



Checklist

for reporting a company event

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The purpose of this document is to help users who are unsure which consideration must be made and which documents must be sent when reporting activities to ENLI. This document is structured so you only need to read this page. If you need a more detailed checklist, we recommend reading the subsequent appendices (appendices A to C).

It is emphasized that the following checklist is not exhaustive, but is only intended as a help, where ENLI has included the most frequently issues ENLI has received. Please remember that it is important that the information in this checklist always is compared with the information in ENLI's Guidance to the Promotion Code.

1. DOCUMENTS THAT MUST BE UPLOADED TO ENLI

- The programme of the event
- Invitation
- If relevant, a budget
 - Specification of the amount for meals (lunch, dinner, and on-going hospitality)
- If special considerations have been made in connection to programme, venue, transport, catering, accommodation etc., it is recommended to include these considerations in an attached word document
- The event must be reported to ENLI within 10 working days prior to the opening day of the event
 - For further information regarding how to calculate the deadline – please see appendix B

It is important to ensure that all relevant information and documents are submitted in the report to ENLI, as it is not possible to change the reported information to avoid a sanction, if the material has been selected for a random check, cf. The Promotion Code Sec. 21.4.

For information on how to report activities to ENLI, please refer to ENLI's Guidance on reporting an activity to ENLI available at www.enli.dk/en

There is no obligation to report slides drawn up by a third party unless the company has been influential in preparing them.

In connection with developing the company's own event, the following questions can be useful to assess during the planning:

- Is the programme professional?
- Does the programme contain patient cases? If so: who has selected the patient cases?
- Does the invitation contain all relevant information?
- Is the event held abroad? If yes, why?
- Is the venue suitable and what is the general reputation of the venue?
- Is the venue an attraction in itself?
- Are thresholds for meals complied with – in Denmark/abroad?
- Is gourmet catering offered?
- How does the restaurant appear in general reputation?
- If relevant, is air travel (flight class) in accordance with the rules?
- Does the length of the event require catering to be offered?
- Is accommodation necessary and what is the general reputation of the hotel?
- Is there any entertainment during the event?

Appendix A – Considerations regarding a company event

2. PROGRAMME

It must be ensured that:

- The programme is professionally relevant, i.e., must have a specific professional healthcare content and be intended as continuity training for healthcare professionals (e.g., medical presentations on disease, areas of disease, products, and methods of treatment)
- No support is provided for non-healthcare related events/presentations which are also offered to other professional groups – e.g., financial control, organisational development, leadership, computer and collaboration courses, planning meetings, coaching, practice management (e.g., accountancy assistance), comedy/entertainment, political presentations, communication, teacher training, etc.
- The entire programme must be purely professional (unlike sponsorships where the programme simply must be predominantly professional)
- Speakers who are not healthcare professionals have the necessary professional knowledge to teach the target audience (e.g., doctors or nurses)
- Use of patient cases meets the requirements, i.e.:
 - The pharmaceutical company may not have any influence on selection or preparation of patient cases
 - Patient cases, selected by a speaker, must be closely linked to the other professional presentations in the programme, for example to illustrate professional knowledge already reviewed at the event
- Practical meeting equipment (paper, writing tools, key chains etc.) can be distributed at professional events
 - Branding in connection with practical meeting equipment
 - Own event: branding with company name and logo and disease area is allowed
 - Sponsored events: branding with hotel and congress name is allowed
 - Invented and generic names are never allowed

For further information, please refer to Sec. 13.01 in the Guidance to the Promotion Code.

3. INVITATION

It must be ensured, that the invitation states:

- The name of the organiser and the purpose of the event
- The text from Sec.21.08 of the Promotion Code

For further information, please refer to Sec. 13.02 of the Promotion Code.

If you wish to invite hospital-employed healthcare professionals, the invitation must first be sent to the hospital management for approval:

- They choose how many are allowed to participate in the event
- They choose which healthcare professionals are allowed to participate in the event

For further information, please refer to the collaboration agreements between Lif and the five regions, which can be found on ENLI's website.

If invented and generic names appear in the invitation, the compulsory text (the information in Sec. 5.01 in the Promotion Code) must be an integrated part of the invitation.

For further information, please refer to Sec. 3.01 of the Promotion Code.

4. VENUE

It must be ensured that the venue:

- Is appropriate i.e., the venue has facilities suitable for a professional event
- Is not generally known for its entertainment facilities.
 - The venue is not an attraction in itself
 - The venue must not be a draw
 - Three exceptions where a venue is accepted even if it is known for entertainment:
 - The venue is not an attraction in itself
 - It is obvious that the event is taking place when there is no general access to entertainment, or that no kind of entertainment is taking place – e.g., at Parken Stadium at a time when there is no sport or concerts
 - The venue is similarly known for its meeting facilities, which in general are considered separate from entertainment facilities – e.g., DGI Byen Conference
- Is not generally regarded as luxurious/extravagant, i.e., the following may not be used:
 - 5-star hotels, Michelin restaurants, castles, mansions, estates, golf hotels, ski, and beach hotels (in season), boat trips etc.

To determine whether a venue appears luxurious/extravagant, it is useful to:

- Do a search on bookingsites such as Trivago.com, Booking.com, Hotels.com,
- Do a regular google search, and look at unbiased quality ratings and other similar publicly, available information, such as reviews in various newspapers, magazines,
- Search the ENLI website under published cases,
- Contact ENLI for guidance.

For further information, please refer to Sec. 13.03 and Sec. 13.10 in the Guidance to the Promotion Code.

5. EVENTS ABROAD

Pharmaceutical companies are not allowed to host events abroad, unless:

- Most of the invitees comes from abroad, and the location of most of the invitees' countries of origin makes it significantly more advantageous to host the event in another country, by logistical reasons or
- Due to the location of the relevant resource or expertise subject or theme of the activity, makes it significantly more advantageous to host the event in another country for logistical reasons.

Remember:

- Include a justification that the venue is located abroad, when the event is reported to ENLI,
- Pharmaceutical companies have an obligation to notify the healthcare professional on affiliation reporting to the Danish Medicines Agency in connection with participation in professional events abroad supported by the company, cf. Sec. 13.13 of the Promotion Code.

For further information regarding events abroad, please refer to Sec. 13.03 in the Guidance to the Promotion Code.

6. HOSPITALITY

Hospitality may be given only to the extent necessary for the professional event:

- Only hospitality at a reasonable level and strictly limited to the main purpose of the meeting.
- Only possible to meet actual costs for travel, meals, accommodation, registration fees, etc.
- It is not allowed to give hospitality to a companion of the participant – even if the participant/ accompanying person pays for own expenses related to the event (i.e., the company may not act as a "travel agent" for accompanying spouses/partners).

6.1 Accommodation:

- Accommodation may only be provided if it is necessary given the extend of the event
 - As a rule, accommodation can only be provided if the event has a duration of at least six hours, and
 - There are professional activities both the day before and the day after the overnight stay
- Pharmaceutical companies cannot provide support for an extended vacation-related stay for healthcare professionals in connection with the event,
 - If the healthcare professional wishes to change the departure and/or return journey due to another professional event, the company can only pay for transport if the other event is sufficiently professional so that the pharmaceutical company would also be able to support this event.
- Accommodation may not be offered to the companion of a participant - even if the participant/accompanying person pays his/her own expenses related to the event.
- Accommodation must comply with the same requirements as venues, i.e., no accommodation in places that appear luxurious, cf. Sec. 13.10 in the Promotion Code.

6.2 Transport:

Pharmaceutical companies can offer the following transport:

- Rail travel – regardless of the choice of class (e.g., 1st and 2nd class),
- Air travel to professional events (to which the healthcare professional has been invited) in
 - Europe: Economy class may be offered.
 - Outside of Europe: Economy class or “extended” economy class can be offered.
- Air travel to consultants who offer professional services (speaker):
 - Europe: Economy class may be offered.
 - Outside of Europe: Economy class or “extended” economy class can be offered.
- “Business Class” is acceptable at all levels if the traveler is in a wheelchair etc.
- If justified by special logistical issues, ENLI may derogate from the above based on a specific assessment of logistics, price, class, and any alternative solutions and accept flights in a higher class than stated above.
- Air travel in “First Class” is never permitted.

ENLI recommends that companies contact ENLI for guidance before deviating from the above and accepting higher class flights than indicated above.

It is not allowed to offer representation to a companion of a participant - even if the participant/companion pays his/her own expenses related to the event. Thus, the company may not act as a "travel agent" for accompanying spouses/partners.

Please indicate in the report to ENLI, which class is offered if air travel is covered (ex. economy class).

If transport is not booked at the time of reporting to ENLI, please state in "Other comments" type of transport (ex. flight, train), if applicable flight class and arrival and departure time.

- If relevant, the following information can be provided: "Flight have not yet been booked, but participants fly at economy class and travels in connection to the opening and closing time of the event".

For further information, please refer to Sec. 13.05 and 13.07 in the Guidance to the Promotion Code.

7. THRESHOLDS

It must be ensured, that the offered catering does not exceed the maximum price for meals for healthcare professionals:

- Meals in Denmark:
 - For professional meetings up to 2 hours: 100 kr.
 - For other meeting activities: lunch: 450 kr., dinner: 850 kr., all-day meeting: 1.400 kr.
- Meals outside of Denmark:
 - EFPIA-countries – these countries' national limits can be found in ENLI's EFPIA map at www.enli.dk
 - For other countries outside Europe - these countries' meal caps may be used if they otherwise meet the requirements set out in Article 13(7)
- All the amounts are including beverages, VAT and gratuity.
- Meeting packages must be specified so the cost of breakfast, lunch, and dinner, as well as ongoing catering during the day, is clearly shown.
- When the event is reported to ENLI the specified amount must always be disclosed, even if the catering has not yet been ordered.

For further information, please refer to Sec. 13.08 in the Guidance to the Promotion Code.

8. ENTERTAINMENT

It must be ensured that the event does not include entertainment, such as:

- Music or other performance
 - A magician, a band, concerts, opera, theatre, sporting events or entertainment, stand-up comedy, sightseeing, wine tasting etc.
- Acts involving people who are generally considered to be “celebrities”.
 - Artists, bands, actors, athletes etc.

It is irrelevant whether healthcare professionals themselves bear the cost of the entertainment, as there is a total ban on organising entertainment.

For further information, please refer to Sec. 13.09 in the Guidance to the Promotion Code.

Appendix B – Deadline for reporting to ENLI

Own events must be reported to ENLI no later than 10 working days before the opening of an event.

This means that if the company's event takes place from Monday the 17th of April to Wednesday the 19th of April, the event must be reported to ENLI on www.enli.dk no later than the 29th of March.

The following calculation has been made to calculate the report deadline in relation to the above example:

Wednesday the 29 th of March	Last day possible of reporting to ENLI 1
Tuesday the 30 th of March	2
Friday the 31 st of March	3
Saturday the 1 st of April	Weekend
Sunday the 2 nd of April	Weekend
Monday the 3 rd of April	4
Tuesday the 4 th of April	5
Wednesday the 5 th of April	6
Thursday the 6 th of April	Maundy Thursday
Friday the 7 th of April	Good Friday
Saturday the 8 th of April	Weekend
Sunday the 9 th of April	Easter
Monday the 10 th of April	Easter Monday
Tuesday the 11 th of April	7
Wednesday the 12 th of April	8
Thursday the 13 th of April	9
Friday the 14 th of April	10
Saturday the 15 th of April	Weekend
Sunday the 16 th of April	Weekend
Monday the 17 th of April	Event – day one
Tuesday the 18 th of April	Event – day two
Wednesday the 19 th of April	Event – day three

For further information regarding the deadline of reporting, please refer to Sec. 21.05 in the Guidance to the Promotion Code.

Appendix C - Definitions

DEFINITIONS

Organiser/co-organiser

As a pharmaceutical company you are considered an organiser of an event, if you

- Choose who to invite as participants
- Prepare the programme and choose the speakers
- Choose the venue
- Choose the catering at the event
- Send out the invitation to the event and/or appear as the sender

If the pharmaceutical company helps to determine just one of the above, the company will be considered a co-organizer. The same rules apply, whether you are an organiser or a co-organiser.

Healthcare professional: Doctors, dentists, pharmacists, nurses, pharmaeconomists, midwives, bioanalysts, clinical dietitians, radiographers, social and health assistants, and students in these disciplines.

The general public: Anyone who is not covered by the definition of a healthcare professional.