

### **Guidance on reporting a case to ENLI**



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The purpose of this guide is to help new users through ENLI's reporting procedure. The next three pages (pp. 4 - 6) show how to access the reporting system. This procedure must be followed regardless of the type of case you are reporting. After page 6 you can use the guide to find the specific information for the type of report you are about to start.

You can report the following type of cases:

\*Report

- Professional events

- \* Company event
- \* Sponsorship to third parties
- \* Exhibition stand
- \* Sponsorship to participation
- Promotional material

\*Pre-approval

\*Complaint

\*Appeal

The information in this guide cannot stand alone. To gain full knowledge of the rules, please refer to ENLI's guidance to the Promotion Code.

#### www.enli.dk





### Report at ENLI's webside



Click on the red icon on the left of the page to report an event or promotional material





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Log in





#### www.enli.dk Login Front page FAQ Use this box if you previously Log in Email: have entered your email address Danish reporting site Password ...... and received a password. Remember me on this computer Login ENLI's privacy policy Forgotten password Enter your email address and we will send a password to your Enter your email: Send password email address. Create a new user Ethical Committee for the If you are a new user, press "New Pharmaceutical Industry New user Lersø ParkAlle 101 user" to proceed. 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

# Select the type of case you want to report



for lægemiddelindustrien

#### Reporting a company event





#### www.enli.dk CaseType Did you choose the right type of case? 🕕 V Front page Report FAQ ReportType Did you choose the right type of report? 🕕 Professional events $\mathbf{v}$ Change password Log out EventType Company event V Create case Danish reporting site

ENLI's privacy policy

# Reporting a company event page 1





www.enli.dk		Company event Page 1 - Reporter
	My company is affiliated with ENLI	
Front page FAQ	I represent the following affiliated company:	
Change password Log out	Reporter´s email :	F
Danish reporting site	Reporter´s name :	*
	Reporter 's title :	
ENLI's privacy policy	Reporter 's direct telephone number:	*
	Reporter´s mobile number :	
	The reference person of the case :	0
	The relevant email :	0
Ethical Committee for the	Fields with * r	must be filled in.

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø

Page 1 of 4 Next >>

### Reporting a company event page 2





www.enli.dk		Company event Page 2 - Details
Front page FAQ Change password	It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.	
Log out	Title :	0.
Danish reporting site	Venue :	0.
ENLI's privacy policy	City :	0 *
	COUNTRY :	0*
	Opening of the event :	Time: 0 *
	Closing of the event :	Time: 0 *

The venue must not be known for its entertainment facilities or appear extravagant or luxurious - which means no use of 5-star hotels, castles, manor houses, mansions, estates and beach hotels, etc.

For further information, please refer to Article 13 (10) of the Guidance to the Promotion Code.



### Reporting a company event page 2 (hospital-employed HCP)



# Reporting a company event page 2 (catering)





Remember to specify the costs (especially for meeting packages) for breakfast, lunch, dinner and catering during the day.

If breakfast is included in hotel accommodation, please state this in the field: "Other comments".

Keep in mind that the price-cap is not the same in all EFPIA countries, why it is important to examine if all limits are met.

Please refer to EFPIA meal-cap chart: <u>http://www.enli.dk/en/thresholds-for-meals-</u><u>drinks/</u>

For meals in countries outside EFPIA countries, price levels are based on the Danish price-cap.

For further information, please refer to Article 13 (7) and (8) of the Guidance to the Promotion Code.

### Reporting a company event page 2 (transport)

		_	
Is your company paying for transport?			
Total transport costs per person in DKK incl. VAT			0
Departure time :		Time:	0
Arrival time :		Time:	0
Departure time of return :		Time:	0
Arrival (return) :		Time:	0
Is your company paying for accommodation?			
Total cost of accommodation per person in DKK incl. VAT :			0
Hotel name :			0
Hotel adress :			
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review,			Ð
please enter the information here or attach it on the next page			
Your company's PO-number:			
Your company's reference			
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	*		
Fields with <b>*</b> must be filled	in.		
	<< B	ack Page 2 d	of 4 Ne



If flight expenses are covered, please state flight class (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 any \*flight class

\*arrival and departure time or:

Eg:"Flight have not yet been booked, but participants fly at economy class and travel in connection to the opening and closing time of the event".

For further information, please refer to Article 13 (5-7) of the Guidance to the Promotion Code.

Accommodation must comply with the same requirements as venues, ie. no accommodation that appear luxurious, cf. Article 13 (10) of the Promotion Code.

### Reporting a company event page 3 (attach documents)





If you have special considerations in connection with the choice of venue, accommodatransport, program, catering etc., please attach (e.g. in a word document) your considerations.

Remember that the compulsory information (the information in Article 5 (1) of the Promotion Code) must be an integrated part of the invitation, if trade names or generic names are stated in the invitation. For further information, please refer to ENLI's guidance to the Promotion Code, Re Article 3 (1).

## Reporting a company event page 4 (approve the report)

Please approve the reported inform	C	ompany event Page 4 - Accept
My company is affiliated with ENLI		
I represent the following affiliated company:		
Is your company paying for accommodation?		
Total cost of accommodation per person in DKK incl. VAT :		0
Hotel name :		0
Hotel adress :		
		6
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
Your company 's PO-number:		
Your company 's reference		
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).		
Attach program: anmeldelse til ENLI .docx Attach your company's invitation to the participants:		
invitation.docx Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach.		
Please note that the size of the attached files must not exceed 50 Mb per file		
	Approve	
		<< Back Page 4 of 4



Before you select "Approve", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control.

This means that if your case is selected in a random control, you cannot subsequently change the reported material and thereby bring the report in accordance with the rules in order to avoid penalty, cf. The Promotion Code, Article 21(4).

Remember, only press "Approve" once (you send a report for each time you press "Approve").

Once you have selected "Approve", you will within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Report a sponsorship to third parties





www.enli.dk		
Front page	CaseType	Report 🗸 Did you choose the right type of case? 🕕
FAQ Change password	ReportType	Professional events $\checkmark$ Did you choose the right type of report? $($
Log out	EventType	Sponsorship to third parties 💙
Danish reporting site		Create case

ENLI's privacy policy

### Report a sponsorship to third parties page 1

	Sponsorship to third parties	Page 1 - Repor
My company is affiliated with ENLI		
I represent the following affiliated company:		
Reporter´s email :		
Reporter's name :		*
Reporter's title :		
Reporter's direct telephone number:		*
Reporter's mobile number :		
The reference person of the case :		0
The relevant email :		0

Fields with \* must be filled in.

rter

Page 1 of 4 Next >>

etisk nævn

### Report a sponsorship to third parties page 2

Sponsorship to third parties Page 2 - Details It is the reporters/person requesting the preapproval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information. Title : A Venue : 6 ' City : 6 \* COUNTRY : Opening of the event : 6 \* Time: Closing of the event : 6 \* Time: The organizer's name : 6\* Organizer's CVR-number. Total amount given in sponsorship, incl. VAT : 6 \*

The venue must not be known for its entertainment facilities or appear extravagant or luxurious - which means no use of 5-star hotels, manor houses, mansions, castles. estates and beach hotels, etc.

For further information, please refer to Article 13 (10) of the Guidance to the Promotion Code.

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### Reporting a sponsorship to third parties etisk nævn page 2 (hospital-employed HCP)



### Reporting a sponsorship to third parties etisk nævn page 2 (catering)

Is your company paying for any meals/refreshments?	<b>⊘</b> 0	a b
Number of days	1 × *	If
Meals/refreshments per person in DKK incl. VAT per day 1:		р
Breakfast:		К
Lunch:		li e
Dinner:		П
refreshments during the day:		h h
Total amount per day:	*	<u>d</u>
Other comments:		F
		р
		F
Total meals/refreshments paid per person	*	1

Remember to specify the costs (especially for meeting packages) for breakfast, lunch, dinner and catering during the day. Please attach a budget.

f breakfast is included in hotel accommodation, please state this in the field: "Other comments".

Keep in mind that the price-cap is not the same in all EFPIA countries, why it is important to examine if all limits are met.

Please refer to EFPIA meals list: http://www.enli.dk/en/thresholds-for-mealsdrinks/

For meals in countries outside EFPIA countries, price levels are based on the Danish price-cap.

For further information, please refer to Article 13 (7) and (8) of the Guidance to the Promotion Code.

# Reporting a sponsorship to third parties etisk nævn page 2 (transport)

Is your company paying for transport?		If the sponsorship covers air transport, please
Total transport costs per person in DKK incl. VAT	0	state the flight class (e.g. Economy class).
Departure time :	Time: 1	
Arrival time :	Time: 1	Note that different rules apply depending on
Departure time of return :	Time: 🕕 🌖	whether the narticinants/sneakers fly inside or
Arrival (return) :	Time:	outside Europe
Is your company paying for accommodation?		outside Lutope.
Total cost of accommodation per person in DKK incl. VAT :	6	
Hotel name :	0	For further information please refer to Article
Hotel adress :		13 (5-7) of the Guidance to the Promotion Code.
	•	
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
Your company's PO-number		
Tour company site number.		Assessment adation must comply with the comp
Your company's reference		Accommodation must comply with the same
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	*	requirements as venues, i.e. no accommodation that appear luxurious, cf. Article 13 (10) of the
Fields with * must be filled	1 in.	Promotion Code.

<< Back Page 2 of 4 Ne:

### Reporting a sponsorship to third parties etisk nævn page 3 (attach documents)



		Sponsorship to third parties Page 3 - Attack
	Attach program: *	Gennemse Attach
AQ	Attach a sponsorship agreement: *	Gennemse Attach
hange password og out	Attach your company's invitation to the participants:	Gennemse Attach
anish reporting site	Attach appendix :	Gennemse Attach appendix
NLI's privacy policy	Multiple attachments can be uploaded. Simply repeat the proced "browse - add attachment" for each desired appendix that you w attach.	ure ish to
	Please note that the size of the attached files must not exceed 50	0 Mb per
		<< Back Page 3 of 4 Next >>
thical Committee for the 'harmaceutical Industry ersø ParkAlle 101 '100 København Ø		<< Back Page 3 of 4 Next >>
thical Committee for the harmaceutical Industry ersø ParkAlle 101 100 København Ø hone: 3920 2575 ekretariat@enli.dk	Attach the organizer's budget for the	<< Back Page 3 of 4 Next >> e event.

# Reporting a sponsorship to third parties etisk nævn page 4 (approve the report)

	-	Page 4 - Acce
Please approve the reported infor	mation	
company is affiliated with ENLI		
epresent the following affiliated company:		
Is your company paying for accommodation?		
Total cost of accommodation per person in DKK incl. VAT :		0
Hotel name :		6
		•
Hotel adress :		
		0
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review,		
please enter the information here or attach it on the next page		
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please enter the information here or attach it on the next page		
please enter the information here or attach it on the next page		
please enter the information here or attach it on the next page Your company's PO-number: Your company's reference		
please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI		
Please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules. including The General Data Protection Resultation (GDPR).		
Please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anneldelse til ENLI .docx	⊻	
Please enter the information here or attach it on the next page Your company's PO-number: Your company's PO-number: I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anneldelse til ENLI .docx Attach your company's invitation to the participants: invitation.docx	V	
Please enter the information here or attach it on the next page Your company's PO-number: Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anmeldelse til ENLI .docx Attach your company's invitation to the participants: invitation.docx Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach.		
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Please enter the information here or attach it on the next page Your company's PO-number: Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anmeldelse til ENLI .docx Attach your company's invitation to the participants: invitation.docx Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach. Please note that the size of the attached files must not exceed 50 Mb per file	Approve	

Before you select "Approve", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control. This means that if your case is selected for inspection, you cannot subsequently change the reported material and thereby bring the report in accordance with the rules in order to avoid sanction, cf. The Promotion Code, Article 21(4).

Please ensure that the following information is provided:

- \* Date of when sponsorship commitments are given
- \* Correct amount for catering (if catering is covered)
- \* Flight class (if sponsorship covers air transport)

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Reporting an exhibition stand





www.enli.dk		
Front page	CaseType	Report V Did you choose the right type of case? 1
FAQ	ReportType	Professional events
Log out	EventType	Exhibition stand
Danish reporting site		Create case
ENLI's privacy policy		

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

Reporting an	exhibition stand
page 1	



<b>S</b> etisk	nævn
for lægemie	ddelindustrien

www.enli.dk			Page 1 - Reporter
	My company is affiliated with ENLI		
Front page FAQ	I represent the following affiliated company:		
Change password Log out	Reporter´s email :	K	
Danish reporting site	Reporter's name :		*
	Reporter's title :		
ENLI's privacy policy	Reporter's direct telephone number:		*
	Reporter 's mobile number :		
	The reference person of the case :		0
	The relevant email :		0
Ethical Committee for the	Fields with *	must be filled in.	

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Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø

# Reporting an exhibition stand page 2

www.enli.dk		Exhibition s	tand Page 2 - Deta
Front page FAQ Change password Log out	It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information. Title :		0.
Danish reporting site	Venue :	¥	0
ENLI's privacy policy	City :		0*
	COUNTRY :		0.
	Opening of the event :	Time:	0 *
	Closing of the event :	Time:	0 *
	The organizer's name :		0 •
Ethical Committee for the Pharmaceutical Industry	Organizer´s CVR-number.		0
2100 København Ø Phone: 3920 2575	Square meter prize in DKK for exhibition stand, incl. VAT :		0.
sekretariat@enli.dk	If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
	Your company 's PO-number:		
	Your company 's reference		
	I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	.*	
	Fields with * must be filled	in.	



Section 13 (10) regarding venues does not apply the purchase of exhibition stands.

However, it must be determined whether it is a purchase of an exhibition stand or actually a sponsorship. It is the price per square meter that is decisive.

When buying an exhibition stand, it can be reckoned that a square meter price of DKK 2,000 including VAT for a wholeday event in a rented, external location with about 50-80 delegates is acceptable. A higher square meter price would only be acceptable if so indicated by the market price due to the possibility of exposure or the like.

For further information, please refer to Article 18 (3) of the Guidance to the Promotion Code

# Reporting an exhibition stand page 3 (attach documents)



www.enli.dk	Attach program: *	Gennemse	Exhibition stand Page 3 - Attach
Front page	Attach contract: *	Gennemse	Attach 🕕
FAQ Change password	Attach appendix :	Gennemse	Attach appendix
Log out	Multiple attachments can be uploaded. Simply repeat "browse - add attachment" for each desired appendix	the procedure that you wish to	
Danish reporting site	attach.	,	
ENLI's privacy policy	Please note that the size of the attached files must no file	t exceed 50 Mb per	

Fields with \* must be filled in.

<< Back Page 3 of 4 Next >>

Ethical Committee for the
Pharmaceutical Industry
Lersø ParkAlle 101
2100 København Ø
Phone: 3920 2575
sekretariat@enli.dk



# Reporting an exhibition stand page 4 (approve the report)

Please approve the reported info	rmation	. , Page 4 - Au
ompany is affiliated with ENLI		
present the following affiliated company:		
Is your company paying for accommodation?		
Total cost of accommodation per person in DKK incl. VAT :		0
Hotel name :		6
Hotel adress ·		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number:		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number:		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). ttach program: anmeldelse til ENLI .docx		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). ttach program: anmeldelse til ENLI .docx ttach your company's invitation to the participants: ivitation.docx		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). tttach program: anmeldelse til ENLI .docx tttach your company's invitation to the participants: vitation.docx		
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sonctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). ttach program: anmeldese til ENLI .docx ttach your company's invitation to the participants: witation.docx hultiple attachments can be uploaded. Simply repeat the procedure browse - add attachment" for each desired appendix that you wish to ttach.		
If your company has paid for additional expenses than these reported above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLE's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). ttach program: anneldelse til ENLI .docx ttach poor company's invitation to the participants: nvitation.docx tuitiple attachments can be uploaded. Simply repeat the procedure browse - add attachment" for each desired appendix that you wish to ttach.	Approve	

for lægemiddelindustrien

Before you select "Approve", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control. This means that if your case is selected for inspection, you cannot subsequently change the reported material and thereby bring the report in accordance with the rules in order to avoid sanction, cf. The Promotion Code, Article 21(4).

Please ensure that the following information is provided:

\* The size of the exhibition stand (number of sqm2)

\* Number of expected participants

\* The exhibition stand is separate from the professional content of the event

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Report a sponsorship to participation





#### www.enli.dk

Front page	CaseType	Report	$\checkmark$	Did you choose the right type of case? ۯ
FAQ Change password	ReportType	Professional events	$\checkmark$	
Log out	EventType	Sponsorship to particip	oation V	
Danish reporting site		Create case		
ENLI's privacy policy				$\mathbf{N}$

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

### Report a sponsorship to participation page 1

		; Page 1 - Reporter
My company is affiliated with ENLI		
I represent the following affiliated company:		
Reporter's email :		
Reporter's name :		*
Reporter's title :		
Reporter's direct telephone number:		*
Reporter's mobile number :		
The reference person of the case :		0
The relevant email :		0
Fields with * must be filled	in.	

Page 1 of 4 Next >>

# Report a sponsorship to participation page 2

		Page 2 - Details
It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.		
Title :		0.
Venue :		0 *
City :	(	0 *
COUNTRY :		0 *
Opening of the event :	Time:	0 *
Closing of the event :	Time:	0 *
The organizer´s name :	(	0 *
Organizer´s CVR-number.	(	0
Total amount given in sponsorship, incl. VAT :		ð •

The venue must not be known for its entertainment facilities or appear extravagant or luxurious - which means no use of 5-star hotels, castles, manor houses, mansions, estates and beach hotels, etc.

for lægemiddelindustrien

For further information, please refer to Article 13 (10) of the Guidance to the Promotion Code.

# Reporting a sponsorship to participation for Lagemiddelindustrien page 2 (hospital-employed HCP)



Select the region(s) where the invitation is sent to.

# Reporting a sponsorship to participation for lægemiddelindustrien page 2 (catering)

is your company paying for any meals/refreshments?	V 🜖
Number of days	1 × *
Meals/refreshments per person in DKK incl. VAT per day 1:	
Breakfast:	
Lunch:	
Dinner:	
refreshments during the day:	
Total amount per day:	*
Other comments:	
	4
Total meals/refreshments paid per person	*

Remember to specify the costs (especially for meeting packages) for breakfast, lunch, dinner and catering during the day.

If breakfast is included in hotel accommodation, please state this in the field: "Other comments".

Keep in mind that the price-cap is not the same in all EFPIA countries, why it is important to examine if all limits are met.

Please refer to EFPIA meals list: http://www.enli.dk/en/thresholds-for-mealsdrinks/

For meals in countries outside EFPIA countries, price levels are based on the Danish price-cap.

For further information, please refer to Article 13 (7) and (8) of the Guidance to the Promotion Code.

# Reporting a sponsorship to participation for lægemiddelindustrien page 2 (transport)

Is your company paying for transport?			If the sponsorship covers air transport, please
Total transport costs per person in DKK incl. VAT		0	state the flight class (e.g. Economy class).
Departure time :	Time:	0	
Arrival time :	Time:	0	Note that different rules apply depending on
Departure time of return :	Time:	0	whether the participants/speakers fly inside or
Arrival (return) :	Time:	0	outside Europe.
Is your company paying for accommodation?			
Total cost of accommodation per person in DKK incl. VAT :		0	For further information please refer to Article
Hotel name :		0	13 (5-7) of the Guidance to the Promotion Code.
Hotel adress :		_	
If your company has paid for additional expenses than those reported above, or if you have any additional information relevant to the review, please enter the information here or attack it on the next page		0	
			Accommodation must comply with the same requirements as venues, i.e. no accommodation
Your company s PO-number:			that appear luxurious, cf. Article 13 (10) of the
Your company's reference			Promotion Code
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	e *		
Fields with * must be fille	d in.		
	<< Back Page 2	2 of 4 Ne:	

# Reporting a sponsorship to participation for lægemiddelindustrien page 3 (attach documents)



www.enli.dk	Attach program: *	Sponsorship to participation Page 3 - Attach Gennemse Attach	
Front page FAQ Change password	Attach your company's invitation to the healthcare professionals: * Attach appendix :	Gennemse Attach Gennemse Attach	You can optionally attach a
Log out Danish reporting site	Multiple attachments can be uploaded. Simply repeat the procedur "browse - add attachment" for each desired appendix that you wisl attach.	e h to	budget that shows which expenses the sponsorship
ENLI's privacy policy	Please note that the size of the attached files must not exceed 50 I file	Mb per	covers.
	Fields with must b	pe filled in. << Back Page 3 of 4 Next >>	

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

If you have any considerations in relation to the choice of venue, accommodation, transport, program, catering etc., please attach your considerations.

### Reporting a sponsorship to participation strike nævn page 4 (approve the report)

Please approve the reported infor	mation	Page 4 - Acce
company is affiliated with ENLI		
epresent the following affiliated company:		
Is your company paying for accommodation?		
Total cost of accommodation per person in DKK incl. VAT :		0
Hotel name :		6
		0
above, or if you have any additional information relevant to the review,		
above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page		
above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company's PO-number:		
above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company's PO-number: Your company's reference		
above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).		
above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company's PO-number: Your company's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anneldelse til ENLI .docx		
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above, or if you have any additional information relevant to the review, please enter the information here or attach it on the next page Your company 's PO-number: Your company 's reference I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR). Attach program: anmeldelse til ENLI .docx Attach program: anmeldelse til ENLI .docx Attach your company's invitation to the participants: invitation.docx Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach.		
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Before you select "Approve", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control. This means that if your case is selected in a random control, you cannot subsequently change the reported material and thereby bring the report in accordance with the rules in order to avoid sanction, cf. The Promotion Code, Article 21(4).

Please ensure that the following information is provided:

- \* Date of when sponsorship commitments are given
- \* Correct amount for catering (if catering is covered)
- \* Flight class (if sponsorship covers air transport)

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Reporting promotional material





#### www.enli.dk

Front page	CaseType	Report V	Did you choose the right type of case? ႐
FAQ	ReportType	Promotional material	
Change password			
Log out		Create case	
Danish reporting site			

ENLI's privacy policy

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

# Reporting promotional material page 1





www.enli.dk		Promotiona	al material Page 1 - Reporter
	My company is affiliated with ENLI		
Front page FAQ	I represent the following affiliated company:		
Change password Log out	Reporter´s email :		
Danish reporting site	Reporter´s name :		*
	Reporter's title :		
ENLI's privacy policy	Reporter's direct telephone number:		*
	Reporter's mobile number :		
	The reference person of the case :		0
	The relevant email :		0
Ethical Committee for the	Fields with <b>*</b>	must be filled in.	

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

Page 1 of 4 Next >>

# Reporting promotional material page 2



www.enli.dk		Promotional material Page	e 2 - Details
Front page FAQ Change password	It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.		
Log out	Choose type of advertising. If it does not appear on the list, please state ( this under "Other forms of advertising"	(Choose) * Andet/other	
Danish reporting site	Other types of advertising :	Annonce Brochure/detailer e-newsletter	
ENLI's privacy policy	Invented name and generic name (Sær- og/eller fællesnavn) in advertisement :	Hjemmeside Kartotekskort Lægebrev/newsletter	
	If you have any additional information relevant to the report, you can state the information here or attach it on the next page F F I	Markedsanalyse Postkort PPT-præsentation Reminder Roll-up Tablet præsentation	
Ethical Committee for the Pharmaceutical Industry	Your company's PO-number:		
Lersø ParkAlle 101 2100 København Ø	Your company's reference		
Phone: 3920 2575 sekretariat@enli.dk	I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	- *	
	Fields with <b>*</b> must be filled in.		

<< Back Page 2 of 4 Next >>

for lægemiddelindustrien

### **Reporting promotional material** page 3 (attach documents)



for lægemiddelindustrien				
www.enli.dk Front page	Attach advertising: *	Promotional material Page 3 - Atta Gennemse Attach	ach	
FAQ Change password Log out	Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish attach.	re sh to		Remember to attach summary
Danish reporting site	Please note that the size of the attached files must not exceed 50 f file	Mb per		and relevant references.
ENLI's privacy policy	Fields with * must b	be filled in.	· ·	
		<< Back Page 3 of 4 Next >	>>	

_<<	Back	Page	3 of	4	Next
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Ethical Committee for the
Pharmaceutical Industry
Lersø ParkAlle 101
2100 København Ø
Phone: 3920 2575
sekretariat@enli.dk

# Reporting promotional material page 4 (approve the report)

Please approve the reported inf	ormation	Promotional material Page 4 - Accep
My company is affiliated with ENLI		
I represent the following affiliated company:		
advertisement :		
If you have any additional information relevant to the report, you can state the information here or attach it on the next page		
, Your company 's PO-number:		
Your company's reference		
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	V	
ttach advertising: Liste over tilsluttede irksomheder 12-06-2019.pdf		
lultiple attachments can be uploaded. Simply repeat the procedure browse - add attachment" for each desired appendix that you wish to ttach.		/
lease note that the size of the attached files must not exceed 50 Mb per $\ensuremath{le}$		
A	pprove	F
		<< Back Page 4 of



Before you select "Approve", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control.

This means that if your case is selected for inspection, you cannot subsequently change the reported material and thereby bring the report in accordance with the rules in order to avoid sanction, cf. The Promotion Code, Article 21(4).

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Reporting a pre-approval





www.enli.dk		
Front page	CaseType	Pre-approval V Did you choose the right type of case? 1
FAQ Change password	Pre-approvalType	Ordinary pre-approval
Log out		Create case
Danish reporting site		
ENLI's privacy policy		

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

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# Reporting a pre-approval page 1





Phone: 3920 2575 sekretariat@enli.dk

www.enli.dk	0	rdinary pre-approval Page 1 - Reporter
	My company is affiliated with ENLI	
FAQ	I represent the following affiliated company:	
Change password Log out	Reporter's email :	:
Danish reporting site	Reporter's name :	*
	Reporter's title :	
ENLI's privacy policy	Reporter's direct telephone number:	*
	Reporter's mobile number :	
	The reference person of the case :	0
	The relevant email :	0
Ethical Committee for the	Fields with * must be filled in.	
Pharmaceutical Industry		Page 1 of 4 Next >>
Lersø ParkAlle 101		2
2100 København Ø		

# Reporting a pre-approval page 2



www.enli.dk		Ordinary pr	e-approval Page 2 - Details
Front page FAQ Change password	It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.		/
Log out	Yes, I would like to request for a pre-approval for a basic fee of 6000 DKK plus VAT plus a possible supplementary hourly rate of 2000 DKK plus VAT per commenced hour in excess of 2 hours. However, an	□ <b>()</b> *	
Sumon reporting site	additional hourly rate can only be invoiced by my acceptance.		/
ENLI's privacy policy	Your company's PO-number:		
	Your company's reference		
	The following activity is requested to be approved :		*
Ethical Committee for the	I hereby agree that all reported information may be registered by ENLI	*	
harmaceutical Industry			

Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk I hereby agree that all reported information may be registered by ENLI if or use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).

Fields with \* must be filled in.

<< Back Page 2 of 4 Next >>



Remember to specify what you want pre-approved.

If you want an event or a sponsorship pre-approved, please state if you want a pre-approval of: program, catering, transport, accommodation, venue, etc.

If you need guidance before reporting a pre-approval, please call us (+45 3920 2575).

# Reporting a pre-approval page 3 (attach documents)



etisk	nævn
for lægemic	delindustrien

www.enli.dk	Ordinary pre-approval Page 3 - Attach Attach appendix : Attach appendix	
Front page FAQ Change password Log out	Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach. Please note that the size of the attached files must not exceed 50 Mb per	Remember to include all relevant references regarding
Danish reporting site	file Fields with * must be filled in.	the promotional material.
ENELS privacy policy	<< Back Page 3 of 4 Next >>	

Ethical Committee for the		
Pharmaceutical Industry		
Lersø ParkAlle 101		
2100 København Ø		
Phone: 3920 2575		
sekretariat@enli.dk		

# Reporting a pre-approval page 4 (approval of report)

Ordinary pre-approval Page 4 - Accept

Please approve the reported information

My company is affiliated with ENLI

I represent the following affiliated company:

The following activity is requested to be approved :

I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).

Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach.

Please note that the size of the attached files must not exceed 50 Mb per file  $% \left( {{\rm{T}}_{\rm{T}}} \right)$ 



Approve

< Back Page 4 of 4



Before you select "Approve", please check if all relevant information and documents are attached.

The company is responsible for providing the necessary and accurate information on the activity in connection with the request, so that the Investigator Panel easily can decide on the pre-approval on an informed basis.

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

### Reporting a complaint



etisk nævn				
www.enli.dk				
Front page	CaseType	Complaint  V Did you choose the	right type of case? 🕦	
FAQ Change password Log out	ComplaintType	(Choose type of complaint) Ordinary complaint Urgent complaint		
Danish reporting site				
ENLI's privacy policy				
	ENLI calls for ( ENLI.	alogue between the companie	es involved before a complaint is reporte	ed to
	It is possible t	complain about ENLI affiliated	companies' breach of ENLI rules.	

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

It is free to complaint if the complaint is successful. The party who is not successful with a complaint will be charged a fee of 6,000 DKK plus VAT. If both parties are partially successful, the fee of 6,000 DKK + VAT is shared equally between the two parties.

For the rapid processing of complaints a fee of 25,000 DKK plus VAT is paid.

### Reporting a complaint – page 1



<b>S</b> etisk	nævn
for lægemi	ddelindustrien

www.enli.dk		Ordinary complaint Page 1 - Reporter
	My company is affiliated with ENLI	
Front page FAQ	I represent the following affiliated company:	
Change password Log out	Reporter's email :	
Danish reporting site	Reporter's name :	*
	Reporter's title :	
ENLI's privacy policy	Reporter´s direct telephone number:	*
	Reporter's mobile number :	
	The reference person of the case :	0
	The relevant email :	1
	Fields with <b>*</b> m	ust be filled in.

Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø Phone: 3920 2575 sekretariat@enli.dk

Page 1 of 4 Next >>

# Reporting a (ordinary) complaint page 2



💽 etisk nævn

for lægemiddelindustrien

# Reporting a (urgent) complaint page 2



www.enli.dk	Urgent complaint Page 2 - Details	
Front page FAQ Change password	It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.	
Log out	Yes, thank you, I would like to file an urgent complaint which must be settled within 8 working days of receipt of the complaint at ENLI (DKK 25.00 olwe VAT)	The description can
Danish reporting site	Z5,000, - plus VAT) Your company 's PO-number:	
ENLI's privacy policy	Your company's reference	optionally be indicated
	Name the company that you wish to complain about (in case of complaints about several companies, one complaint per company must be filed/submitted) : [(Choose)	complaint can be attached
Ethical Committee for the	State the grounds for the complaint :	(in a word document) on page 4 of the reporting
Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø	0	scheme.
Phone: 3920 2575 sekretariat@enli.dk	Rules : (Choose) V 0 *	
	At least one complaint must be added	
	State the complaints (pleas/anbringender) :	
	0	

I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).

Fields with \* must be filled in.

<< Back Page 2 of 4 Next >>



# Reporting a complaint page 3 (attach documents)



www.enli.dk	Attach appendix : Ge	Ordinary complaint Page 3 - Attach annemse Attach appendix	
Front page FAQ Change password Log out	Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach. Please note that the size of the attached files must not exceed 50 Mb per		
Danish reporting site	file		Remember to attach all
ENLI's privacy policy	Fields with * must be filled in.	<< Back Page 3 of 4 Next >>	relevant documents.

Ethical Committee for the		
Pharmaceutical Industry		
Lersø ParkAlle 101		
2100 København Ø		
Phone: 3920 2575		
sekretariat@enli.dk		

### Reporting a complaint page 4 (approval of report)

Please approve the reported information	Ordinary complaint Page 4 - Accept
My company is affiliated with ENLI	
I represent the following affiliated company:	
State the grounds for the complaint :	
	0
Etiske regl : § 13 stk.1 litra	
State the complaints (pleas/anbringender) :	
I hereby agree that all reported information may be registered by ENLI for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	
Multiple attachments can be uploaded. Simply repeat the procedure "browse - add attachment" for each desired appendix that you wish to attach.	
Please note that the size of the attached files must not exceed 50 Mb per file	
Approve	·



Before you select "Approve", please check if all relevant information and documents are attached.

It is the complainant's responsibility to ensure that the complaint contains all information relevant to the Investigator Panel's assessment of the complaint. A complaint may be rejected if it is not sufficiently justified.

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes - receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

<< Back Page 4 of 4

### Reporting an appeal





The appeal must be in writing and include a statement of the assessment and information supported by the appeal. The appeal is reported on ENLI's website. The Appeals Board receives the appeal together with the case material (from the original ENLI case) from the Secretariat of ENLI, cf. Article 11, of the Code of Procedure for ENLI.

Submitting a case to the Appeals Board does not have suspensive effect, which means that ENLI's decision is valid until the Appeals Board decides otherwise.

A fee of DKK 6,000 + VAT is required to appeal a decision by the Investigator Panel, , cf. Article 7 (8), of Penalties and Fees Regulations.

## Reporting an appeal page 1



<b>S</b> etisk	nævn
for lægemi	ddelindustrien

www.enli.dk		Appeal Page 1 - Reporter
	My company is affiliated with ENLI	
Front page FAQ	I represent the following affiliated company:	
Change password Log out	Reporter´s email :	rr.o.
Danish reporting site	Reporter´s name :	*
	Reporter's title :	
ENLI's privacy policy	Reporter´s direct telephone number:	*
	Reporter's mobile number :	
	The reference person of the case :	0
	The relevant email :	0
This is a second second second	Fields with <b>*</b> mu:	st be filled in.
Etnical Committee for the Pharmaceutical Industry		Page 1 of 4 Next >>
Lersø ParkAlle 101		2
2100 København Ø		
Phone: 3920 2575		

sekretariat@enli.dk

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# Reporting an appeal page 2





www.enli.dk		Appeal Page 2 - Details
Front page FAQ Change password	— It is the reporters/person requesting the pre- approval/complainant/appellants obligation to ensure that all reported information is correct, accurate and adequate. ENLI may require documentation for all reported information.	
Danish reporting site	Journal number of the case in the first instance	0
	State the appeal (grounds/anbringender) :	
ENLI's privacy policy		
	Your company's PO-number:	
	Your company's reference	
Ethical Committee for the Pharmaceutical Industry Lersø ParkAlle 101 2100 København Ø	I hereby agree that all reported information may be registered by ENLI * for use by ENLI's handling of the case and may be used for statistical purposes and that decisions on the basis of the information resulting in sanctions, may be published on the ENLI website in accordance with the rules, including The General Data Protection Regulation (GDPR).	
Phone: 3920 2575	Fields with * must be filled in.	
sekretariat@enli.dk	<< B	ack Page 2 of 4 Next >>



# Reporting an appeal page 3 (attach documents)



Ethical Committee for the		
Pharmaceutical Industry		
Lersø ParkAlle 101		
2100 København Ø		
Phone: 3920 2575		
sekretariat@enli.dk		



# Reporting an appeal page 4 (approval of report)



Before you select "Approve", please check if all relevant information and documents are attached.

Remember, only press "Approve" once (you send a report for each time you press "Approve"). Once you have selected "Approve", you will - within 5-10 minutes receive a receipt for your report. However, it may take longer if you have send large and/or many attachments along with your report.

