that the event is organised by the pharmaceutical company. ENLI analogously follows the Danish Medicines Agency's affiliation rules that apply to healthcare professionals' participation in panel debates. According to the Danish Medicines Agency, a healthcare professional's participation in a panel debate as part of an open event organised by a pharmaceutical company is considered an affiliation that is subject to notification - even if no fee is paid.
- Yes, the collaboration is subject to the Patient Organisation Code regardless of whether the company pays the patient organisation a fee, cf. Section 2(5) of the Patient Organisation Code. Despite the fact that the patient organisation did not receive a fee, it is ENLI's assessment that the patient organisation receives publicity and is made visible by participating in the company's event, which is why this is a benefit in kind of significant value given by the company to the patient organisation.*
As mentioned above, ENLI follows by analogy the Danish Medicines Agency's affiliation rules that apply to healthcare professionals' participation in panel debates, according to which a healthcare professional's participation in a panel debate without remuneration, in a

pharmaceutical company's open event, is considered an affiliation that is subject to notification. Similarly, cooperation with representatives of patient organisations must be disclosed in accordance with section 7(1) (company website) and (3) (annual reporting to ENLI) of the Patient Organisation Code.

- c. No, the entire event is not subject to the Patient Organisation Code just because a representative of a patient organisation sits on the debate panel.*
- d. No, the entire event is not subject to the Patient Organisation Code if a representative of a patient organisation (as an audience and without invitation) participates in the event*

- 6.** A pharmaceutical company organizes an event that is open to everyone but is partly targeted at patient organizations. The company has invited three different patient organizations to participate as audience members in their event. Is the open event subject to the Patient Organisation Code?

A: *Yes, the open event is subject to the Patient Organisation Code, as the company has actively invited patient organisations to participate in their event and has thus decided that the event is relevant to the invited patient organisations. There is thus a contact between a pharmaceutical company and a patient organisation, cf. section 2(5) of the Patient Organisation Code. As the patient organisation only participates as an audience, the event is considered to be of insignificant non-financial value and the participation will therefore not be subject to the requirements of written and public disclosure (cf. sections 6-7 of the Patient Organisation Code).*

- 7.** A patient organisation wishes to hold an event at Folkemødet to raise awareness of the disease the organization is working to combat. In this connection, the patient organisation has asked a pharmaceutical company for financial support of DKK 40,000 to cover the rental of a tent, fees for speakers, banners, flyers and advertising. Can the pharmaceutical company provide support for this? If so, should a written agreement be drawn up with the patient organisation?

A: *Yes, the pharmaceutical company may provide support for the patient organisation's awareness event, as it is a disease area that the patient organisation works to combat. The pharmaceutical company must draw up a written agreement containing the points specified, to the extent relevant, in section 6 of the Patient Organisation Code.*

There are no requirements regarding how the agreements must be drawn up, which means that an e-mail containing the points in section 6 of the Patient Organisation Code comply with the provision.

Decision makers

- 8.** A pharmaceutical company is organising an open event where they will invite two politicians as panel debaters.
- a. Is the event subject to the Lobbying Code because of the politicians' panel participation?
 - b. Must the pharmaceutical company enter into a written agreement with the politicians?

- c. Is the event subject to the Lobbying Code if a politician randomly attends the event as an audience member?
- d. Can the company give two bottles of wine to the politicians as a 'thank you' for attending the panel?
- e. Can the company pay politicians a fee as a 'thank you' for participating in the panel?

A:

- a. *No, the event itself is not subject to the Lobbying Code, but the pharmaceutical company's interaction with the two politicians is subject to the Lobbying Code.*
- b. *No, the Lobbying Code does not require the pharmaceutical company to enter into a written agreement with the politicians.*
- c. *No, in the case of an open event that is open to all and where decision-makers have not been directly invited, ENLI does not consider the event to be subject to the Lobbying Code.*
- d. *No, the pharmaceutical company may not give two bottles of wine to politicians as a 'thank you' for panel participation, cf. section 15 of the Lobbying Code.*
- e. *Yes, the pharmaceutical company may pay a fee to the politicians for their panel participation, provided that the fee is proportionate to the service, cf. section 14(c) of the Lobbying Code.*

Mixed target group

- 9. A pharmaceutical company wants to organise a quiz at Folkemødet where participants test their knowledge in a disease area. The participants in the quiz consist of a representative of the Danish Nurses' Association (a healthcare professional), a health policy spokesperson (parliamentary politician) and a representative of a patient organisation. The winner receives a textbook about the disease. Will the company be able to organise the requested quiz?

A: *No, the pharmaceutical company cannot organise the requested quiz.*

As the participants are a healthcare professional (Danish Nurses' Association), a decision-maker (health policy spokesperson) and a representative of a patient organisation, the rules in the Promotion Code, the Lobbying Code and the Patient Organisation Code must be observed.

The Promotion Code prohibits the organisation of competitions for and awarding prizes to healthcare professionals, cf. Art. 12(2) of the Promotion Code.

Section 13 of the Lobbying Code prohibits both direct and indirect financial support to a politician. The pharmaceutical company may therefore not give the prize to the decision-maker if the competition is won by the decision-maker, cf. also ENLI's decision in case EN-2023-2964.

- 10. A company wants to organise an open debate event at Folkemødet. To ensure a good debate with active participation from the audience, the company wants to invite the following participants to the event: the president of a medical society, three healthcare professionals, representatives from two patient organisations and five politicians. The participants are invited as audience members

and not as panel debaters. Does the event fall outside ENLI's competence as the event is open to all?

A: *No, although the event is open to all, the event falls within ENLI's jurisdiction as a result of the company actively sending out invitations:*

- *The event must comply with the rules of the Promotion Code, as the company has invited healthcare professionals (chairman of a medical society and three healthcare professionals)*
- *The event must comply with the rules of the Patient Organisation Code, as the company has invited patient organisations/representatives of patient organisations)*

The event must therefore comply with the rules of the Promotion Code, Patient Organisation Code and Lobbying Code, including that the programme for the event must comply with the professionalism criterion in section 13(1) of the Promotion Code.

Closed events

11. A pharmaceutical company wants to organise five different roundtable meetings with different participants. These are closed events, as all participants are invited by the company. Are the following meetings subject to ENLI's jurisdiction?

- a. Only healthcare professionals are invited to the first roundtable
- b. Only representatives of various patient organisations are invited to the second roundtable
- c. Only politicians are invited to the third roundtable
- d. Humanitarian organisations and a representative of a think tank are invited to the fourth roundtable meeting
- e. Healthcare professionals, representatives of various patient organisations, politicians and humanitarian organisations are invited to the fifth roundtable meeting

A: *Yes, all five meetings are generally subject to ENLI's jurisdiction*

- a. *Since the meeting (wholly or partly) targets healthcare professionals (by invitation), the meeting must comply with the rules of the Promotion Code.*
- b. *The meeting must comply with the Patient Organisation Code, as representatives of patient organisations are invited. See point 5 regarding closed events for more information.*
- c. *Since politicians are invited to the meeting, the rules of the Lobbying Code must be observed.*
- d. *Whether the fourth round table meeting is subject to ENLI's jurisdiction depends on whether one of the humanitarian organisations can be considered 'other organisations' in the Patient Organisation Code. If one of the organisations works for a specific disease, patient group or an organisation working for consumer interests that has a health policy focus, the meeting must comply with the Patient Organisation Code. If this is not the case, the meeting is not subject to ENLI's rules.*
- e. *The fifth meeting must comply with the rules in the Promotion Code, the Lobbying Code and the Patient Organisation Code.*

Participant is both a Healthcare Professional and a Decision-Maker – Which Code Applies?

12. A pharmaceutical company wishes to invite the following individuals (a–e) to participate in a debate event. The invitee is a qualified medical doctor but is not invited in their capacity as a healthcare professional; rather, the invitation is based on their current position. Does the event fall within the scope of the Promotion Code if the participant is a healthcare professional, but is being invited due to the fact that:

- a. The participant is the director of a Danish hospital?
- b. The participant is a politician?
- c. The participant is the chairperson of a medical society?
- d. The participant is a representative of the Danish Doctors Association?
- e. The participant is a professor at the University of Copenhagen??

A: *If healthcare professionals are invited by virtue of their position/function at an overarching management level, and they are not involved in patient care (e.g., a business executive), or if the individual is an actual decision-maker, the event will not fall within the scope of the Promotion Code.*

- a. *When a hospital director in Denmark is invited to a debate event, the event falls outside the scope of the Promotion Code, provided that the healthcare professional is invited by virtue of their senior management role and has no involvement in patient care.*
- b. *When a politician, who is also a healthcare professional, is invited to a debate event, the event falls outside the scope of the Promotion Code if the individual is invited in their political capacity. However, the event must comply with the Lobbying Code.*
- c. *When the chairperson of a medical society is invited to a debate event, the Promotion Code must be observed, as a medical society is regarded as an association of individual healthcare professionals.*
- d. *When a representative of the Danish Doctors Association is invited to a debate event, the Promotion Code must be observed, as the Danish Doctors Association is likewise regarded as an association of individual healthcare professionals, in the same manner as a medical society.*
- e. *When a professor at the University of Copenhagen is invited to a debate event, the Promotion Code must be observed, as the individual is considered a healthcare professional.*