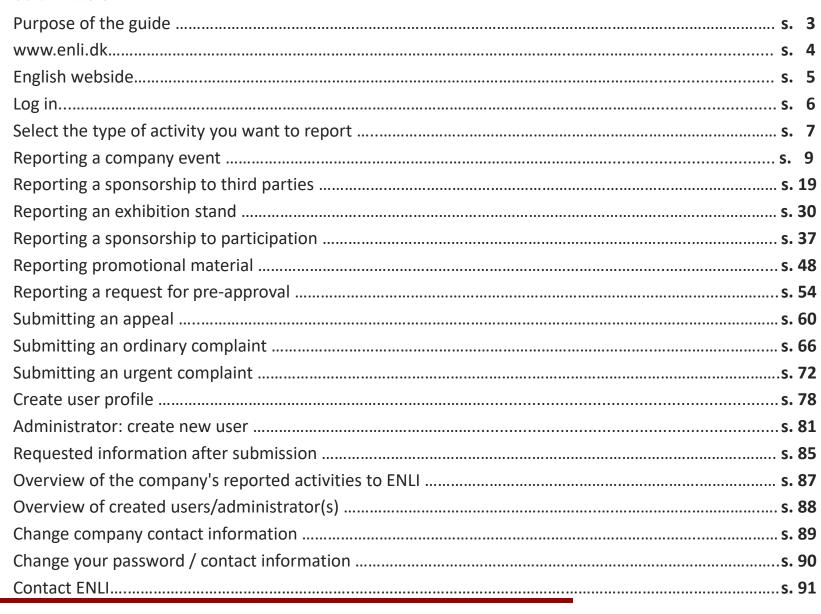


Guidance on reporting activities in ENLIsag



INDEX





Purpose of the reporting guide



The purpose of this guide is to help users through ENLI's case management system - ENLIsag. The next pages will show you how to access the reporting system. You can use this guide as a reference where you can find information about the type of report you need to make, how to change your password, create new users for your organisation, etc.

You can report the following type of activities:

*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





Om Etisk Nævn for Lægemiddelindustrien Regler Europakort - bespisningslofter E4ethics Offentliggjorte sager Nyhedsbreve Regioner - aftaler Samarbejder med patientforeninger Samarbejder med hospitaler/donationer Eksterne parter Ankenævnet Årsberetninger og sagsstatistik Tidsfrister



Ofte stillede spørgsmål om

Persondatapolitik (GDPR)

ENLI's anmeldersite



NYT

- Nyhedsbrev af 13. januar 2025 kan findes på ENLI's hjemmeside
- Listen over virksomheder, der har tilsluttet sig ENLI's kompetence er opdateret pr. 1. januar
 2025

Tilsluttede virksomheder

Her kan du se, hvilke virksomheder, der er tilsluttet de brancheetiske regler og selvjustits under ENLI's kompetence.

Læs mere

Introduktion til ENLI

ENLI har udarbejdet en introduktion til ENLI, hvor det er muligt at få overordnet viden om ENLI, herunder hvem der står bag ENLI, hvorfor der er behov for et selvjustitsorgan, ENLI's organisering samt ENLI's sagsbehandling mv.

Du kan læse guiden her.

Læs mere

Eksterne parter

ENLI har udarbejdet en guide til brug for bl.a. medicinske selskaber og andre, der samarbejder med de lægemiddelvirksomheder, der er tilsluttet ENLI.

Du har mulighed for at læse ENLI's guide om økonomisk sponsorstøtte og udstillingsstande her.

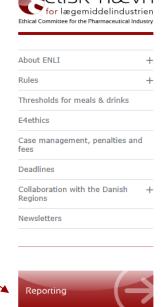
Læs mere

Select ENLI's English website

Report at ENLI's webside



Click on the red icon on the left of the page for reporting to ENLI



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





Find the introduction guide here.

(A) Read more

The parties behind

ENLI is established by the Danish Association of the Pharmaceutical Industry (Lif), the Danish Generic and Biosimilars Medicines Industry Association (IGL), and the Danish Association for Parallel Importers of Medicines. In addition, a number of associations and companies outside the abovementioned associations have the opportunity to join ENLI for an annual affiliation fee.

ENLI has published an introduction to ENLI where it

is possible to gain general knowledge about ENLI,

Read more







Introduction to ENLI **Function**

ENLI controls and sanctions that the pharmaceutical companies affiliated with ENLI comply with the Danish legislation and industry ethics. That is, rules that regulate the pharmaceutical companies' collaboration with and information for healthcare professionals, decision makers, patient associations and hospitals.

(A) Read more

Affiliated companies

Here you can see which companies are subject to the ethical rules under ENLI's jurisdiction.

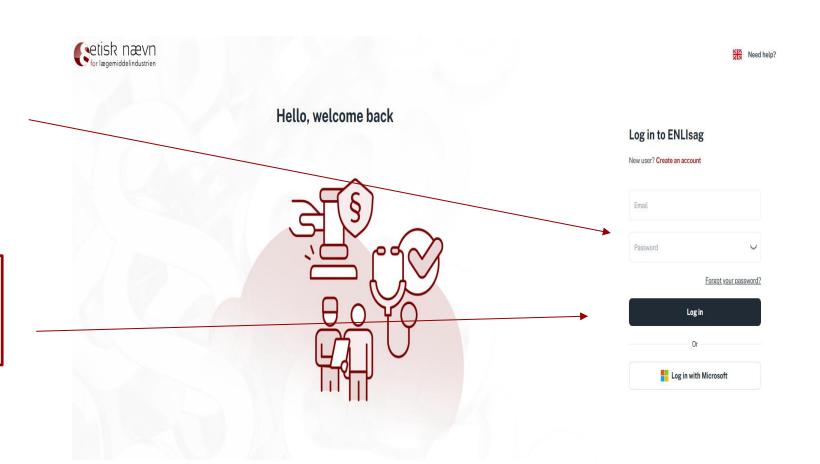
Read more

Log in



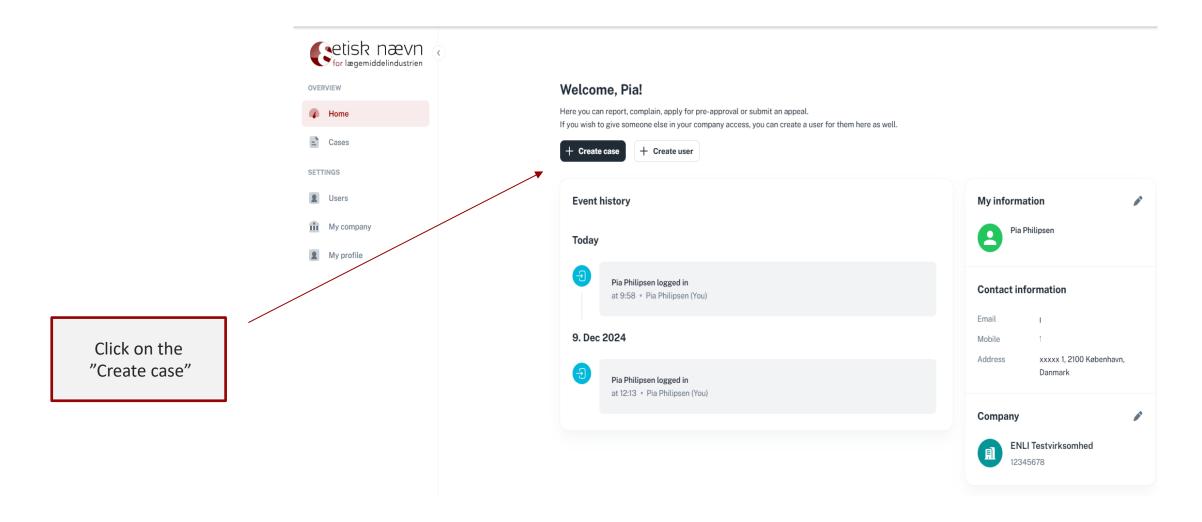
Enter you email and the password you received in your welcome email

When the email address and password fields are filled in, click 'Log in'



Select the type of activity you want to report





Select the type of case you want to report

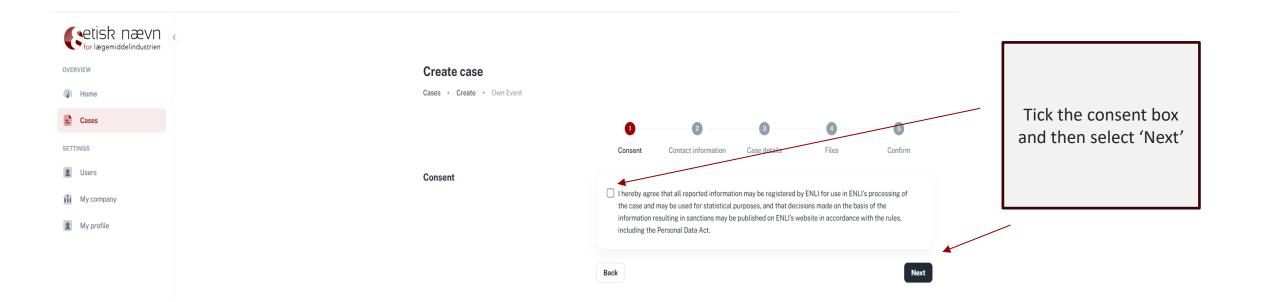


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Home		Case type Specify which case type you wish to create	Report				
Cases							
SETTINGS			Advertising material				
2 Users			Advertising material \rightarrow				
m My company							
My profile							
			Pre-approval				
			Ordinary pre-approval $$				
			Appeal				
			Appeal →				
			Complaint				
			Ordinary complaint $ ightarrow$ Urgent complaint $ ightarrow$				

Select which case type to report.

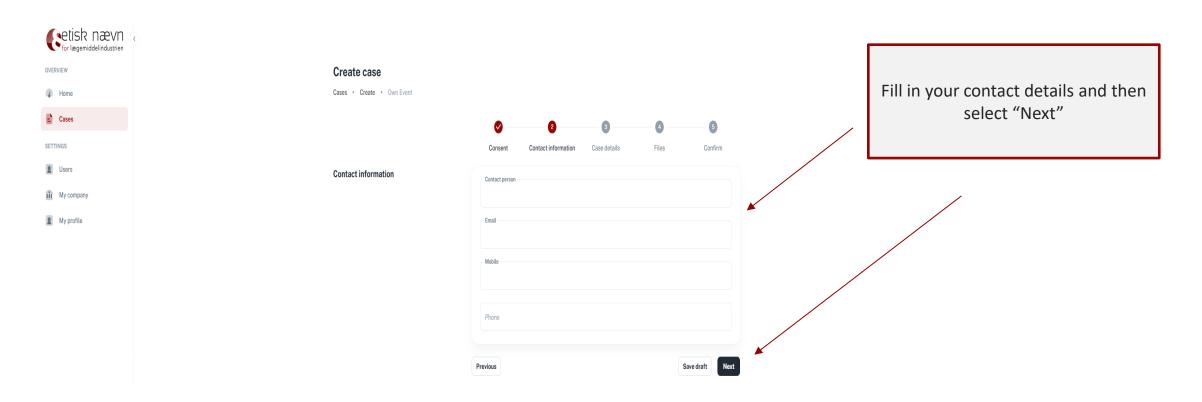
Reporting a company event – step 1: Consent





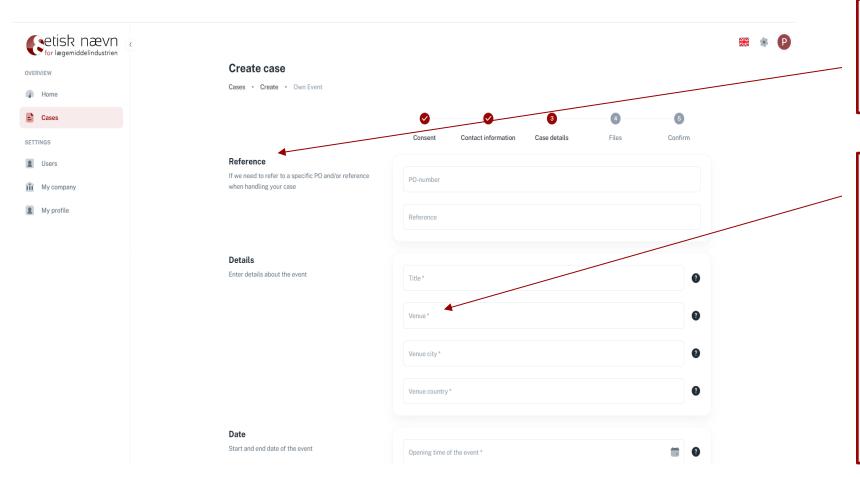
Reporting a company event – step 2: Contact information





Reporting a company event – step 3: Case details





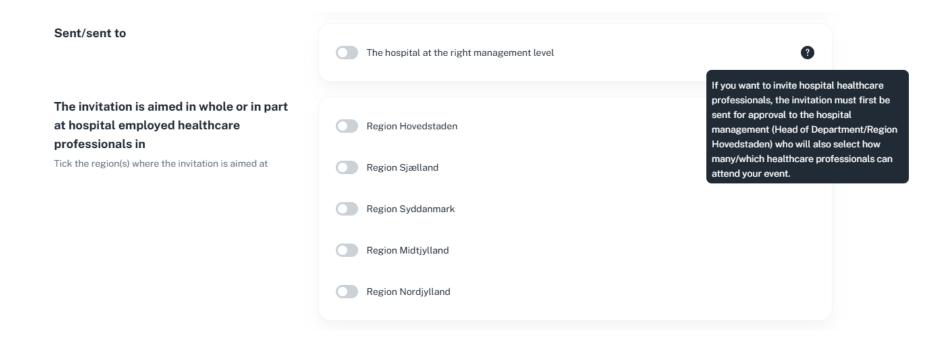
Enter the company's own reference/PO number, if applicable.

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

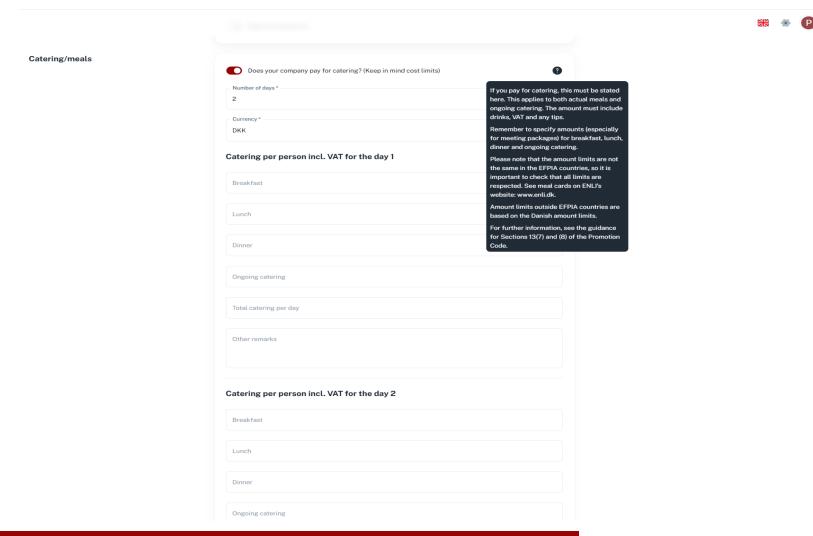
For further information, see the guidance to Sec. 13(10) of the Promotion Code.

Reporting a company event – step 3: Case details - Hospital





Reporting a company event – step 3: Case details - Catering



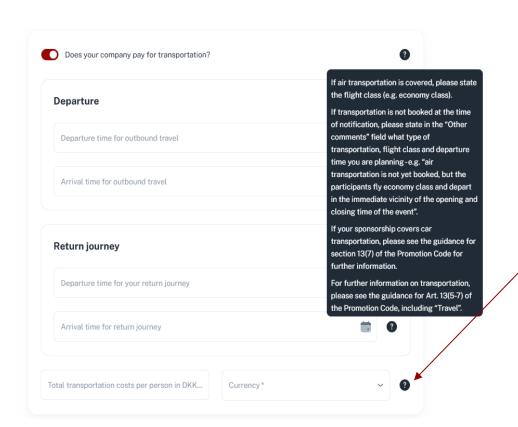


If breakfast is included in the hotel accommodation, please indicate this in "Other comments"

Reporting a company event – step 3: Case details - Transportation







Remember to select currency.

If you can't find the currency you need, the amount must be converted to Danish kroner.

Reporting a company event – step 3: Case details – Accomodation / Other

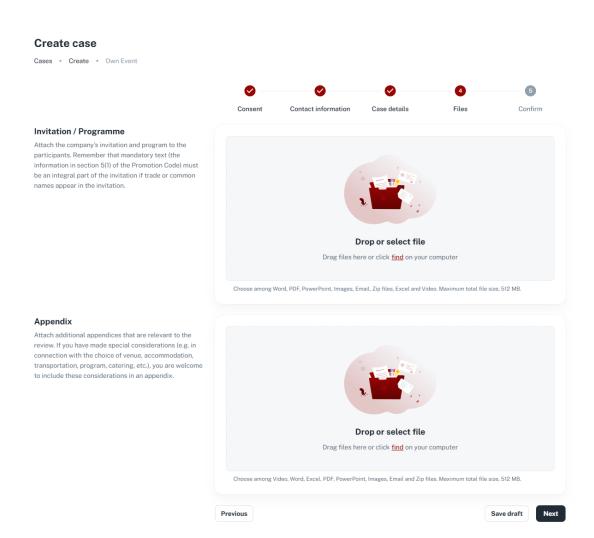


Accomodation Does your company pay for accommodation? Accommodation must comply with the Total accommodation costs per person in DK... Currency * same requirements as meeting venues, i.e. no accommodation in places that appear luxurious, cf. Section 13(10) of the Promotion Code. Hotel name * Hotel address* Other If your company has paid for additional expenses beyond Other comments those listed above, or if you have additional information relevant to the notification (e.g. considerations related to the choice of venue, transportation, accommodation, catering, program, etc.), you can write the information in "Other comments" or include the information in an appendix attached on the next page. Previous Save draft

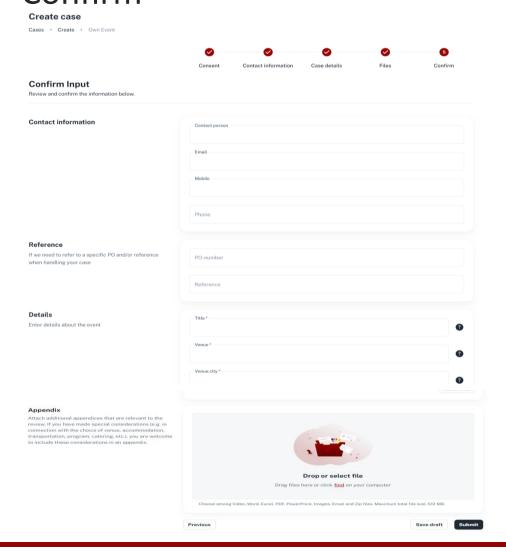
Reporting a company event – step 4: Files







Reporting a company event – step 5: Confirm





Before you select "Submit", 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).

Receipt



Receipt for case submission

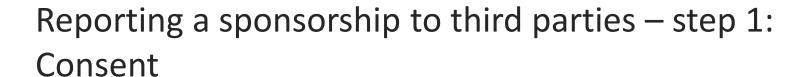
Thank you for your submission!

Your case has been received and registered with case number Aa-2024-0125-C. We will only contact you if your case is selected for random checks and there is something that does not seem to comply with the rules.

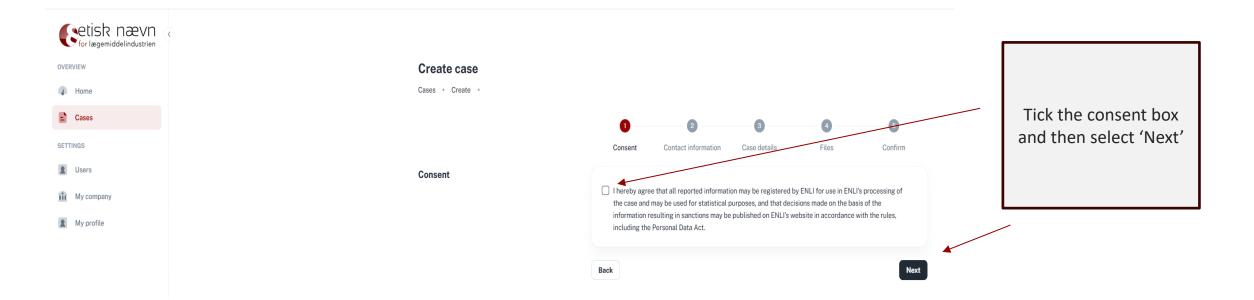
Below you can see the details we have registered in your case:

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ail	Reference Not given			
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Venue city				
Venue country				
Date				
Opening time of the event				
Ending time of the event				

Finally, you will receive a receipt for your reporting.

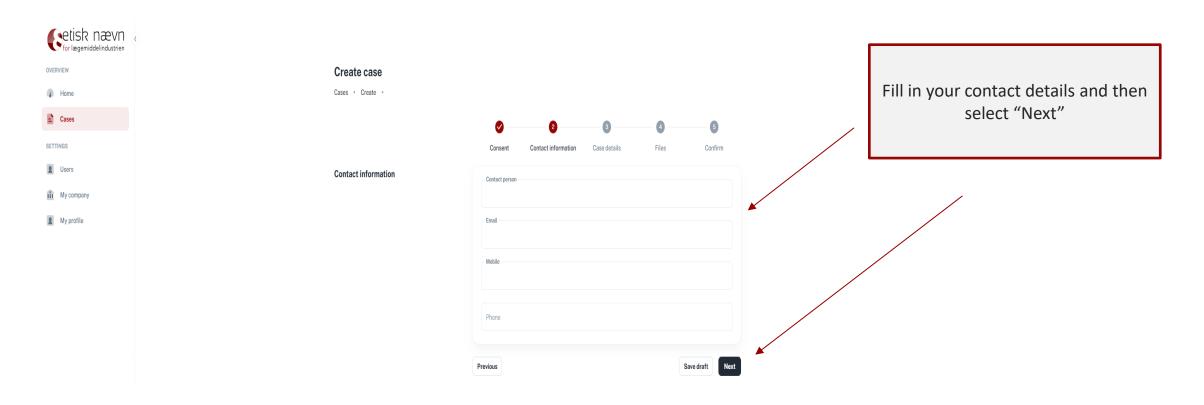






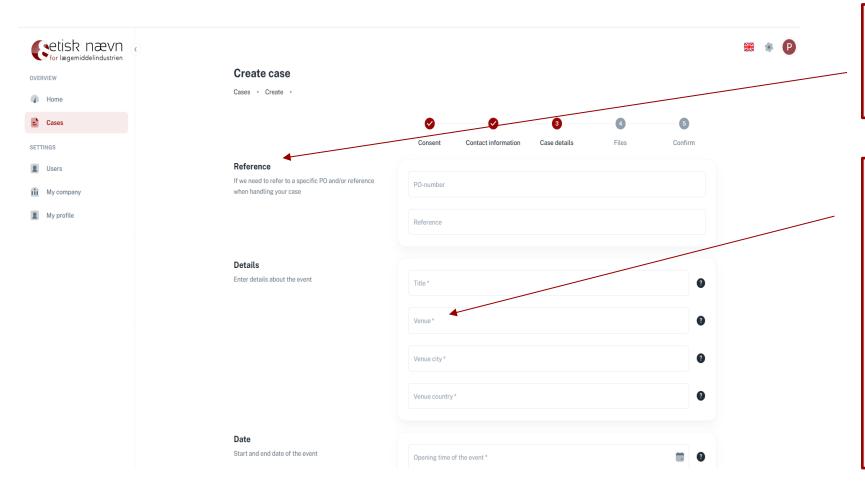
Reporting a sponsorship to third parties – step 2: Contact information





Reporting a sponsorship to third parties – step 3: Case details

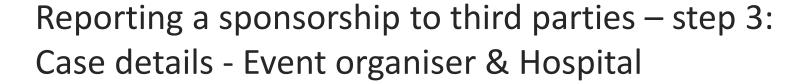




Enter the company's own reference/PO number, if applicable.

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

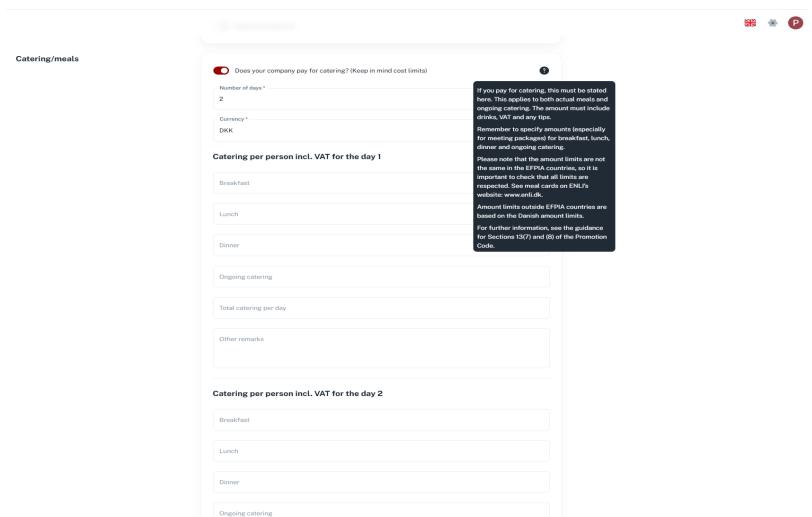
For further information, see the guidance to Sec. 13(10) of the Promotion Code.





Organiser Enter details about the organizer and sponsorship amount	Organiser name * Total amount given in sponsorship, incl. VAT * Currency *	3 ✓ 3			
Sent to		ponsoring a hospital in			
The invitation is aimed in whole or in part at hospital employed healthcare professionals in	education	with the hospital's continuing event, please tick the box next to where the hospital is located.			
	Region Sjælland Region Syddanmark				
	Region Midtjylland				
	Region Nordjylland				

Reporting a sponsorship to third parties – step 3: Case details - Catering





If breakfast is included in the hotel accommodation, please indicate this in "Other comments"

Reporting a sponsorship to third parties – step 3: Case details - Transportation



Transportation Does your company pay for transportation? f air transportation is covered, please stat the flight class (e.g. economy class). Departure ransportation, please see the guidance for section 13(7) of the Promotion Code for Departure time for outbound travel * For further information on transportation, please see the guidance for Art. 13(5-7) of Arrival time for outbound travel * the Promotion Code, including "Travel". Return journey Departure time for your return journey * Arrival time for return journey * Total transportation costs per person in DKK...

Remember to select currency.

If you can't find the currency you need, the amount must be converted to Danish kroner.

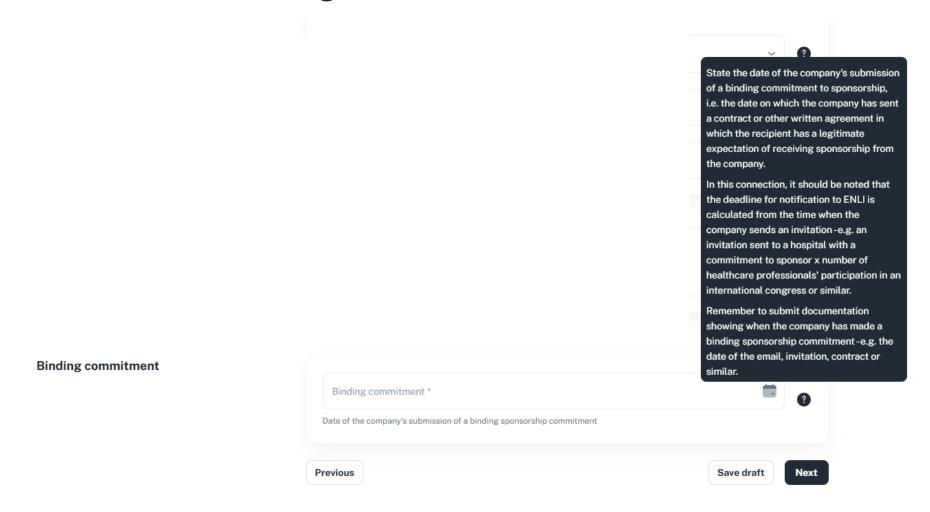
Reporting a sponsorship to third parties – step 3: Case details – Accomodation / Other



Accomodation Does your company pay for accommodation? Accommodation must comply with the Total accommodation costs per person in DK... Currency * same requirements as meeting venues, i.e. no accommodation in places that appear luxurious, cf. Section 13(10) of the Promotion Code. Hotel name * Hotel address* Other If your company has paid for additional expenses beyond Other comments those listed above, or if you have additional information relevant to the notification (e.g. considerations related to the choice of venue, transportation, accommodation, catering, program, etc.), you can write the information in "Other comments" or include the information in an appendix attached on the next page. Previous Save draft

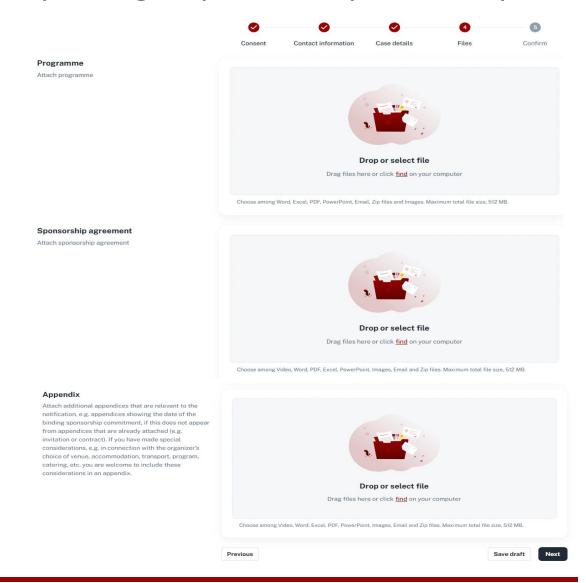
Reporting a sponsorship to third parties – step 3: Case details – Binding commitment





Reporting a sponsorship to third parties – step 4: Files





Reporting a sponsorship to third parties – step 5: Confirm



create case					
	Consent	Contact information	Case details	Files	- 6 Confirm
Confirm Input leview and confirm the information below.					
contact information	Contact person				
	Email				
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	Venue city *				0
appendix					
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Before you select "Submit", 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).

Receipt



Receipt for case submission

Thank you for your submission!

Your case has been received and registered with case number Ab-2024-0125-C. We will only contact you if your case is selected for random checks and there is something that does not seem to comply with the rules.

Below you can see the details we have registered in your case:

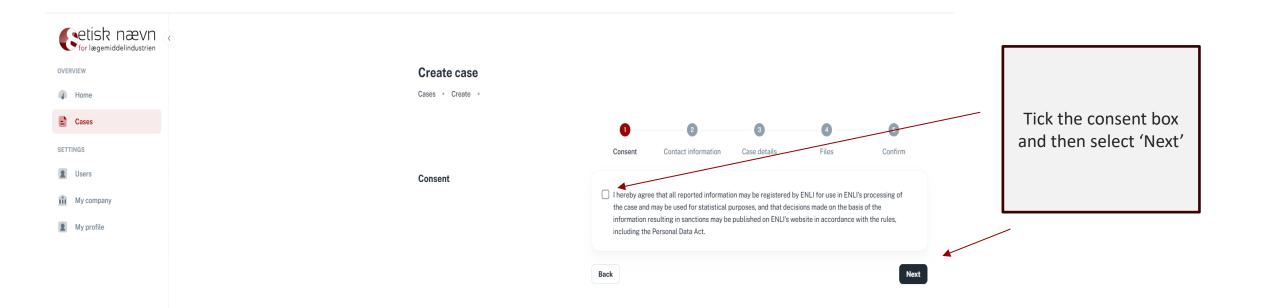


Contact information Name Email Mobile Phone	Your reference PO number Not given Reference Not given
Event	
Details	
Title	
Venue	
Venue city	
Venue country	
Date	
Event opening time	
Event end time	
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Finally, you will receive a receipt for your reporting.

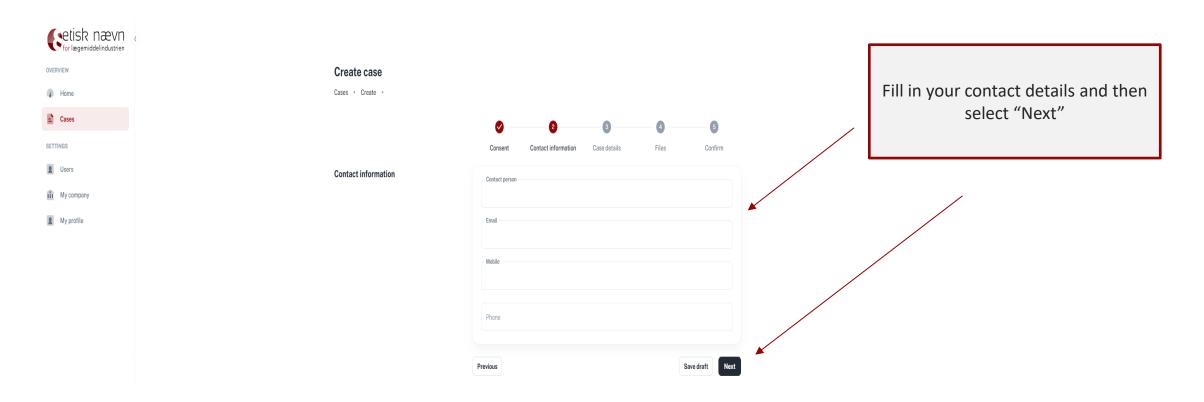
Reporting an exhibition stand – step 1: Consent





Reporting an exhibition stand – step 2: Contact information





Reporting an exhibition stand – step 3: Case details



Create case							
Cases • Create • Exhibition stand							
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	Event end time ^s					•	

Enter the company's own reference/PO number, if applicable.

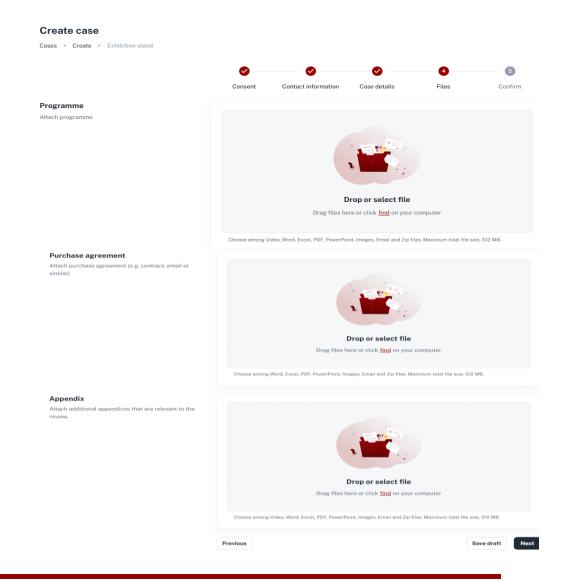
Reporting an exhibition stand – step 3: Case details



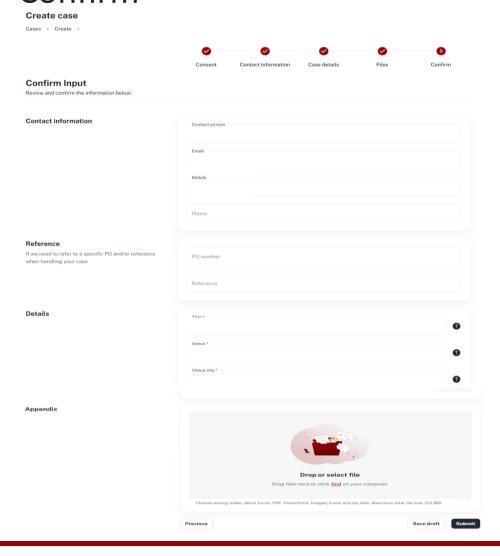
Organiser	Organiser name *	•
Economy	Square meter price in DKK on exhibition sta Currency *	~ ②
	Number of square meters *	Specify the price per square meter of the exhibition stand, not the total purchase price.
	Total purchase price for the exhibition stand * Currency *	As a rule of thumb, a price per square meter of DKK 2,000 incl. VAT for a full-day event that takes place at a rented, external location and with approximately 50-80
	Number of participants *	participants corresponds to the market price. If the total purchase price for the exhibition
Other		stand includes items other than the exhibition stand (e.g. expenses for participant fees, catering, logo in program,
If you have additional information relevant to the notification, you can write the information in "Other comments" or include the information in an appendix attached on the next page.	Other comments	administration fee to external party/organizer), this should not be included in the price per square meter.
a	Previous	For further information, see the guidance to Section 18(3) of the Promotion Code. Save draft Next

Reporting an exhibition stand – step 4: Files





Reporting an exhibition stand – step 5: Confirm

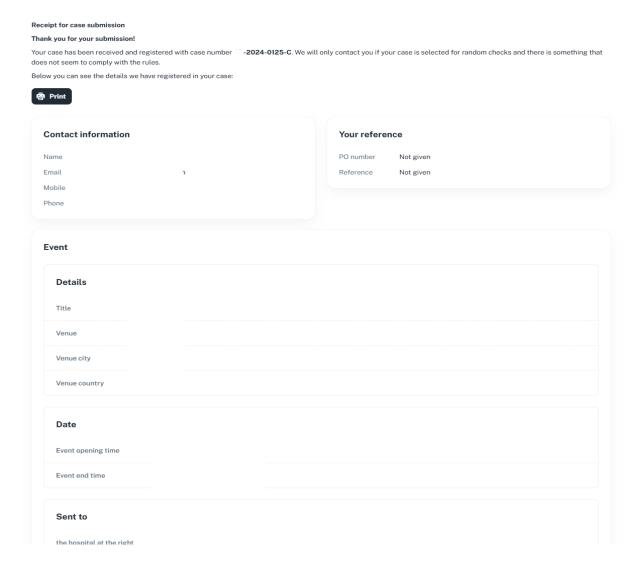




Before you select "Submit", please check if all relevant information and documents appear in your report. It is the notified documentation that is examined if the report is selected in a random control.

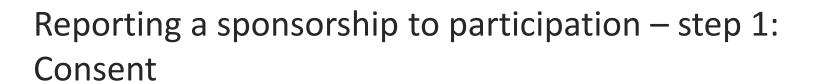
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Receipt

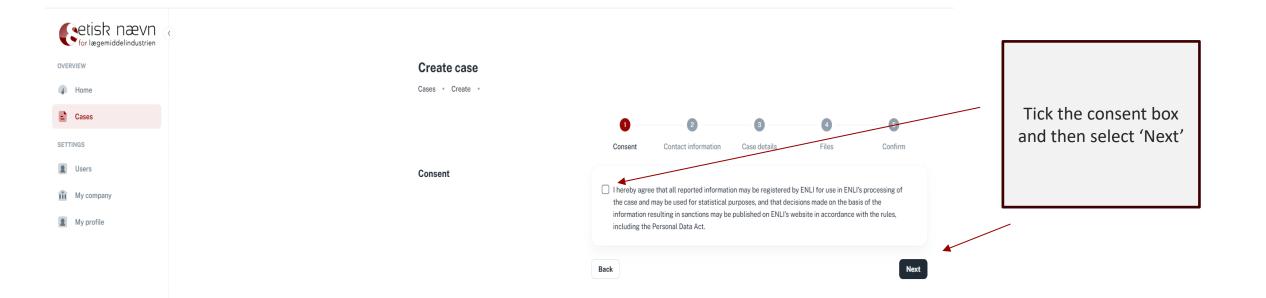




Finally, you will receive a receipt for your reporting.

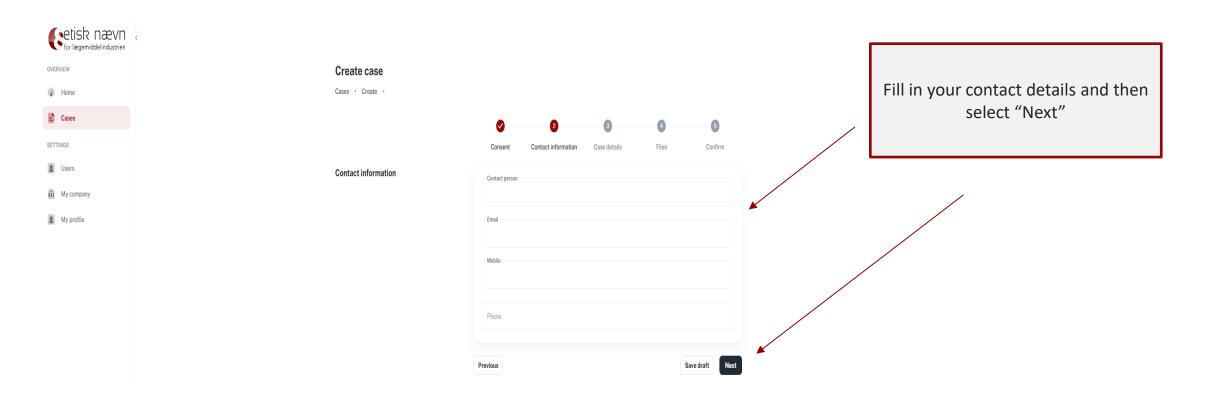






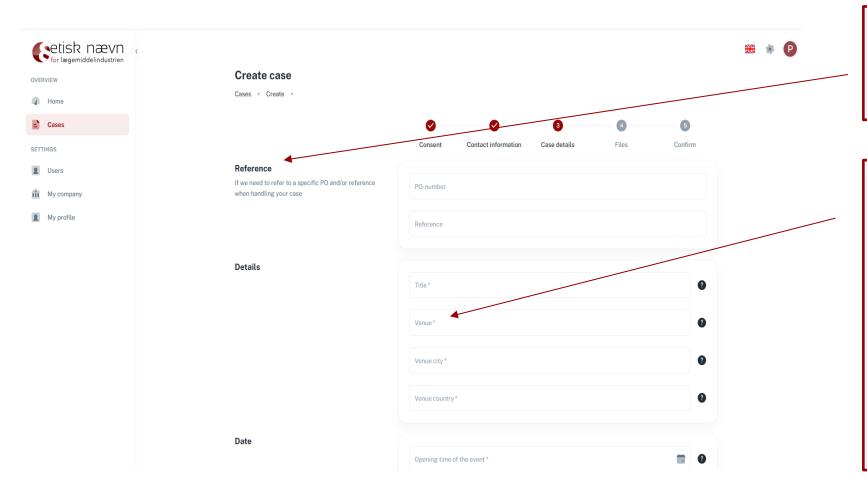
Reporting a sponsorship to participation – step 2: Contact information





Reporting a sponsorship to participation – step 3: Case details

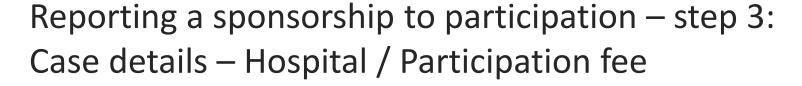




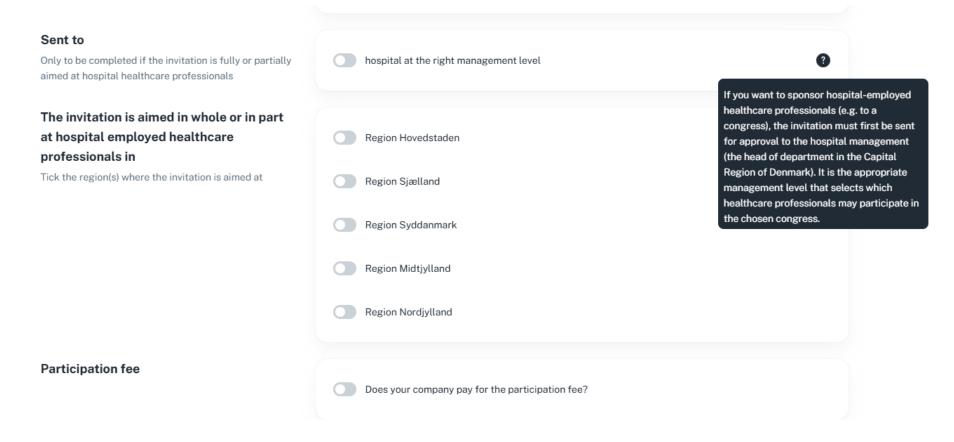
Enter the company's own reference/PO number, if applicable.

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

For further information, see the guidance to Sec. 13(10) of the Promotion Code.

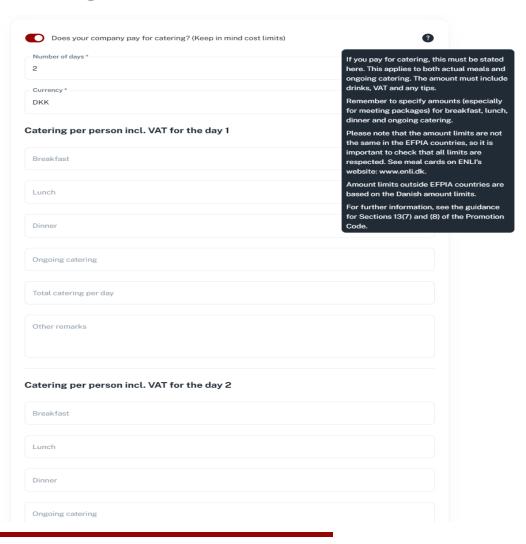






Reporting a sponsorship to participation – step 3: Case details - Catering





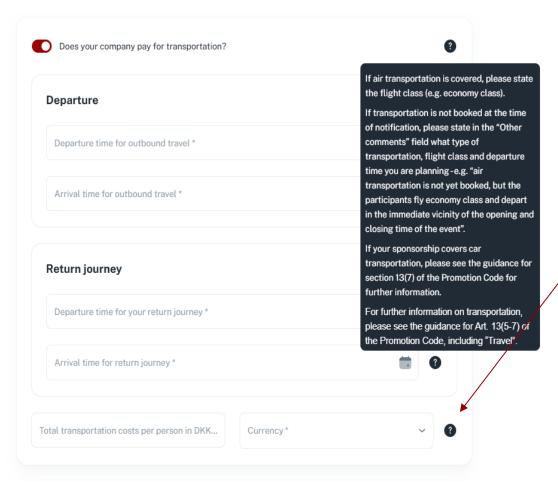


If breakfast is included in the hotel accommodation, please indicate this in "Other comments"

Reporting a sponsorship to participation — step 3: Case details - Transportation



Transportation



Remember to select currency.

If you cannot find the currency you need, the amount must be converted to Danish kroner.

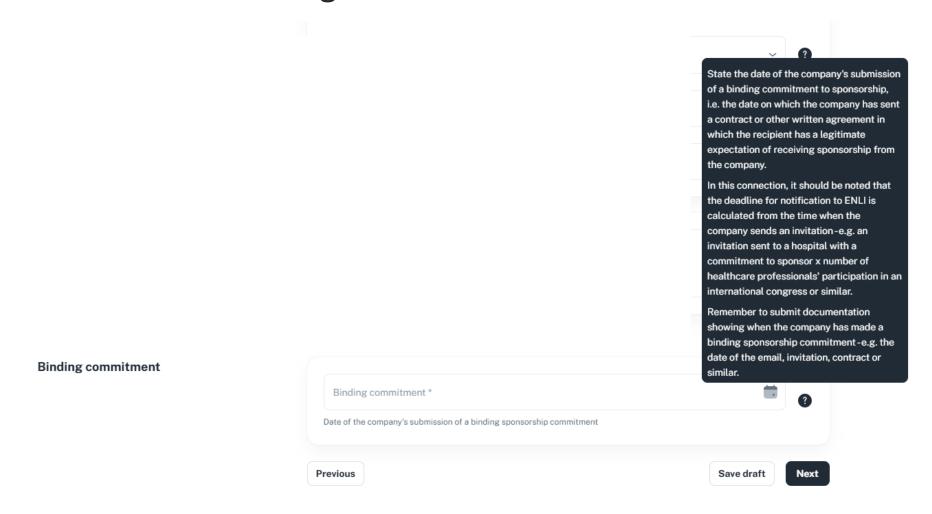
Reporting a sponsorship to participation – step 3: Case details – Accomodation / Other



Accomodation Does your company pay for accommodation? Accommodation must comply with the Total accommodation costs per person in DK... Currency * same requirements as meeting venues, i.e. no accommodation in places that appear luxurious, cf. Section 13(10) of the Promotion Code. Hotel name * Hotel address* Other If your company has paid for additional expenses beyond Other comments those listed above, or if you have additional information relevant to the notification (e.g. considerations related to the choice of venue, transportation, accommodation, catering, program, etc.), you can write the information in "Other comments" or include the information in an appendix attached on the next page. Previous Save draft

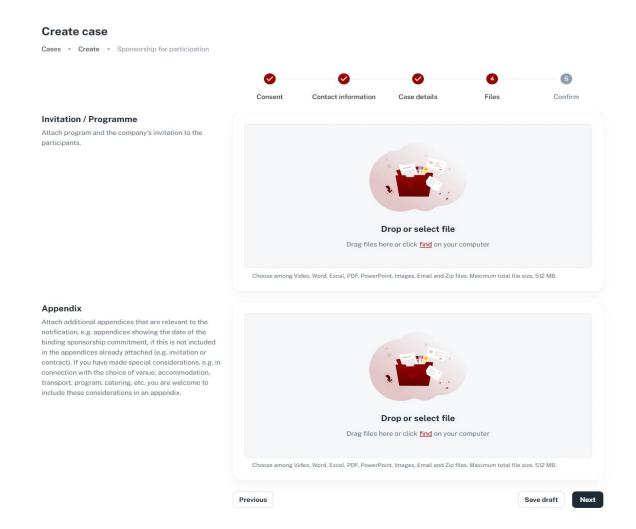
Reporting a sponsorship to participation – step 3: Case details – Binding commitment





Reporting a sponsorship to participation – step 4: Files





Reporting a sponsorship to participation – step 5: Confirm

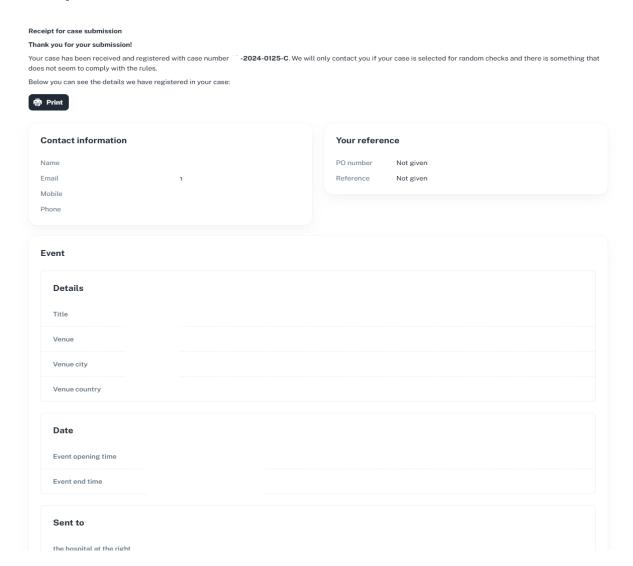


Create case					
	Consent	Contact information	Case details	Files	Confirm
Confirm Input Review and confirm the information below.					
Contact information	Contact person				
	Email				
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If we need to refer to a specific PO and/or reference when handling your case	PO-number				
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	Venue city *				•
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Before you select "Submit", 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.

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Receipt

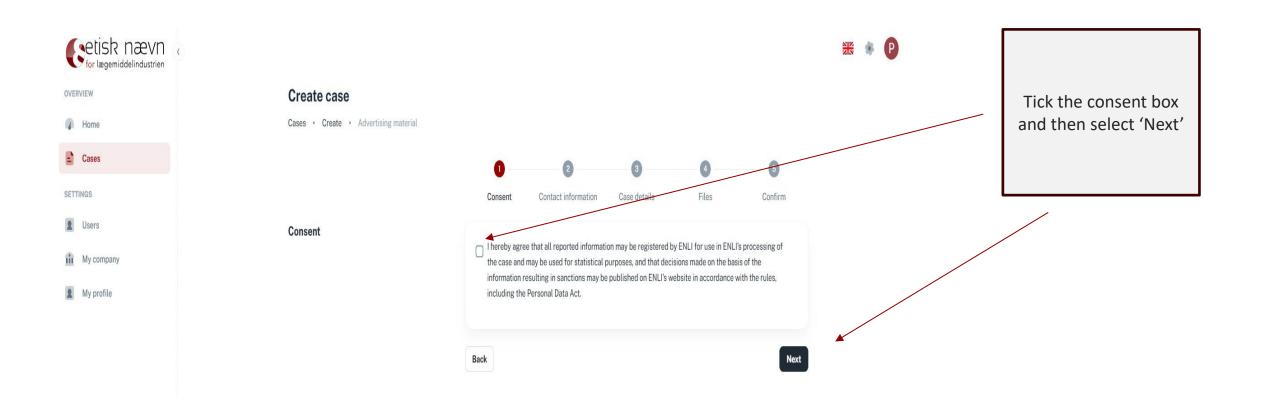




Finally, you will receive a receipt for your reporting.

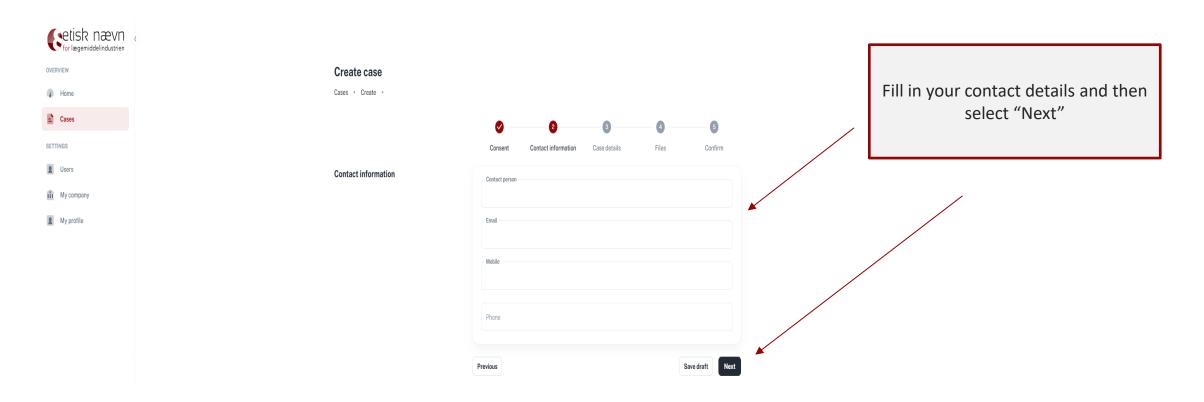
Reporting promotional material – step 1: Consent





Reporting promotional material – step 2: Contact information





Reporting promotional material – step 3: Case details

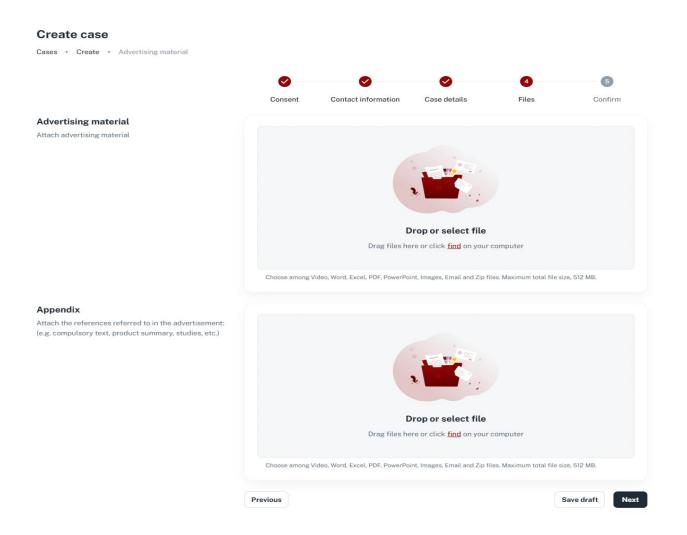


Create case Cases • Create • Advertising material 5 Contact information Consent Confirm Reference If we need to refer to a specific PO and/or reference PO-number when handling your case Reference Details Type of advertisement * If the desired ad type is not listed, select "Other" Trade and/or common name in advertising ' If you have additional information relevant to the Other comments notification, you can write it in "Other comments" or attach it in an appendix on the next page. Previous

Enter the company's own reference/PO number, if applicable.

Reporting promotional material – step 4: Files





Reporting promotional material – step 5: Confirm



Create case						
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	Consent	Contact information	Case details	Files	Confirm	
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Before you select "Submit", 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.

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Receipt

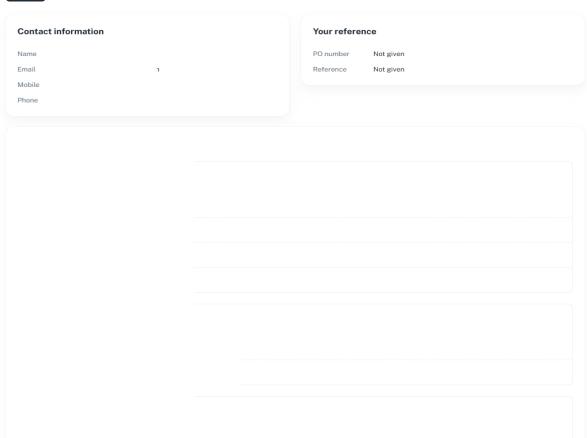
Receipt for case submission

Thank you for your submission!

Your case has been received and registered with case number and the second seco does not seem to comply with the rules.

Below you can see the details we have registered in your case:



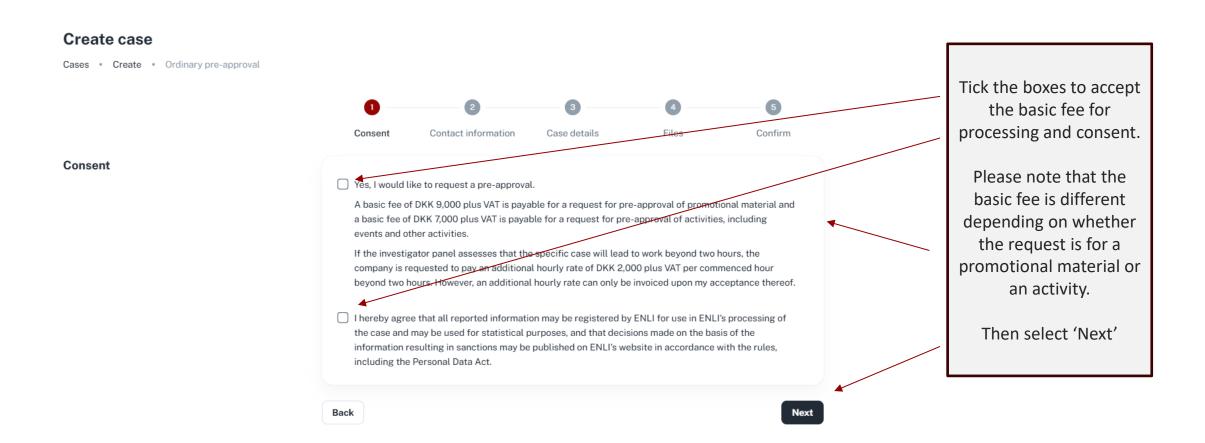




Finally, you will receive a receipt for your reporting.

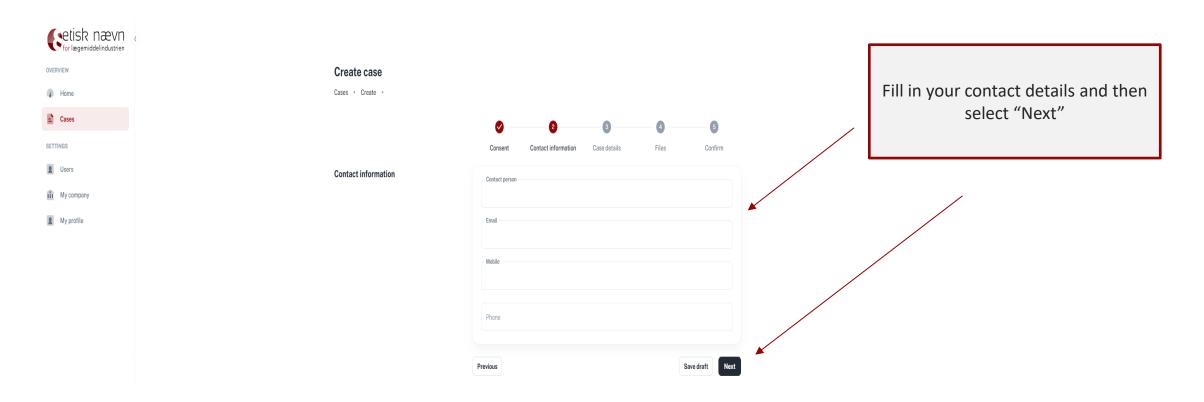
Reporting a request for pre-approval – step 1: Consent





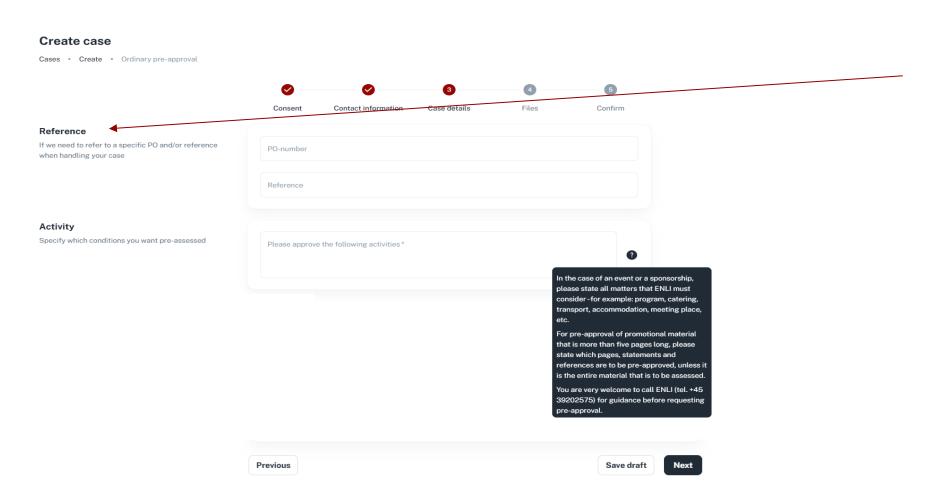
Reporting a request for pre-approval – step 2: Contact information





Reporting a request for pre-approval – step 3: Case details





Enter the company's own reference/PO number, if applicable.

Reporting a request for pre-approval – step 4: Filer

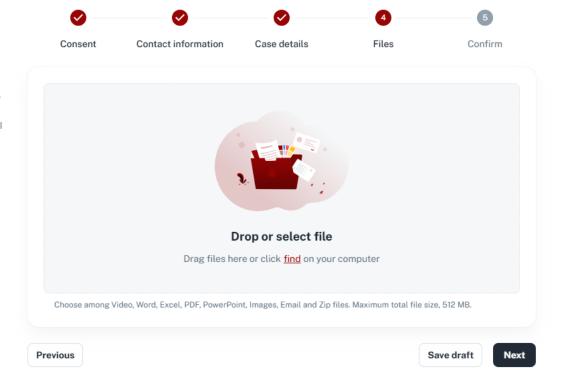


Create case

Cases · Create · Ordinary pre-approval

Appendix

Attach appendices It is the company's responsibility to provide the necessary and accurate information about the activity in connection with the request so that ENLI can make a decision on pre-approval on an informed basis.



Reporting a request for pre-approval – step 5: Confirm

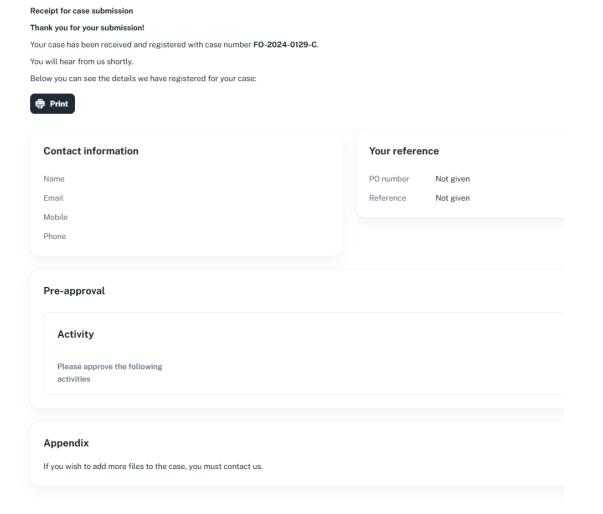


Cases · Create · Own Event **Confirm Input** Review and confirm the information below. **Contact information** Reference If we need to refer to a specific PO and/or reference PO-number when handling your case Attach appendices It is the company's responsibility to provide the necessary and accurate information about the activity in connection with the request so that ENLI can make a decision on pre-approval on an informed Drop or select file Drag files here or click find on your computer

Before you select "Submit", 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).

Receipt

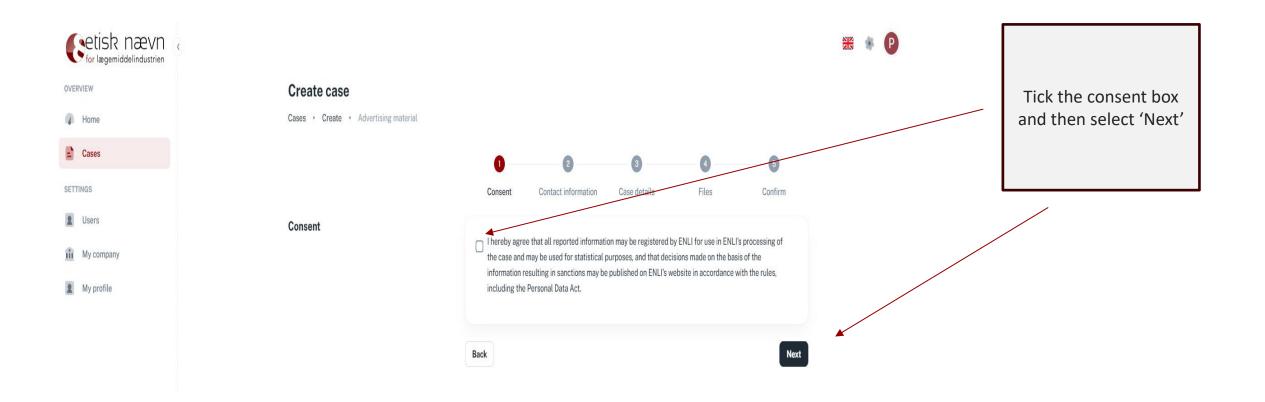




Finally, you will receive a receipt for your request.

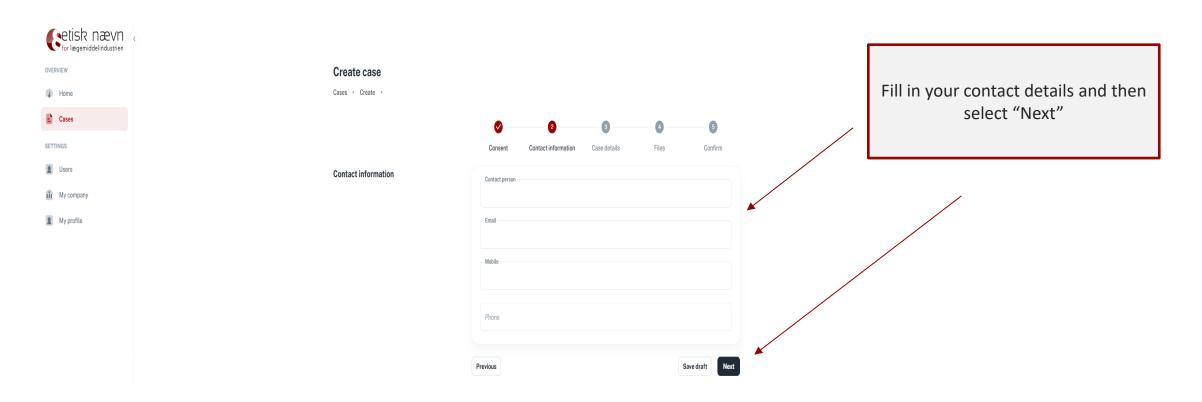
Submitting an appeal – step 1: Consent





Submitting an appeal – step 2: Contact information





Submitting an appeal – step 3: Case details

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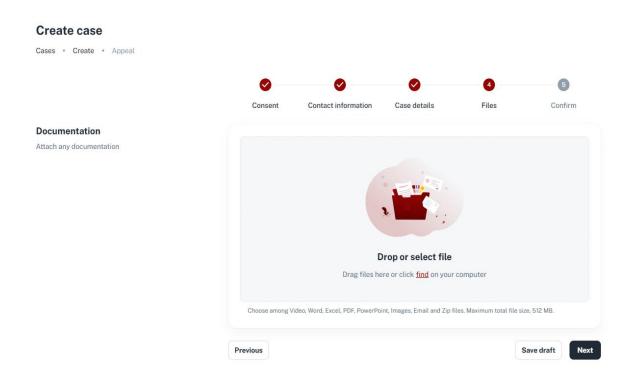
Create case

Cases • Create • Appeal 5 Consent Contact information Case details Reference If we need to refer to a specific PO and/or reference PO-number when handling your case Reference Information It costs DKK 6,000 plus VAT to appeal a decision made Journal number of the 1st instance case being appealed * by the Investigator Panel State the grounds for appeal (pleas) * The appeal must include a statement of the views and information on which the appeal The deadline for appeal is 21 working days after the company's receipt of the Investigator Panel's decision. Appeals received after this deadline will be The Appeals Board receives the appeal together with the correspondence in the case from ENLI's secretariat, cf. Rules of Procedure for ENLI § 11. Bringing a case before the Appeals Board does not have suspensive effect, which means that ENLI's decision is valid until the Appeals Board makes another decision. Further information about appeals can be found in section 11 of the Rules of Procedure for ENLI, which can be found on ENLI's website: www.enli.dk. Previous Save draft

Enter the company's own reference/PO number, if applicable.

Submitting an appeal – step 4: Files

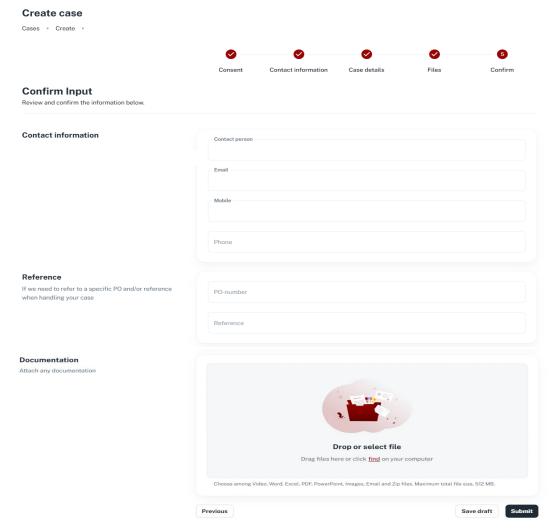






Submitting an appeal – step 5:

Confirm





Before you select "Submit", please check if all relevant information and documents appear in your report.

Receipt



Receipt for appeal submission

Thank you for your submission!

Your appeal has been received and registered with case number AN-2024-0131-C. We will contact you once we have reviewed your appeal.

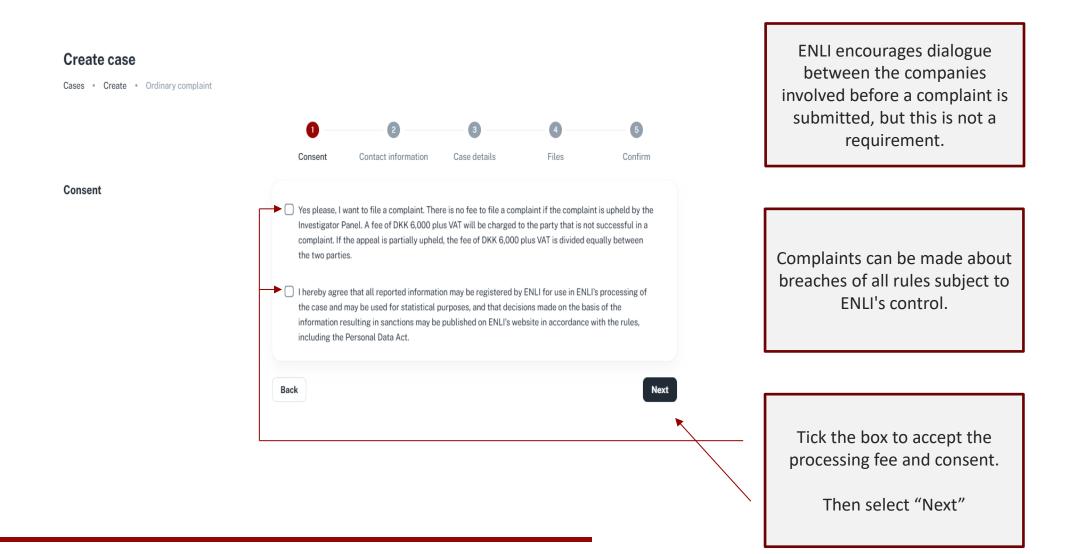
Below you can see the details we have on file for your appeal:

Print **Contact information** Your reference Name PO number Not given Email Reference Not given Mobile Phone Appeal Information Journal number of the 1st instance case being appealed State the grounds for appeal (pleas) Documentation If you wish to add more files to the case, you must contact us.

Finally, you will receive a receipt for your request.

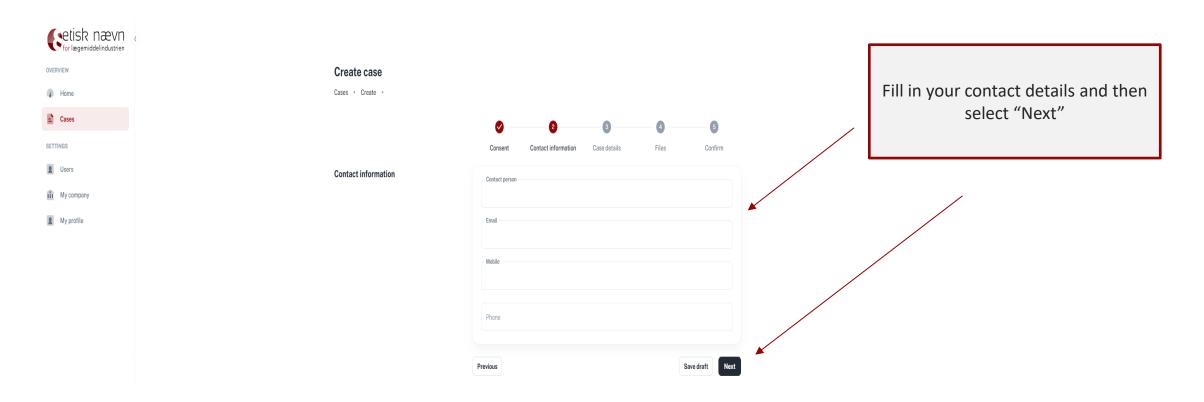
Submitting an ordinary complaint – step 1: Consent





Submitting an ordinary complaint – step 2: Contact information

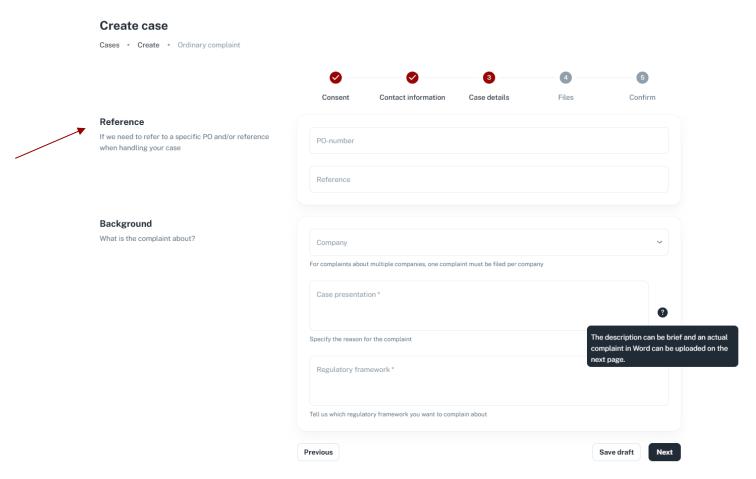




Submitting an ordinary complaint – step 3: Case details

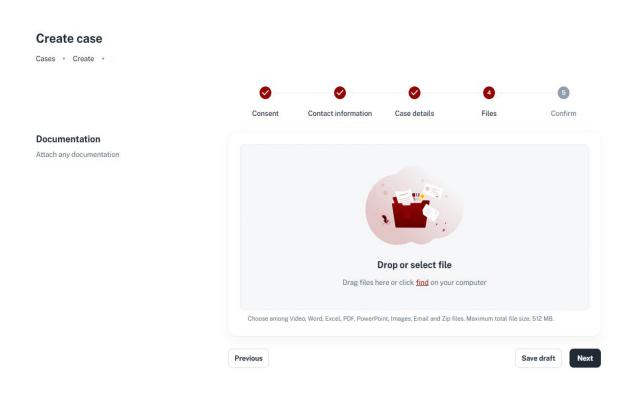


Enter the company's own reference/PO number, if applicable.



Submitting an ordinary complaint – step 4: Files







Submitting an ordinary complaint – step 5: Confirm

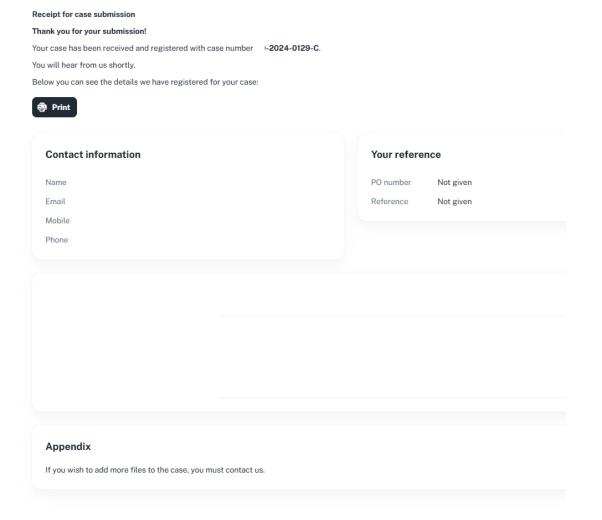


Create case	
ases • Create •	
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	Consent Contact information Case details Files Confirm
Confirm Input leview and confirm the information below.	
ontact information	Contact person
	Email
	Mobile
	Phone
deference	
If we need to refer to a specific PO and/or reference when handling your case	PO-number
	Reference
ocumentation	
tach any documentation	
	Drop or select file
	Drag files here or click <u>find</u> on your computer
	Choose among Video, Word, Excel, PDF, PowerPoint, Images, Email and Zip files. Maximum total file size, 512 MB.
	Previous Save draft

Before you select "Submit", please check if all relevant information and documents appear in your report.

It is your (the complainant's) responsibility to ensure that the complaint contains all information relevant to ENLI's assessment of the complaint. A complaint can be rejected if it is not sufficiently substantiated.

Receipt

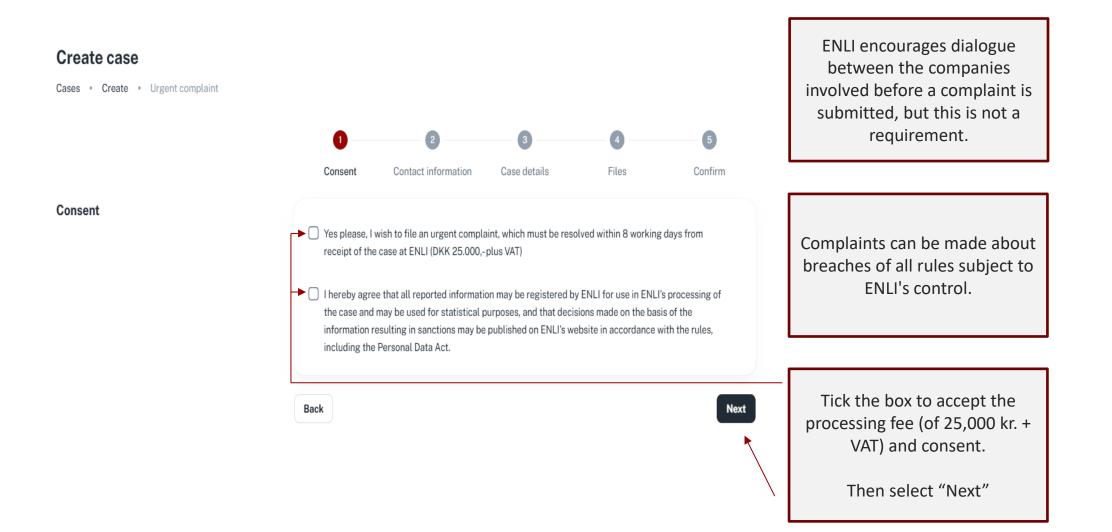




Finally, you will receive a receipt for your complaint.

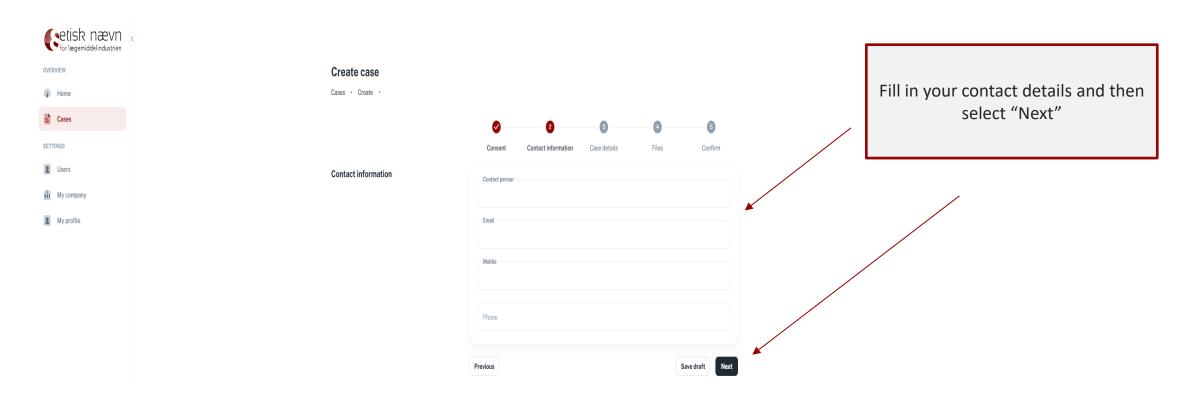
Submitting an urgent complaint – step 1: Consent







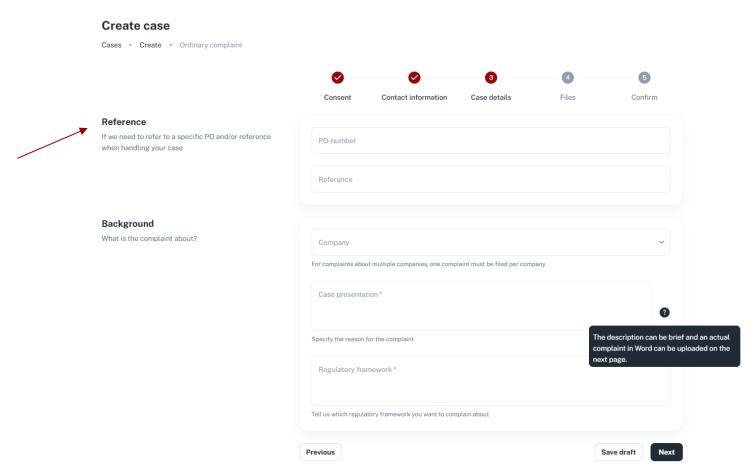




Submitting an urgent complaint – step 3: Case details

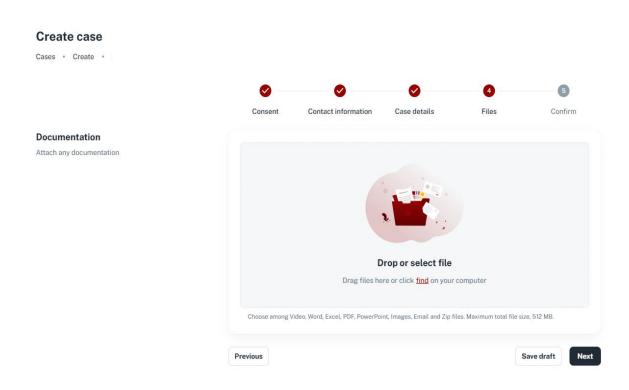


Enter the company's own reference/PO number, if applicable.



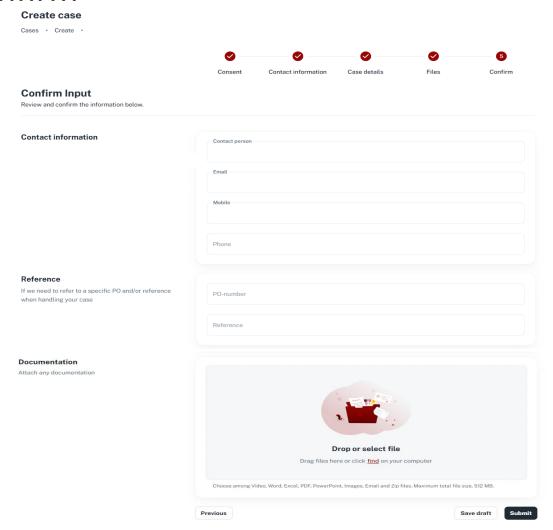
Submitting an urgent complaint – step 4: Files







Submitting an urgent complaint – step 5: Confirm

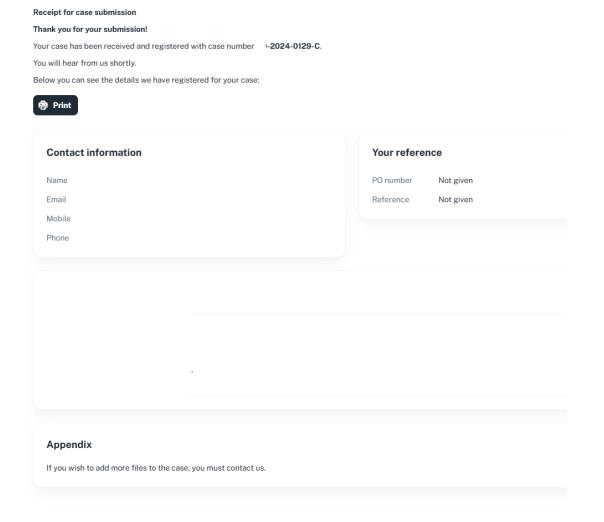




Before you select "Submit", please check if all relevant information and documents appear in your report.

It is your (the complainant's) responsibility to ensure that the complaint contains all information relevant to ENLI's assessment of the complaint. A complaint can be rejected if it is not sufficiently substantiated.

Receipt





Finally, you will receive a receipt for your complaint.

77

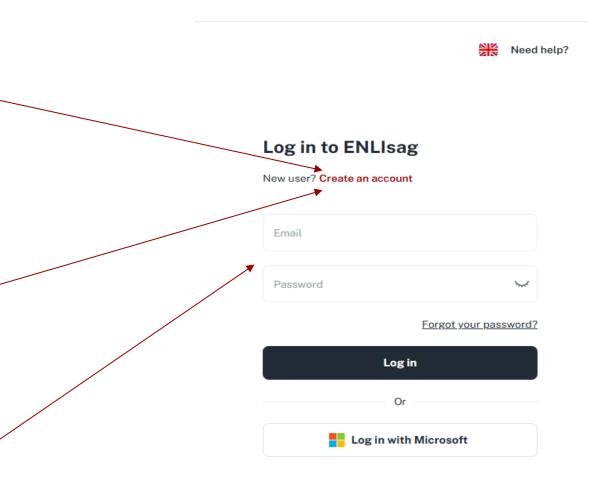
Create user profile



If you are employed by (or are a consultant for) a pharmaceutical company affiliated with ENLI and you do not have a user profile, i.e. you are not registered in ENLI's notifier system (ENLIsag), you must select 'Create an account'

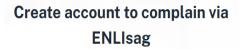
If you are not affiliated with a pharmaceutical company and you would like to submit a complaint to ENLI, you must also select 'Create an account'

If you are employed by (or are a consultant for) a pharmaceutical company affiliated with ENLI and you are already a registered user, you do not need to create an account, simply log in with your email and password (see slide 4).



Create user profile







Create account in ENLIsag Already have an account? Log in First name Last name Job title Email Password By signing up, I accept ENLI's terms of use and privacy, policy. Create account

Fill in the fields and then click 'Create account'

You will then receive an email with a password and a link.

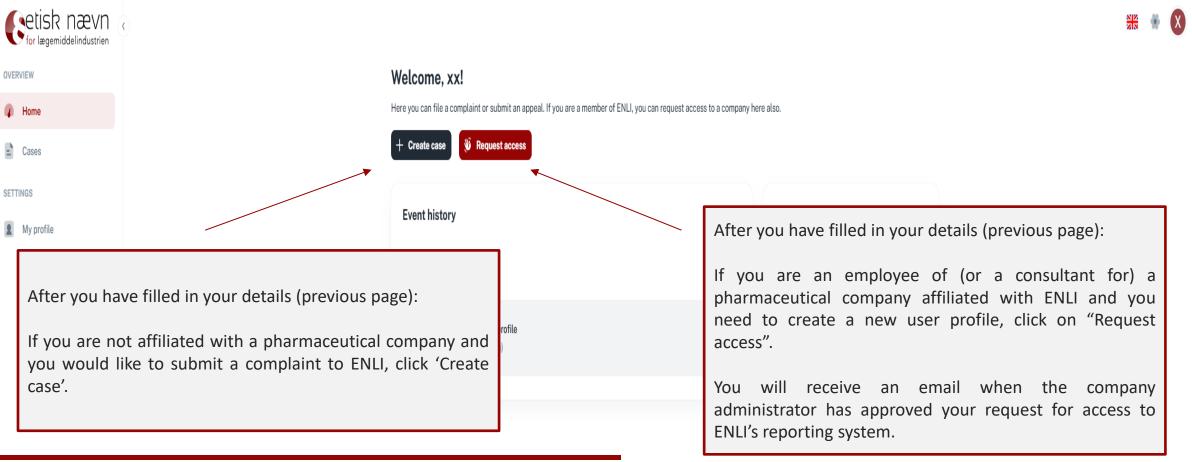
When creating your user profile, the company administrator will be asked to approve your creation.

You can only use ENLIsag once the company administrator has accepted your creation as user.

Create user profile:

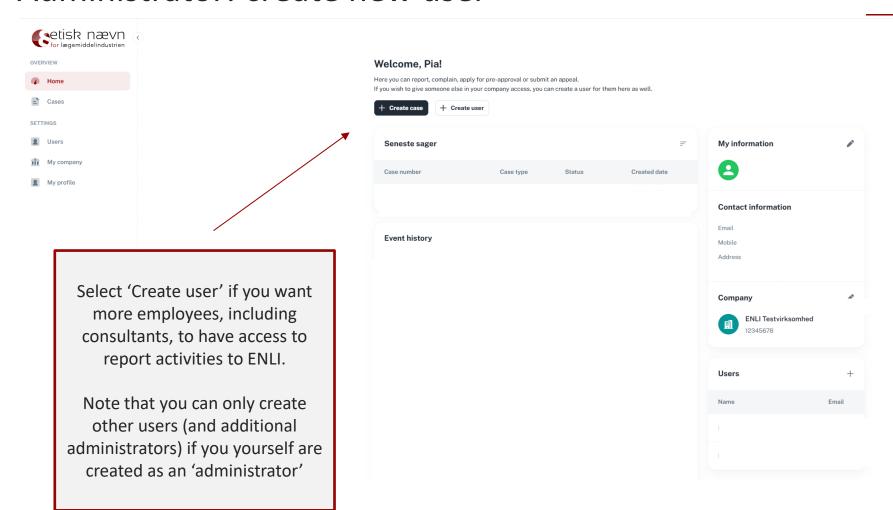


- File a complaint if you are not employed by a pharmaceutical company
- Request the company to access ENLI's report system (ENLIsag)



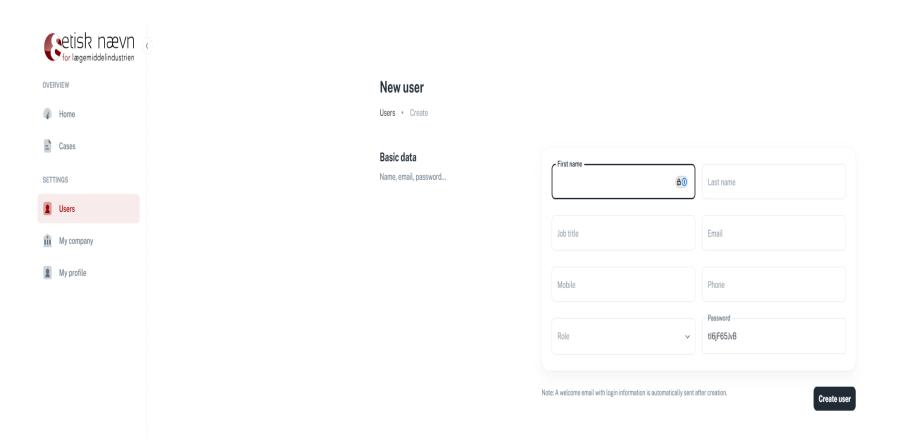
Administrator: create new user





Administrator: create new user

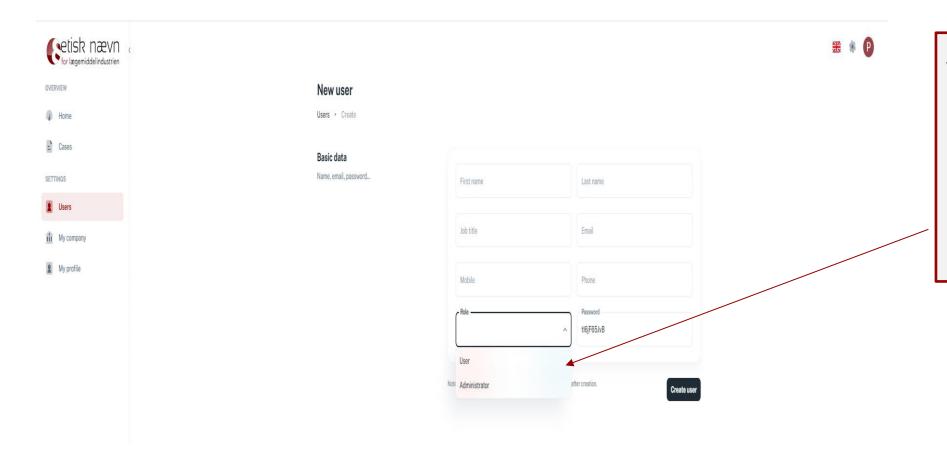






Administrator: create new user





You have to choose whether the new user should be created as 'administrator' or 'user'.

The difference between the roles is that the 'Administrator' can create new users and can see all the company's reports to ENLI. A 'User' does not have these rights.

Administrator: create new user - activation email





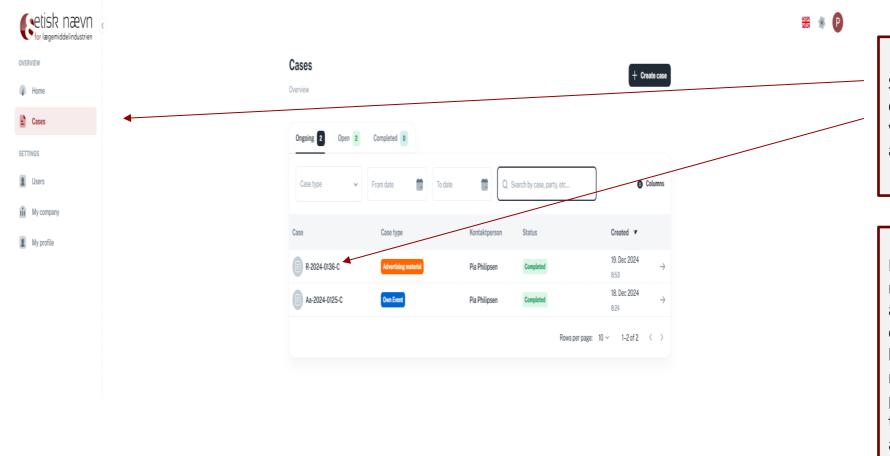
Welcome to ENLIsag

Dear Carina
Pia Philipsen has created a profile for you in ENLIsag.
To log ind you must use your email and the password **Reception1**Click on this link to log in.

After creating a user profile for your colleague or consultant, your colleague/consultant will receive an email with a password and a link to ENLI's reporting system.

Requested information after submission





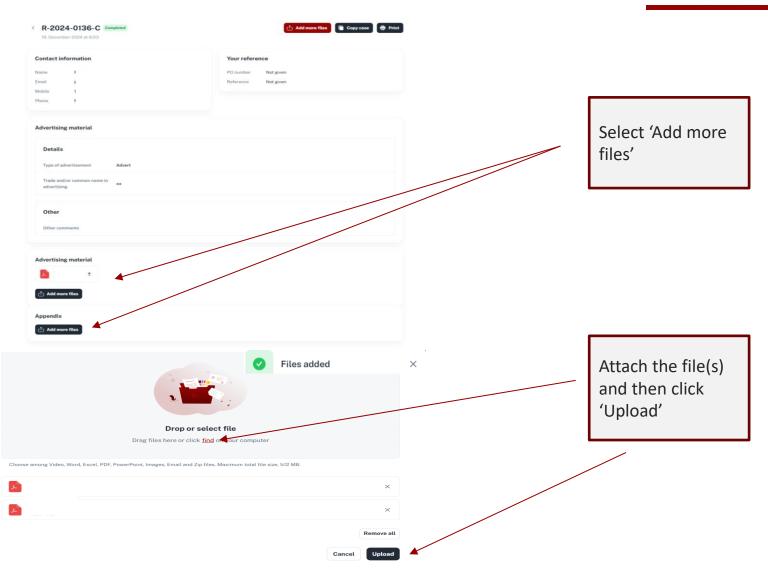
Select 'Cases' and choose the case where you need to add material.

If you want to add material to an already reported case that has not been selected for random control, please contact ENLI to open access to add files.

Requested information after submission

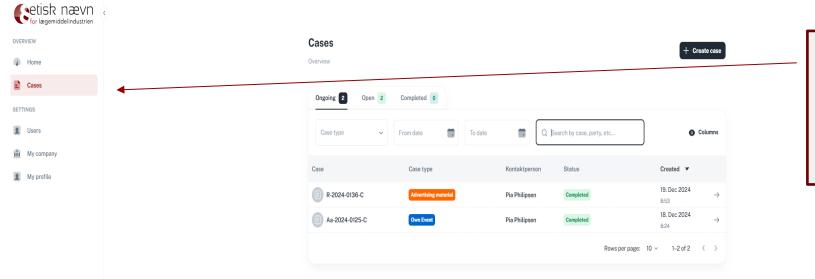






Overview of cases reported to ENLI

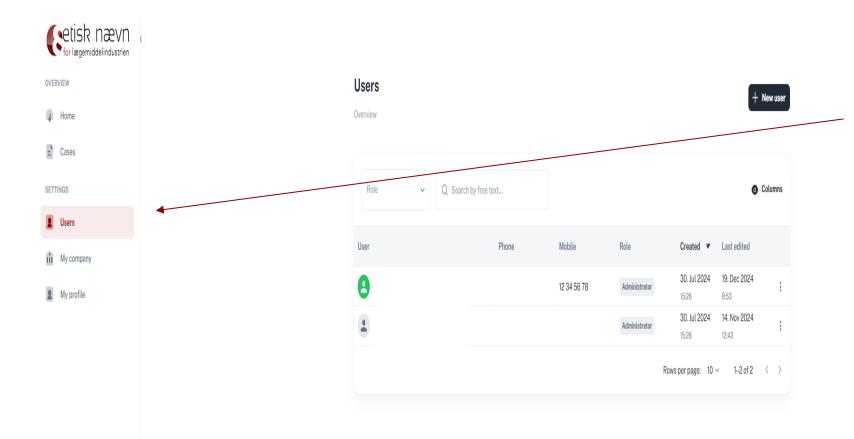




Under the "Cases" tab, the administrator can see all cases that have been reported to ENLI.

Overview of created users / administrator(s)



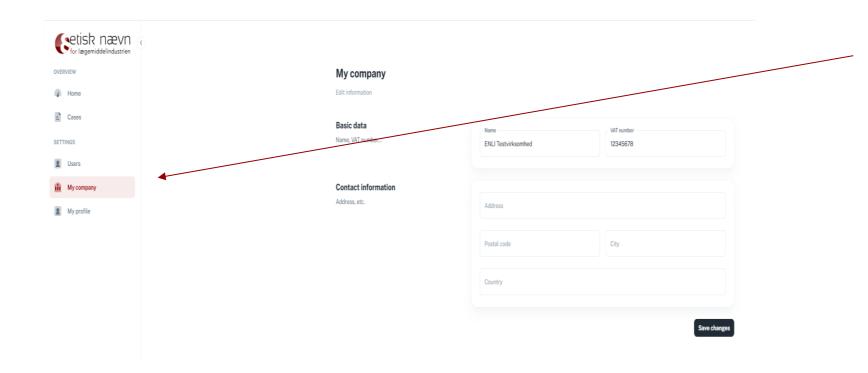


Under the "User" tab, the administrator can see who in the company is set up as users who can report to ENLI.

It is possible to create multiple administrators if the company wishes to do so.

Change company contact information

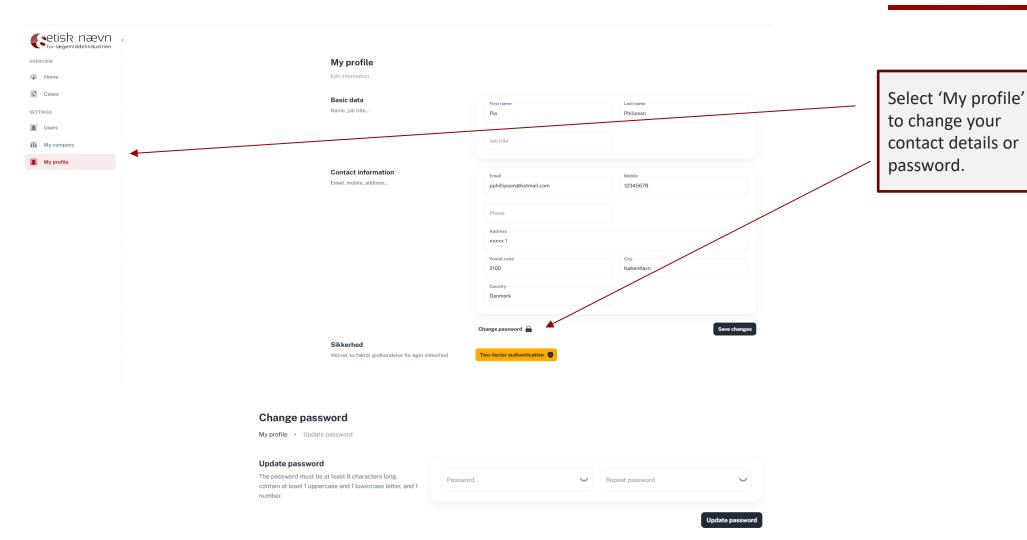




In the 'My company' tab, the administrator can change the company's contact details.

Change your password / contact details





Contact



ENLI, Ethics Committee for the Pharmaceutical Industry

Lersø Parkallé 101

2100 Copenhagen Ø

Denmark

Phone number +45 3920 2575 (9.00 – 15.00)

E-mail address: sekretariat@enli.dk

Homepage: www.enli.dk