

Checklist

for reporting a sponsorship to participation

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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 E).

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 UPLODADED TO ENLI

- The programme of the event
- A contract, agreement or similar document describing the sponsorship (what expenses are covered by the sponsorship) and the amount of the sponsorship
- A budget
 - o specification of the amount for meals (lunch, dinner, and ongoing catering)
 - o air transport which flight class, expected arrival and departure
- If special considerations have been made in connection to programme, venue, transport, catering, accommodation etc., it is recommended to disclose the considerations in the report to ENLI
 - o In an attached word document, if necessary

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

In connection with sponsorships, the following should be considered:

- Is the programme predominantly professional?
- Is the venue suitable and what is the general reputation of the venue?
- If relevant, is air travel (flight class) compliant with the rules?
- Date of departure and return
- If relevant, is accommodation necessary and what is the general reputation of the hotel?
- Is there payment for other persons than the healthcare professional? (companion, spouse)
- Are thresholds for meals compliant with the rules in Denmark /abroad?
- Is gourmet catering offered?
- If relevant, meeting package must be specified?
- What is included in the registrations fee? (social events, subscriptions to journals)
- Is there primary/secondary entertainment? How is entertainment funded?

Appendix A – Considerations regarding sponsorship to participation

2. PROGRAMME

It must be ensured that:

- The programme is predominantly professional.
 - Meaning more than half of the programme meets the criteria on professionalism, cf. Sec. 13.01 in the Promotion Code.
 - For breaks with access to the exhibition area, half of the break is considered professional (if one hour is allocated for a (coffee) break with access to the exhibition area, 30 minutes are counted as professional).

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

Examples of assessment of the criteria on professionalism are given in appendix B below.

3. INVITATION

If the company wishes to invite healthcare professionals employed at a hospital, the invitation must be sent to the hospital management:

- Who selects <u>how many</u> participants who may attend the event.
- Who selects which healthcare professionals may attend in the event.

For further information, please refer to the collaboration's agreement between Lif and the five regions I Denmark on ENLI's website.

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.
 - o The venue is not an attraction in itself
 - The venue must not be a draw.
 - o 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:
 - o 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. 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 the participant's a companion even if the participant/ accompanying person pays his/her own expenses related to the event (i.e., the company may not act as a "travel agent" for accompanying spouses/partners).

For examples on budgets, please refer to appendix C below.

5.1 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,
 - o 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 participant's companion 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.

5.2 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
 - o Europe: Economy class may be offered.
 - o Outside of Europe: Economy class or "extended" economy class can be offered.
- Air travel to consultants who offer professional services (speaker):
 - o Europe: Economy class may be offered
 - o Outside of Europe: Economy class or "extended" economy class can be offered
- "Business Class" is acceptable at all levels if the traveller 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 <u>never</u> 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 participant's companion - 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.

In cases where the budget does not specify the flight class offered to participants/speakers, we recommend the company to contact the organiser for this information so that the company can ensure that ENLI's rules for transport is met.

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

6. THRESHOLDS

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

- Meals in Denmark:
 - o For professional meetings up to 2 hours: 100 kr.
 - o 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 sponsorship 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.

7. ENTERTAINMENT

If the event includes entertainment, it must be examined whether it is "primary" entertainment or "secondary" entertainment:

- "Primary" entertainment is NOT allowed (unless paid for by participants)
 - Stand alone performance.
 - Music or other acts forming part of a stand-alone performance during a dinner or the like.
 - o Performances that are damaging to the industry's credibility and image
 - Concerts, opera, theater, sporting events or entertainment activities, stand-up, magician, sightseeing, lectures, wine tasting etc.

• Performances involving people generally regarded as "known". It is not required that it is a separate activity.

- Artists, bands, actors, athletes etc.
- o Primary entertainment is only allowed if the entertainment is paid for by:
 - The participants themselves or
 - A non-pharmaceutical company

If there is primary entertainment, the company cannot condition the sponsorship on simply going to other permitted professional activity or permitted representation (unless it is clear, that the entertainment is paid for by the participant or funded by a non-pharmaceutical company).

• "Secondary" entertainment - IS allowed

• Activities which participants would not be expected to pay for themselves, and which are not damaging to the industry's credibility and image.

If the event includes an opening- and/or closing ceremony, gala event etc. ENLI recommends that the company contact the organiser to ensure that the activities does not contain elements of entertainment, free bar etc.

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

Appendix B - Programme

Two different programmes are shown below, one of which is not predominantly professional (example 1), while the other is predominantly professional (example 2). The examples show how to assess whether a programme is predominantly professional.

Event: Annual meeting for a medical society

Date of event: The 17th of April to the 19th of April

Number of participants: 120 doctors

Location: Bella Center

Example 1

Programme

08.00 - 09.00 Arrival, registration, and breakfast (non-professional, 60 min.) 09.00 - 10.00 Presentation on disease by a health professional (professional, 60 min.) 10.00 - 11.00 Presentation on disease by a health professional (professional, 60 min.) 11.00 - 11.30 Break / exhibition (professional, 15 min. and non-professional, 15. min.) 11.30 - 12.30 Presentation on disease by a health professional (professional, 60 min.) 12.30 - 13.30 Lunch (non-professional, 60 min.) 13.30 - 14.00 Break / exhibition (professional, 15. min. and non-professional, 15. min.) 14.00 - 15.00 Planning of annual meeting 2021 v/chairman) (non-professional, 60 min.) 15.00 - 16.00 Coffee break / exhibition (professional, 30 min. and non-professional, 30. min.) 16.00 - 17.45 General assembly of the medical society (non-professional, 105 min.) 17.45 - 18.00 Completion by a healthcare professional (professional, 15 min.)

Total duration of the event = 10 hours:

Professional activity = 4 hours and 15 minutes

Non-professional activity = 5 hours and 45 minutes

The programme does <u>not</u> meet the criteria on professionalism, as the programme is not predominantly professional, as non-professional activities (5 hours and 45 minutes) exceed the professional activities in time (4 hours and 15 minutes). Therefore, the company cannot give a sponsorship, as the programme does not comply with Sec. 13.01 in the Promotion Code.

Example 2

Programme

08.00 - 09.00 Arrival, registration, and breakfast		(non-professional, 60 min.)
09.00 - 10.00 Presentation on disease by a health professional		(professional, 60 min.)
10.00 - 11.00 Presentation on disease by a health professional		(professional, 60 min.)
11.00 - 11.30 Break / exhibition	(professional, 15 min. ar	nd non-professional, 15. min.)
11.30 - 12.30 Presentation on disease by a health professional		(professional, 60 min.)
12.30 - 13.30 Lunch		(non-professional, 60 min.)
13.30 - 14.00 Break / exhibition	(professional, 15. min. ar	nd non-professional, 15. min.)
14.00 - 15.00 Presentation on disease by a health professional		(professional, 60 min.)
15.00 - 16.00 Coffee break / exhibition	(professional, 30 min. a	nd non-professional 30. min.)
16.00 - 17.45 General assembly of the medical so	ociety	(non-professional, 105 min.)
17.45 - 18.00 Completion by a healthcare professional (professional, 15		(professional, 15 min.)

Total duration of event = 10 timer:

Professional activity = 5 hours and 15 minutes

Non-Professional activity = 4 hours and 45 minutes

The programme does meet the criteria on professionalism, as the programme <u>is</u> predominantly professional, as professional activities (5 hours and 15 minutes) exceed the non-professional activities in time (4 hours and 45 minutes).

Appendix C - Example of a budget

Arrangement: International congress

Date of event: The 17th of April at 10 a.m. to the 19th of April at 3 p.m.

Participant: 1 doctor

Venue: Bella Center Copenhagen

Programme: Predominantly professional and no entertainment

Expenses	Number	of	Amount
Registration fee	1	5.000	5.000
Lunch	3	350	1.050
Dinner	2	600	1.200
Flight –Sønderborg – CPH/return*	2	2.500	5.000
Accommodation – AC Hotel Bella Sky	2	700	1.400
Copenhagen – 4 stars **			
In total			13.650

^{*} 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

^{**} Breakfast is included in the price for accommodation

Appendix D - Deadline for reporting to ENLI

A sponsorship for participation 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 17^{th} of April to Wednesday the 19^{th} of April, the event must be reported to ENLI on www.enli.dk no later than the 29^{th} of March.

Calculation of the deadline for reporting the sponsorship to ENLI based on the example above:

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

DEFINITIONS:

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.

Sponsorship: There are two types of sponsorship:

o Sponsorship to an external organiser

The company provides financial support to an external party – e.g., a medical society or a congress organiser.

The company has <u>no</u> influence on:

- o Programme, speaker, venue, meals etc. and
- o The company neither sends the invitation nor acts as the sender of the invitation.

Example: the company provides a sponsorship of 50.000 kr. to a medical society to conduct their annual meeting (sponsorship only for the professional part of the meeting).

o Sponsorship to participation

- A healthcare professional requests financial support from a company to pay expenses related to a professional activity or
- The company contacts a healthcare professional to invite him or her to an external professional event e.g., to a congress

The company has <u>no</u> influence on:

o Programme, speaker, venue etc. and

Example, if the company pays for a healthcare professional's expenses for registration fees, flights, accommodation, and meals in connection with a congress or similar.

If the company has influence on just one of the above – e.g., programme - (regardless of which of the two types of sponsorship) the company will be considered as co-organiser of the event.

For further information, please refer to the checklist for reporting a company event.