

User Manual

NDS-WEB2

Published by: <www.swissmedic.ch>

Authors: Swissmedic Narcotics Division

Contents

1	Basic principles of NDS-WEB2	3
2	Registration and application	3
2.1	Self-registration	3
2.2	Login	6
2.3	Change Password	6
2.4	Password validity and requirements	7
2.5	Password forgotten or expired	7
2.6	Account locked	9
2.7	Settings	9
2.8	Notifications	11
3	Import / Export Requests	12
3.1	Creating an Import Request	12
3.2	Creating an Export Request	15
3.3	Request Status	20
4	Endorsement Requests	20
4.1	Endorsement of an import/export	20
4.2	Endorsements for import or export within the time limits	23
4.3	Important information regarding endorsements:	24
5	Cancellation of permits	24
6	Extension of permits	24
7	Different filter possibility, exporting to EXCEL and evaluations	24
7.1	Overview of the requests and view	24
7.2	Filters for import/export requests	25
7.3	Exporting Import / Export Requests to Excel	27
8	Registering new preparations	28
8.1	Creating a request for the registration of new preparations	28
9	Requests for the inclusion of foreign companies	30
9.1	Creating a request for the inclusion of foreign companies	30
9.2	Important information regarding the inclusion of foreign companies	31
10	Statistic Upload	31

1 Basic principles of NDS-WEB2

An import or export permit, issued by Swissmedic, is necessary for the import or export of controlled drugs. The NDS-WEB2 system can be used to submit requests for permits to Swissmedic electronically.

It is mandatory for the licence holder to report imports or exports that have taken place to Swissmedic within 10 working days. Imports or exports are only considered to have taken place when they are duly reported, and the reports constitute an integral part of the permit. They are also carried out via the NDS-WEB2 system.

Also you can simply and safely upload the excel file of the annual statistic.

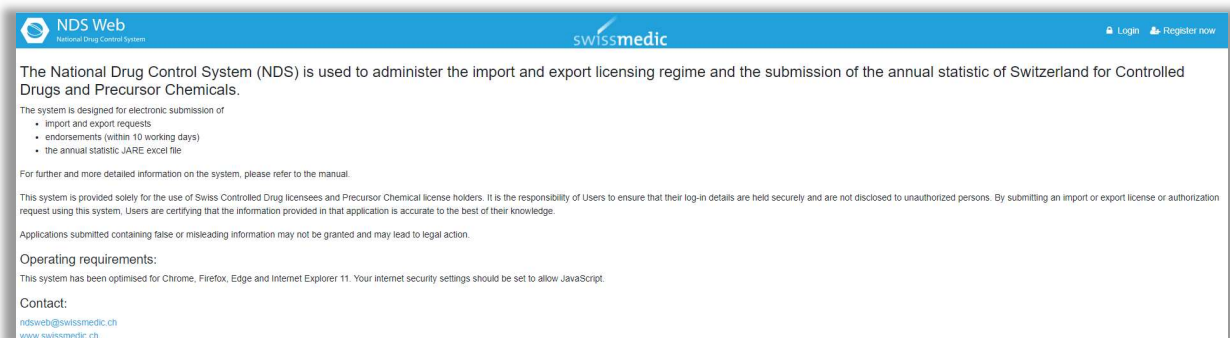
2 Registration and application

2.1 Self-registration

Employees of firms in possession of a licence for handling controlled drugs may register for the system.

Step 1: Home page

To reach the home page, use the URL www.ndsweb.swissmedic.ch



Step 2: Register now

Open the "Register now" tab (top right), and complete the user registration form.

Choose the user type Establishment and a user profile.

<p>User type</p> <p><input type="radio"/> Establishment <input type="radio"/> Cultivation</p> <p>Please pick one</p>	<p>User role</p> <p><input type="radio"/> Manager <input type="radio"/> User</p> <p>Please pick one</p>
---	--

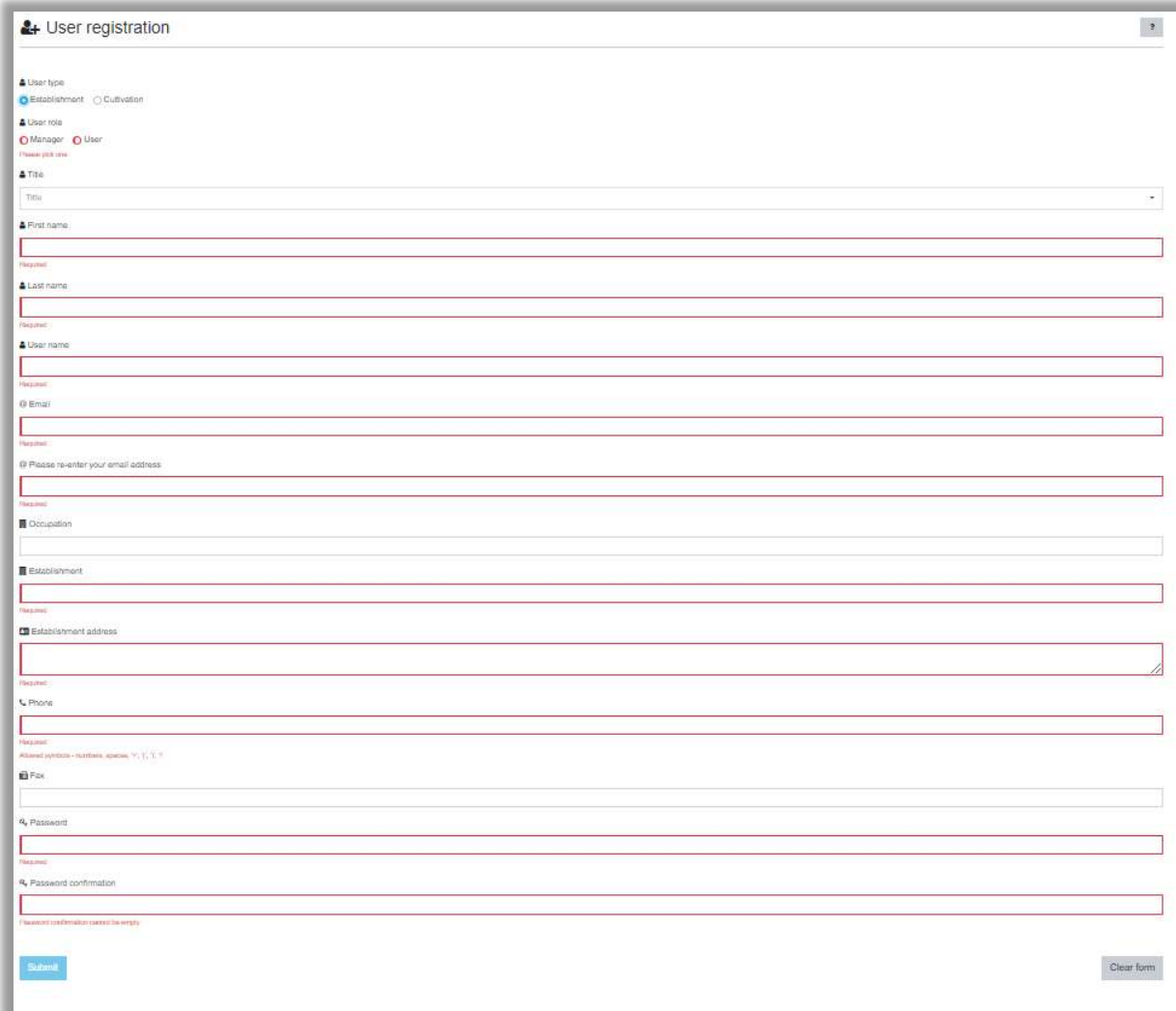
Manager: apply for import/export permits, new preparations/addresses, send in endorsements, upload the annual statistic

User: record a draft version for import/export permits, new preparations/addresses and endorsements, upload the annual statistic

Fill out the red framed boxes <required> and the address box with your details.

Choose a user name and enter a password.

Confirm that you are not a robot.



The screenshot shows the 'User registration' form. It includes fields for User type (Establishment or Cultivation), User role (Manager or User), Title, First name, Last name, User name, Email, Occupation, Establishment, Establishment address, Phone, and Password. The form also includes a 'Submit' button and a 'Clear form' button. Red boxes highlight the required fields: First name, Last name, User name, Email, Establishment address, Password, and Password confirmation.

Click on <Submit> to send the user request to Swissmedic.

The registration cannot be completed, if you entered a user name already in use. In this case you receive an error message. The registration can only be completed, if you change the data.

Step 3: Verification of the email address

The user receives a link to the indicated email address to verify the correctness of the address. Just click on the link; Swissmedic then receives a message, that the verification was successful.

We would like to make sure that you have the access to the email address you used during the registration on the NDSWEB.

[Validate](#)

After the validation, your registration request will be reviewed by the site administration.

You will receive notifications on the further steps.

Thank you.

This link is only valid for a certain time. If the link is no longer active, the following message appears:

✘ Email verification failed or invalid token!

Unfortunately, this link is inactive.

Please inform us if this is the case, so that we can resend you a link.

If the verification was successful, the following message appears:

✔ Email verification successful!

Thank you for verifying your email address.

Your registration request is under review. You will be notified on the outcome.

Step 4: Confirmation by the responsible person

Swissmedic sends a confirmation of user registration by email to the responsible person stated in the licence for handling controlled drugs. By signing it, the responsible person confirms that he / she is allowed to submit requests/upload the annual statistic or to prepare requests/upload the annual statistic. In case the account is for the responsible person, she/he can sign the user registration herself/himself.

Please return the signed form to Swissmedic by email ndsweb@swissmedic.ch.

Step 5: Account activation

On reception of the confirmation, Swissmedic activates the account. You have chosen your login credentials (user name and password) yourself and will therefore not receive any information in this regard.

Your account request was confirmed.

You can access the system under the link below:

[Access the platform](#)

Thank you.

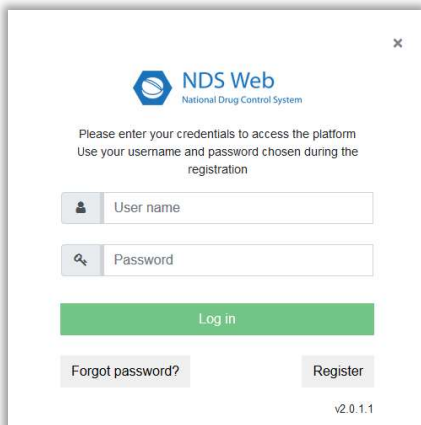
In case of a rejection from Swissmedic, you receive the following message:

Your NDSWEB account/registration request has been rejected or cancelled.

Thank you.

2.2 Login

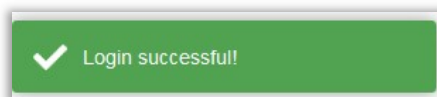
The "Login" function is reached via the homepage www.ndsweb.swissmedic.ch.



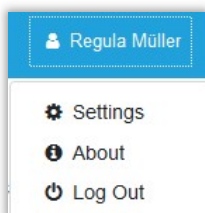
The login form is titled "NDS Web National Drug Control System". It contains the following elements:

- Instructions: "Please enter your credentials to access the platform. Use your username and password chosen during the registration."
- Input fields: "User name" and "Password".
- Buttons: "Log in" (green), "Forgot password?" (grey), and "Register" (grey).
- Version: "v2.0.1.1" at the bottom right.

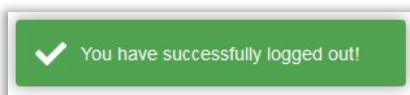
After the successful login, the following message appears:



To log out, please click on your name (top right) and the following menu appears:

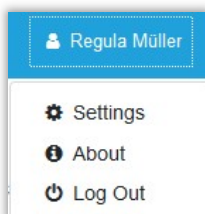


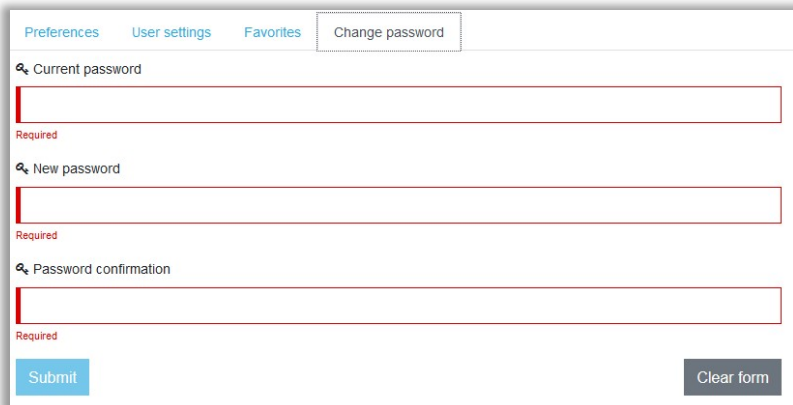
After the successful log out, the following message appears:



2.3 Change Password

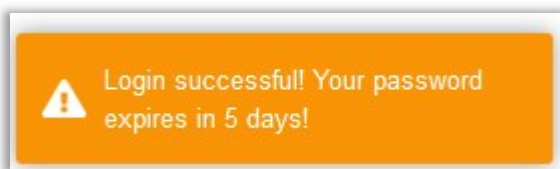
On logging in successfully, you may change your password in the menu <Settings>, under <Change Password>.





2.4 Password validity and requirements

A password is valid for 90 days at a time. 15 days before your password expires, a reminder appears on logging in.

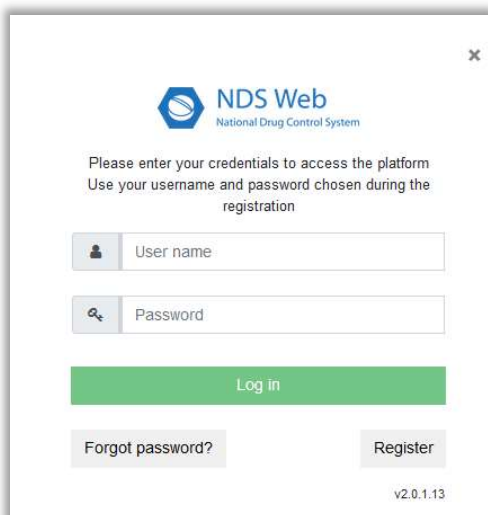


Password requirements:

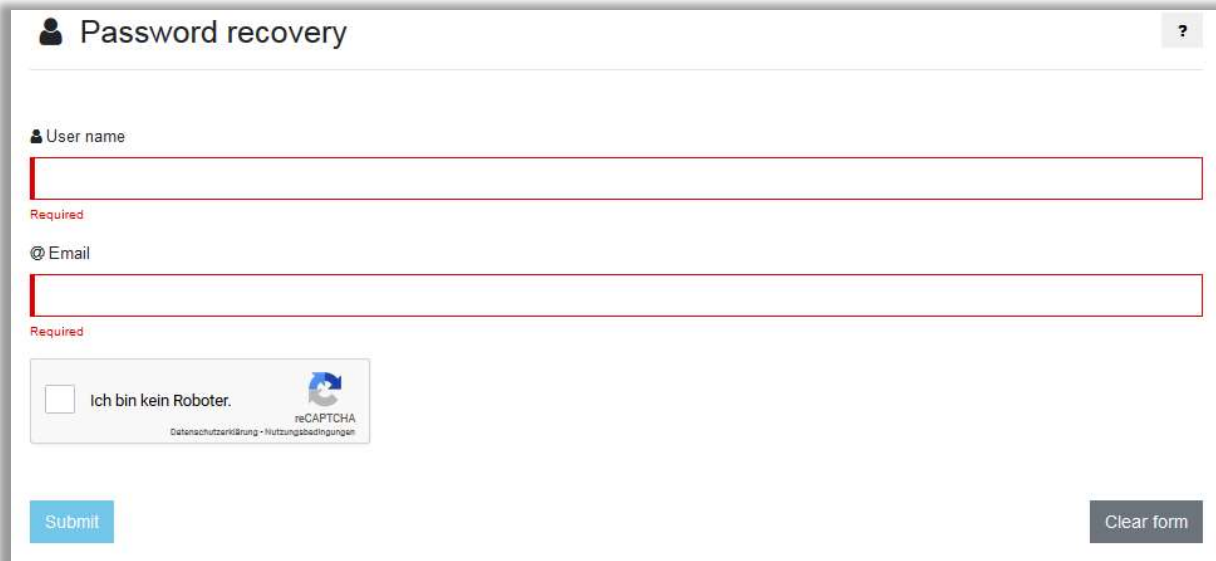
- At least 8 characters, max. 32 characters
- Upper case letters
- Lower case letters
- Numbers
- Special characters

2.5 Password forgotten or expired

If you have forgotten your password or if it has expired, please go to the <Login> screen and click <Forgot password?>.

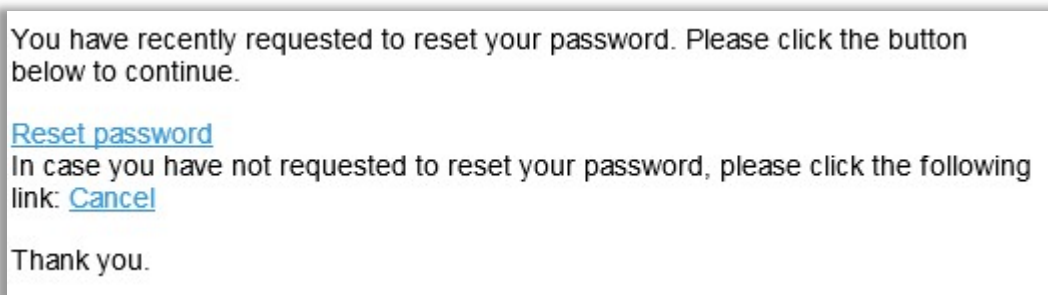


In the following screen, please enter your user name and email address.



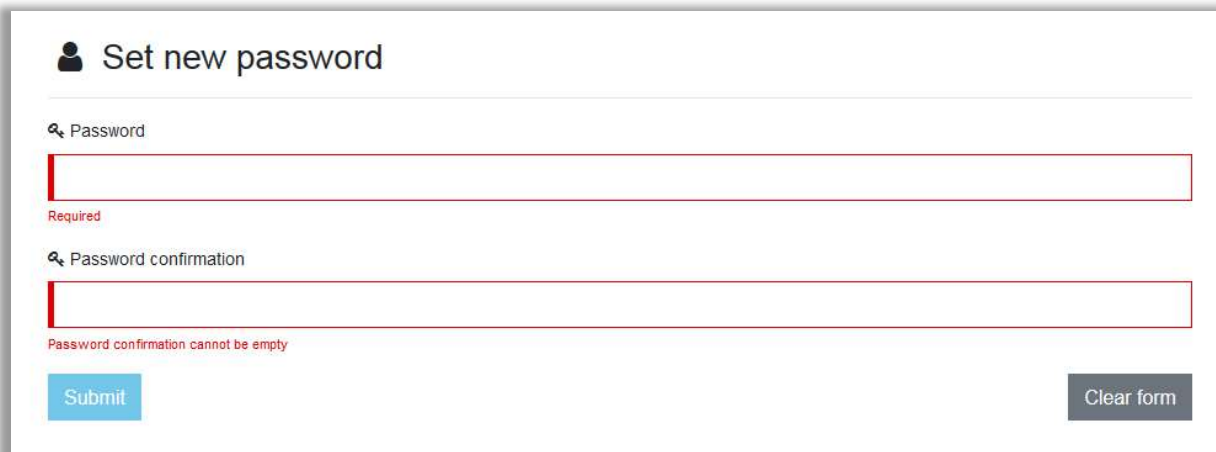
The screenshot shows a web form titled "Password recovery" with a user icon and a help icon. It contains two input fields: "User name" and "@ Email", both marked as "Required". Below these fields is a reCAPTCHA widget with the text "Ich bin kein Roboter." and "reCAPTCHA". At the bottom, there are two buttons: "Submit" (blue) and "Clear form" (grey).

After clicking <Submit> you receive an email with a link to reset your password.



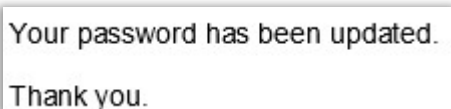
The screenshot shows an email message with the following text: "You have recently requested to reset your password. Please click the button below to continue." followed by a blue link "Reset password". Below this, it says "In case you have not requested to reset your password, please click the following link: [Cancel](#)". The message ends with "Thank you."

When clicking on <Reset password> the following screen opens:



The screenshot shows a web form titled "Set new password" with a user icon. It contains two input fields: "Password" and "Password confirmation", both marked as "Required". Below the "Password confirmation" field, there is a red error message: "Password confirmation cannot be empty". At the bottom, there are two buttons: "Submit" (blue) and "Clear form" (grey).

Enter the new password twice and click on <Submit>. Subsequently the login page opens and you receive an email with the following message:



The screenshot shows an email message with the following text: "Your password has been updated." followed by "Thank you."

If you waited too long to use the link, you receive the following message:

✖ Unfortunately, this link is inactive!

Please restart the process <Forgot Password?> anew.

2.6 Account locked

After entering a wrong password three times, your account is locked.

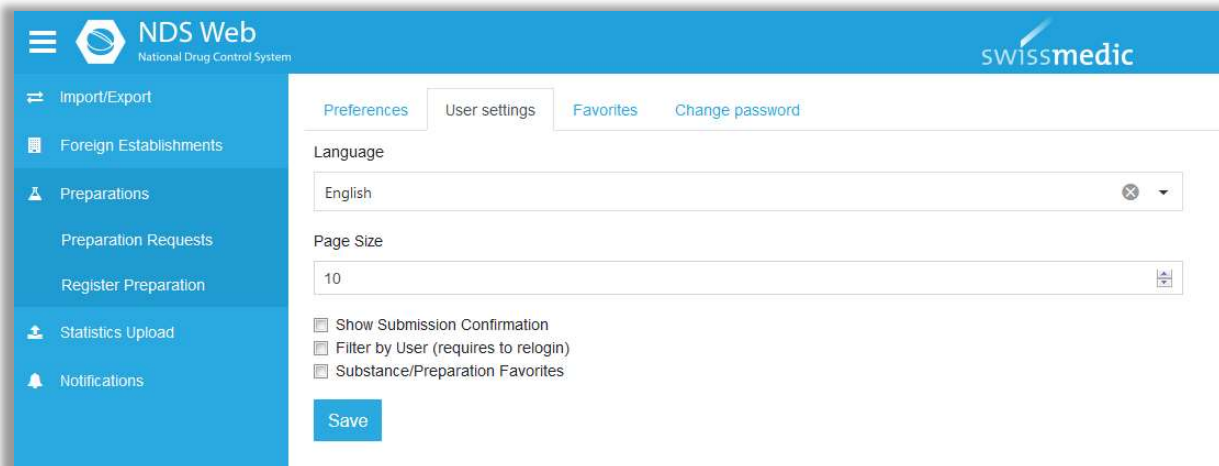
✖ Account is locked

Please send us an email to ndsweb@swissmedic.ch, so that we can unlock your account. You can then login again with your old password or continue as described in point 2.5 to set a new one.

2.7 Settings

In <Preferences> you find your user name, family and first name, email address and establishment code.

For additional user settings, please use the menu <User settings>.



The screenshot shows the 'NDS Web' interface with the 'User settings' tab selected. The left sidebar contains navigation links: Import/Export, Foreign Establishments, Preparations, Preparation Requests, Register Preparation, Statistics Upload, and Notifications. The main content area has tabs for Preferences, User settings, Favorites, and Change password. Under 'User settings', there are fields for 'Language' (set to English) and 'Page Size' (set to 10). Below these are three checkboxes: 'Show Submission Confirmation', 'Filter by User (requires to relogin)', and 'Substance/Preparation Favorites'. A 'Save' button is at the bottom.

Language: The system language available in Switzerland is English.

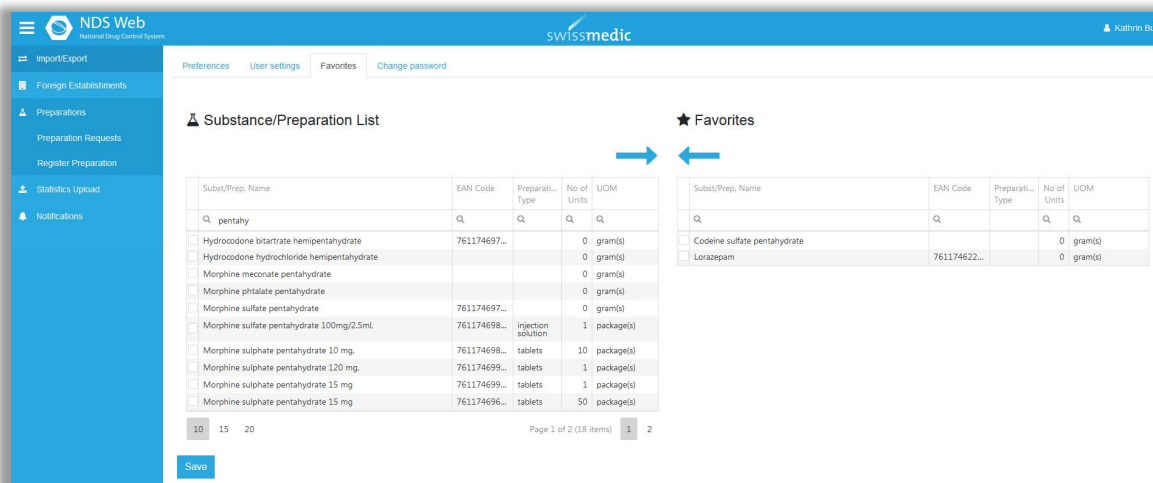
Page Size: This enables users to select the number of requests to display per page.

Show Submission confirmation: If this box is checked, a confirmation of the submission will be displayed once it is sent.

Filter by user: If this box is checked, you will only see the requests that you have submitted. Otherwise, you will see all requests submitted by your company.

Substance/Prep. Favourites: If this function is enabled, favourites may be recorded/shown.

Process favourites



The screenshot shows the NDS Web interface with the 'Substance/Preparation List' on the left and 'Favorites' on the right. A blue arrow points from the 'Substance/Preparation List' to the 'Favorites' section, indicating the process of adding items to favorites.

Subst/Prep. Name	EAN Code	Preparati... Type	No of Units	UOM
Q. pentahy	Q.	Q.	Q.	Q.
<input type="checkbox"/> Hydrocodone bitartrate hemipentahydrate	761174697...		0	gram(s)
<input type="checkbox"/> Hydrocodone hydrochloride hemipentahydrate			0	gram(s)
<input type="checkbox"/> Morphine meconate pentahydrate			0	gram(s)
<input type="checkbox"/> Morphine phtalate pentahydrate			0	gram(s)
<input type="checkbox"/> Morphine sulfate pentahydrate	761174697...		0	gram(s)
<input type="checkbox"/> Morphine sulfate pentahydrate 100mg/2.5ml	761174698...	injection solution	1	package(s)
<input type="checkbox"/> Morphine sulphate pentahydrate 10 mg.	761174698...	tablets	10	package(s)
<input type="checkbox"/> Morphine sulphate pentahydrate 120 mg.	761174699...	tablets	1	package(s)
<input type="checkbox"/> Morphine sulphate pentahydrate 15 mg	761174699...	tablets	1	package(s)
<input type="checkbox"/> Morphine sulphate pentahydrate 15 mg	761174696...	tablets	50	package(s)


Page 1 of 2 (18 items) 1 2

Save

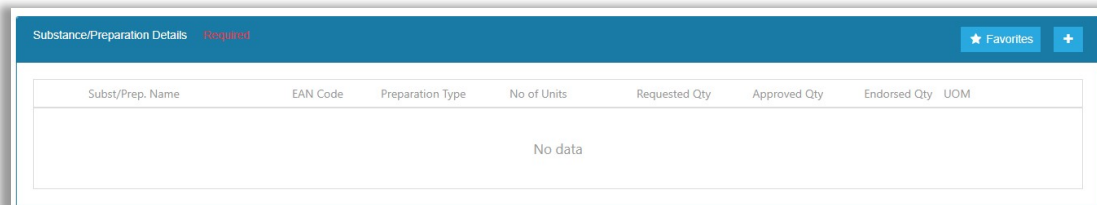
Clicking on <Favorites> opens the favourites. By using the field "Substance/Preparation List" you can search for the name of a substance or a preparation and click the box to select it. Use → to add the substance / preparation to your favourites.

If you wish to remove a substance or a preparation from your favourites, click on the box for the corresponding substance / preparation and remove it by clicking on ←.

To make the changes permanent, please click on <Save> (bottom left).

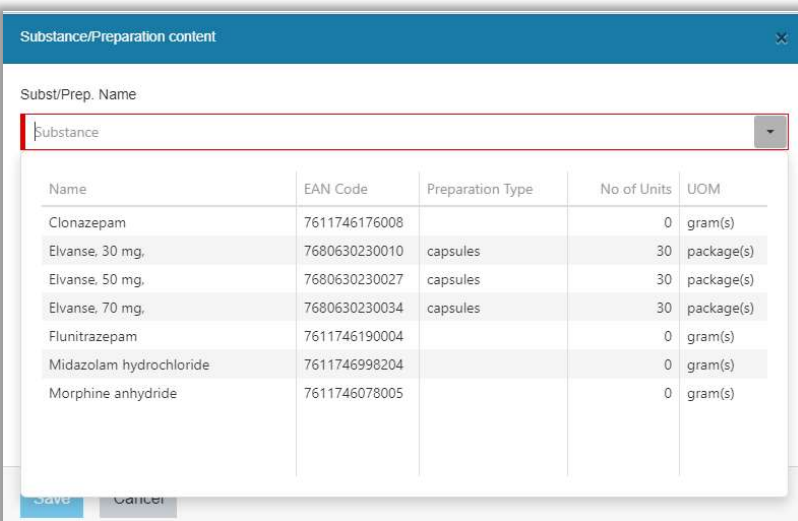
When creating a new request, the activated favourites are indicated with a star  Favorites.

Clicking on the <Favourites> option means that it is only possible to select from the favourites.



The screenshot shows the 'Substance/Preparation Details' form. It has a 'Requested' status and a '★ Favorites' button. The table below is empty with the text 'No data'.

Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
No data							




The screenshot shows the 'Substance/Preparation content' form. It has a search bar with the text 'Substance' and a table below it.

Name	EAN Code	Preparation Type	No of Units	UOM
Clonazepam	7611746176008		0	gram(s)
Elvanse, 30 mg.	7680630230010	capsules	30	package(s)
Elvanse, 50 mg.	7680630230027	capsules	30	package(s)
Elvanse, 70 mg.	7680630230034	capsules	30	package(s)
Flunitrazepam	7611746190004		0	gram(s)
Midazolam hydrochloride	7611746998204		0	gram(s)
Morphine anhydride	7611746078005		0	gram(s)

Save Cancel

If you would like to access all substances / preparations when entering a request, click on the star to remove the display of favourites.

This symbol  indicates that it is again possible to select from all the substances / products.

Substance/Preparation Details Required All Subst/Prep +							
Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
No data							

This way, it is possible to switch between favourites and all substances / preparations without changing the basic setting in <User settings>.

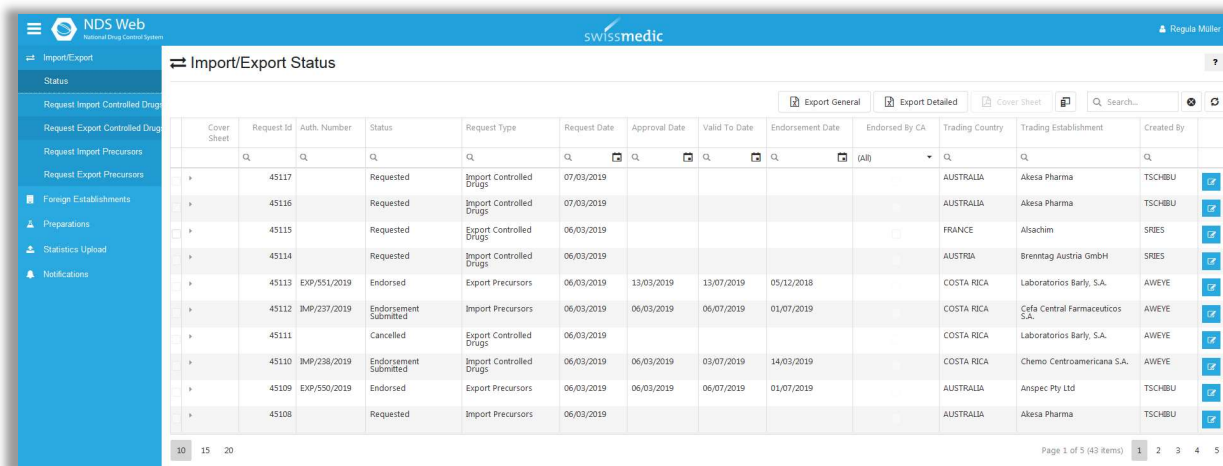
2.8 Notifications

Here you will find important information or news and the manual for NDS-WEB2. Please check this menu regularly.

</

3 Import / Export Requests

In the <Import/Export> menu, select <Status> for an overview of your requests.



Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45117		Requested	Import Controlled Drugs	07/03/2019				(All)	AUSTRALIA	Akessa Pharma	TSCMBU
	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akessa Pharma	TSCMBU
	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE	Alsachim	SRIES
	45114		Requested	Export Controlled Drugs	06/03/2019					AUSTRIA	Brenntag Austria GmbH	SRIES
	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA	Laboratorios Barly, S.A.	AWIWE
	45112	IMP/237/2019	Endorsement Submitted	Import Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		COSTA RICA	Cefa Central Farmaceuticos S.A.	AWIWE
	45111		Cancelled	Export Controlled Drugs	06/03/2019					COSTA RICA	Laboratorios Barly, S.A.	AWIWE
	45110	IMP/238/2019	Endorsement Submitted	Import Controlled Drugs	06/03/2019	06/03/2019	03/07/2019	14/03/2019		COSTA RICA	Chemo Centroamericana S.A.	AWIWE
	45109	EXP/550/2019	Endorsed	Export Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		AUSTRALIA	Anspec Pty Ltd	TSCMBU
	45108		Requested	Import Precursors	06/03/2019					AUSTRALIA	Akessa Pharma	TSCMBU

3.1 Creating an Import Request

Step 1: Select request type

Request Import Controlled Drugs

Request Import Precursors

Requests for precursors must be made separately from those for controlled drugs.

Step 2: Request details

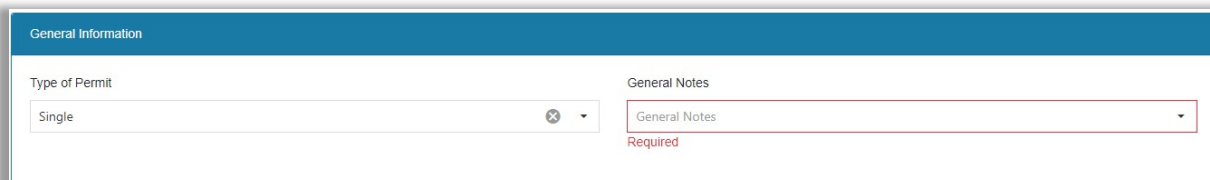
All red framed fields marked <required> are compulsory.

Type of permit:

State whether you are requesting a single or general permit here.

General Notes:

For import requests, it is compulsory to state whether the import is for re-export (within the calendar year) or for domestic use.



General Information

Type of Permit: Single

General Notes: General Notes

Required

Importer Details:

The details of the company you are applying for a request for are already pre-entered.

Importer Details	
Establishment	Swissmedic, Abteilung Betäubungsmittel
Address	Hallerstrasse 7
City	Bern
State	BE
Zip Code	3012

Exporter Details:

Please choose the country and company name of the exporter. Pay attention to companies with more than one entry to choose the correct one.

Exporter Details	
Country	<input type="text" value="Country"/>
	Required
Establishment	<input type="text" value="Establishment"/>
	Required



Substance/Preparation Details:

Details on the substances and preparations can be entered here: .

Substance/Preparation Details Required							
Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
No data							

Substance/Preparation content	
Subst/Prep. Name	
<input type="text" value="Morphine HCl 10mg/1ml"/>	
EAN Code	Preparation Type
<input type="text" value="7611746962144"/>	<input type="text" value="ampoules"/>
No of Units	UOM
<input type="text" value="100"/>	<input type="text" value="package(s)"/>
Requested Qty	
<input type="text" value="100"/>	
<input type="button" value="Save"/>	<input type="button" value="Cancel"/>

To save the details, click [Save](#).

Substance/Preparation Details								All Subst/Prep	+
	Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM	
1.	Morphine HCl 10mg/1ml	7611746962144	ampoules	100	100	0	0	package(s)	 

Attachments:

Attach a pdf of the special permit or other documents necessary for issuing the permit. More than one attachment is possible.

Attachments

Authorization Attachments

File Name	File Size (Kb)
No data	



Please attach a file

Comments:

Comments to Swissmedic can be made under <User comments>, e.g. additional information that should appear on your invoice, the CASRN of substances or for bulk shipments, the number of tablets per kg.

Comments


Type	Source	Comments	Created By	Creation Date
No data				


A text field appears when clicking on . After entering the comment, saving it by clicking on  is absolutely necessary! Without saving, the comment is deleted!

Comments

Type	Source	Comments	Created By	Creation Date

If a preparation or the foreign company's address is not included in the drop-down lists, they can be requested under <Preparations>, <Foreign Establishment> respectively. See sections 7 and 8.

 Foreign Establishments

 Preparations

Step 4: Submit request

You can save the request as draft version or submit it directly.

Submit Request

Save as Draft

The following confirmations are displayed once the request has been successfully submitted:

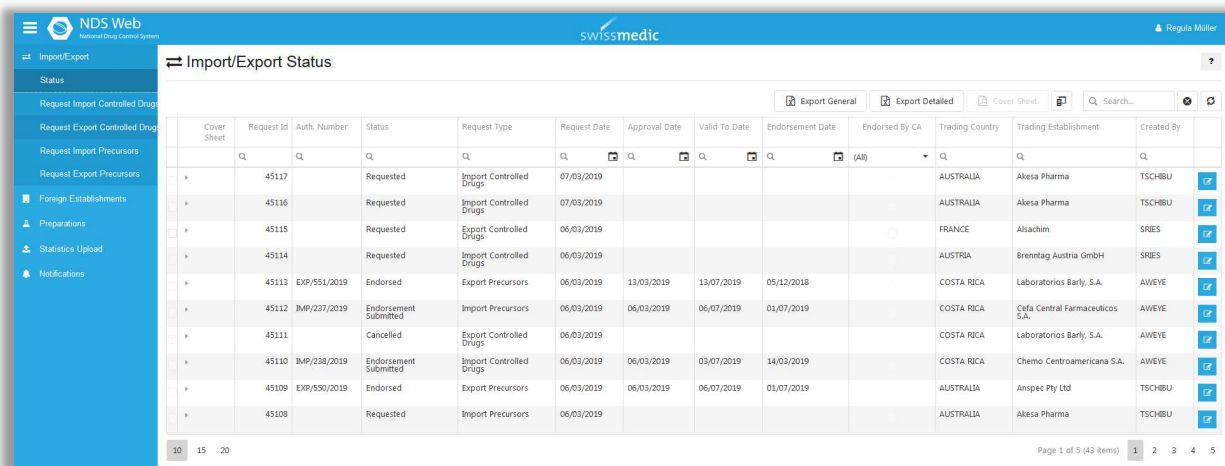


In the overview of requests, under <Import/Export>/<Status>, use  to see the details of the request.

WARNING: Once the request has been submitted, no further modifications are possible.

3.2 Creating an Export Request

In the <Import/Export> menu, select <Status> for an overview of your requests.



Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45117		Requested	Import Controlled Drugs	07/03/2019				(All)	AUSTRALIA	Akessa Pharma	TSCHBU
	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akessa Pharma	TSCHBU
	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE	Alsachim	SRIES
	45114		Requested	Import Controlled Drugs	06/03/2019					AUSTRIA	Brenntag Austria GmbH	SRIES
	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA	Laboratorios Barly, S.A.	AWEYE
	45112	IMP/237/2019	Endorsement Submitted	Import Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		COSTA RICA	Cyfa Central Farmaceuticos S.A.	AWEYE
	45111		Cancelled	Export Controlled Drugs	06/03/2019					COSTA RICA	Laboratorios Barly, S.A.	AWEYE
	45110	IMP/238/2019	Endorsement Submitted	Import Controlled Drugs	06/03/2019	06/03/2019	03/07/2019	14/03/2019		COSTA RICA	Chemo Centroamericana S.A.	AWEYE
	45109	EXP/550/2019	Endorsed	Export Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		AUSTRALIA	Anspec Pty Ltd	TSCHBU
	45108		Requested	Import Precursors	06/03/2019					AUSTRALIA	Akessa Pharma	TSCHBU

Step 1: Select request type

All red framed fields marked <required> are compulsory.

Request Export Controlled Drugs

Request Export Precursors

Requests for precursors must be made separately from those for controlled drugs on other lists.

Step 2: Request details

Type of permit:

State whether you are requesting a single or general permit here.

General Information	
Type of Permit	<input type="text" value="Single"/>

Exporter Details:

The details of your company are already filled in.

Exporter Details	
Establishment	Swissmedic, Abteilung Betäubungsmittel
Address	Hallerstrasse 7
City	Bern
State	BE
Zip Code	3012

Importer Details:

Please choose the country and company name of the importer. Pay attention to companies with more than one entry to choose the correct one.

Importer Details	
Country	<input type="text" value="Country"/>
	Required
Establishment	<input type="text" value="Establishment"/>
	Required

Import authorisation document:

Since electronic import authorisations are not yet recognised on an international level, it is essential to include the original of the import document from the importing country, when creating an export request.

The following information regarding the import document, on which the request is based, should be included in the request:

- Document number (Number)
- Date of issue of the document (Date)
- pdf of the permit (see previous page)

Import Authorization Document ▲

Number

Required

Date

Required

Substance/Preparation details:

Use  to enter the details regarding the substances and preparations.

Substance/Preparation Details Required							
<div> All Subst/Prep. + </div>							
Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
No data							

Substance/Preparation content

Subst/Prep. Name

EAN Code

Preparation Type

No of Units

UOM

Requested Qty

Save

Cancel

To save the information, click .

Substance/Preparation Details							
<div> All Subst/Prep. + </div>							
Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
1. Morphine HCl 10mg/1ml	7611746962144	ampoules	100	100	0	0	package(s)

Attachments:

Attach pdf of foreign import permit (for precursors, also include the End User Statement as an attachment) or other documents necessary for issuing the permit. More than one attachment is possible.

Attachments

Authorization Attachments Required

File Name	File Size (Kb)
No data	



Please attach a file

Comments:



Comments to Swissmedic can be made under <User comments>, e.g. additional information that should appear on your invoice, the CASRN of substances or for bulk shipments, the number of tablets per kg.

Comments

Type	Source	Comments	Created By	Creation Date ↓
No data				

A text field appears when clicking on . After entering the comment, saving it by clicking on  is absolutely necessary! Without saving, the comment is deleted!

Comments

Type	Source	Comments	Created By	Creation Date ↓
				 

If a preparation or the foreign company's address is not included in the drop-down lists, they can be requested under <Preparations>, <Foreign Establishment> respectively. See sections 7 and 8.

 Foreign Establishments

 Preparations

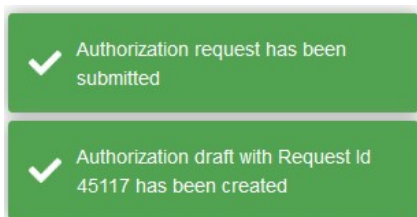
Step 3: Submit request

You can save the request as draft version or submit it directly.

Submit Request

Save as Draft

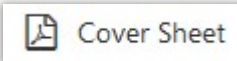
The following confirmations are displayed once the request has been successfully submitted:




Step 4: Cover sheet

Once an export request has been submitted successfully, the <Cover sheet> function can be activated (in status Requested) using the check box.

	Cover Sheet	Request Id	Auth. Number	Status	Request Type
	<input type="checkbox"/>	Q	Q	Q	Q
	<input type="checkbox"/>	45117		Requested	Import Controlled Drugs
	<input type="checkbox"/>	45116		Requested	Import Controlled Drugs
	<input checked="" type="checkbox"/>	45115		Requested	Export Controlled Drugs



After the cover sheet has been generated, the corresponding request is marked with the flag symbol .

Step 5: Sending the original import document with the cover sheet

The cover sheet contains the most important information on the request, and is used to submit the original of the import document. This information permits Swissmedic to uniquely assign the documents to the requests.

In the overview of requests, under <Import/Export>/<Status> use  to see the details of the request.

WARNING: Once the request has been submitted, no further modifications are possible.

IMPORTANT: Please note these aspects regarding import/export requests:

General aspects:

- Only create requests once all the documentation has been received, and then send this to Swissmedic immediately.
- Swissmedic will cancel requests with incorrect information in the foreign address or regarding the substance / preparation.
- Precursors: these requests are set <in review> on reception, since a PEN request must be made. In all cases, Swissmedic issues the permits once a positive response to the PEN request is received.

Export Requests:

- The import authorisation from the importing country constitutes the basis for the export permit.
- The WEB request contains the details regarding the authorisation number and date of issue, plus a pdf of the import authorisation.

- The original of the import authorisation must be sent to Swissmedic by post, together with the cover sheet.
- Cancelling: you receive an email with the information that your request has been cancelled. The reason for cancellation is noted in the request when opening it all the way on the top.

↔ **Import Controlled Drugs Authorization - Cancelled**
Cancellation Reason: test

3.3 Request Status

The following status types are possible:

Draft

Requested

In Review

Approved

Cancelled

Draft endorsement

Endorsement Submit.

Endorsed

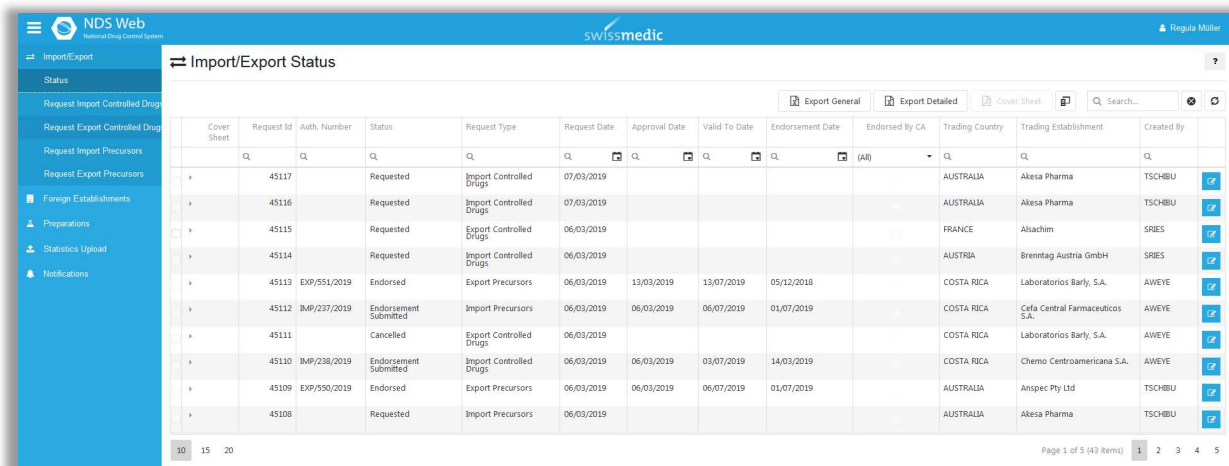
Endorsement Cancel.

Expired

4 Endorsement Requests


4.1 Endorsement of an import/export

In the <Import/Export> menu, select <Status> for an overview of your requests.




Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45117		Requested	Import Controlled Drugs	07/03/2019				(All)	AUSTRALIA	Akessa Pharma	TSCHEBU
	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akessa Pharma	TSCHEBU
	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE	Alsachim	SRIES
	45114		Requested	Import Controlled Drugs	06/03/2019					AUSTRIA	Brenntag Austria GmbH	SRIES
	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA	Laboratorios Barly, S.A.	AWEYE
	45112	IMP/237/2019	Endorsement Submitted	Import Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		COSTA RICA	Cyfa Central Farmaceuticos S.A.	AWEYE
	45111		Cancelled	Export Controlled Drugs	06/03/2019					COSTA RICA	Laboratorios Barly, S.A.	AWEYE
	45110	IMP/238/2019	Endorsement Submitted	Import Controlled Drugs	06/03/2019	06/03/2019	03/07/2019	14/03/2019		COSTA RICA	Chemo Centroamericana S.A.	AWEYE
	45109	EXP/550/2019	Endorsed	Export Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		AUSTRALIA	Anspec Pty Ltd	TSCHEBU
	45108		Requested	Import Precursors	06/03/2019					AUSTRALIA	Akessa Pharma	TSCHEBU

Step 1: Select Request

Use the filter function  to search for the corresponding requests by means of different search criteria such as permit number, status, validity date, etc.

Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country
	Q	Q	Q	Q	Q	Q	Q	Q	(All)	Q
»	45117		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA
»	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA
»	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE
»	45114		Requested	Import Controlled Drugs	06/03/2019					AUSTRIA
»	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA

Use  to see details of the request.

Step 2: Enter the delivery date

Enter the delivery date, which must be within the validity of the permit, under <Endorsement Date>.

General Information

Type of Permit

Single

Endorsement Date

Required

Customs Declaration

Information regarding <Customs Declaration> and a pdf of the permit with customs stamp as an attachment is not required.

Step 3: Enter the delivered quantity

Proceed as follows to enter the delivered quantity:

1. Click on <Edit> in Substance / Preparation Details:

Substance/Preparation Details							
Subst/Prep. Name	EAN Code	Preparation Type	No of Units	Requested Qty	Approved Qty	Endorsed Qty	UOM
1. Phentermine HCl 15 mg	7611746944379	capsules	30	3	3	0	milligram(s)

2. Enter the quantity to be delivered under <Endorsed Qty>. The delivered quantity cannot exceed the approved quantity.

Substance/Preparation content

Subst/Prep. Name

Phentermine HCl 15 mg

EAN Code

7611746944379

Preparation Type

capsules

No of Units

30

UOM

milligram(s)

Requested Qty

3

Approved Qty

3

Endorsed Qty

0

Save

Cancel

- Click on **<Save>** (bottom left) to save the entry

Save

Cancel

- If necessary, attachments regarding the endorsement can be attached here.

Attachments

Authorization Attachments

File Name	File Size (Kb)
Test PDF leer.pdf	8

Endorsement Attachments

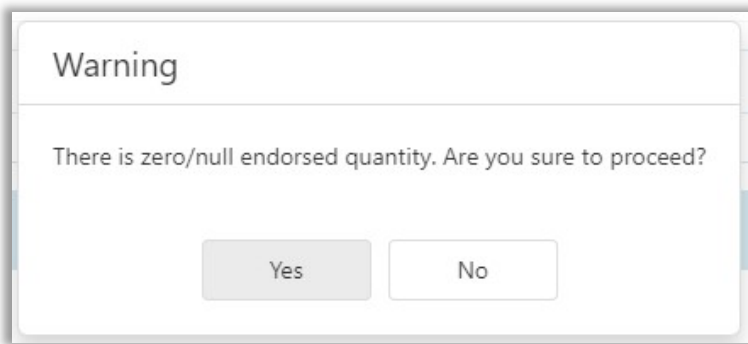
File Name	File Size (Kb)
No data	

Please attach a file

Step 4: Submit endorsement

Submit Endorsement

If a 0 quantity was entered, the following message appears:



Is the 0 quantity an error, click "No" and enter the quantity again, saving the amount entered.

The following confirmations are displayed once the endorsement has been successfully submitted:



After a successful delivery a submission of the originals bearing the official stamp is not required, since these are kept at the company. In the case of follow-up questions, Swissmedic may request the documents.

WARNING: Once the request has been submitted, no further modifications are possible.

4.2 Endorsements for import or export within the time limits

In accordance with Arts. 30 and 34, Ordinance on the Control of Narcotics (BetmKV, SR 812.121.1), a report on the delivery (endorsement) must be provided within the following time limits:

- Single permit : 10 working days following delivery
- General permit: 10 working days following the end of the calendar year

For this reason, endorsements are only possible up to 14 days after the permit expires. After that, the requests change to the "expired" status and an electronic endorsement is no longer possible.

In order to avoid this, the user who has submitted the request receives an e-mail reminder 14 days before the permit expires.

In addition, users are recommended to search for requests by expiry date, using the corresponding filter, and check them.

If the status of a request nevertheless becomes "expired", the endorsement must be reported by e-mail to ndsweb@swissmedic.ch.

If the endorsement was carried out by Swissmedic without an endorsement request being submitted, <Endorsed by CA> is shown. Information regarding the quantity <Endorsed by CA> may be displayed but this is not compulsory. The relevant decision is taken by Swissmedic.

4.3 Important information regarding endorsements:

- Requests and endorsements belong together. All requests submitted via NDS-WEB must also be endorsed via NDS-WEB.
- Endorsements must be submitted within the time limits, but at the very latest 10 days after the permit expires.
- The originals bearing the official stamp no longer need be sent to Swissmedic by post. The originals must be kept at the company and may be required by Swissmedic in the case of follow-up questions.
- A pdf of the originals bearing the official stamp may be attached to the endorsements (optional).
- General permits are only endorsed at the end of the year, with the overall quantity.

5 Cancellation of permits

If a permit is no longer needed, or if no import or export took place, the permit is cancelled as follows:

- All the originals of the permit are returned to Swissmedic by post, with the comment on a note "To be cancelled".
- Using NDS-WEB, the cancellation takes place by entering the following details:
Quantity = 0
Note in User Comment: "Please cancel: originals will be / have been returned. Date of input into the system".

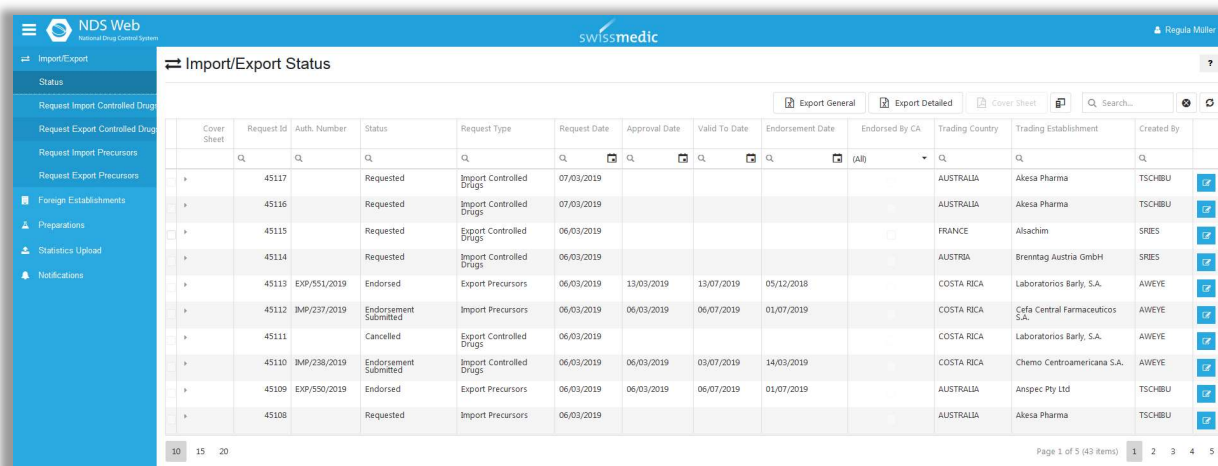
6 Extension of permits

Our permits **CANNOT** be extended. If our export permit expires and the foreign import permit is still valid, you may apply for a new export permit. To do so, please send us all the originals of the expired export permit and endorse it in NDS-WEB using 0, adding the corresponding text in the "Comments" field (see also under "Cancellation of permits" above). In the request for the new export permit (incl. attachments), please note in the comments that this one replaces the old permit (EXP/.... /....) and that the original of the foreign import permit is in Swissmedic's possession.

7 Different filter possibility, exporting to EXCEL and evaluations

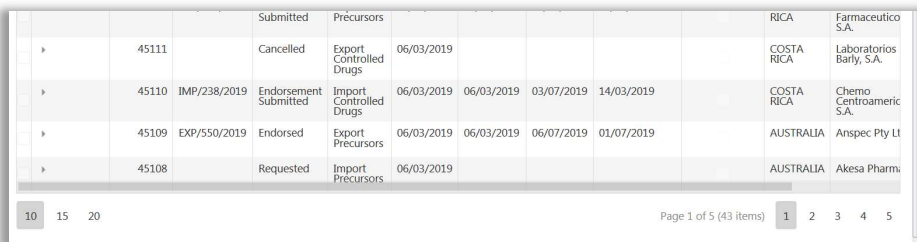
7.1 Overview of the requests and view

In the <Import/Export> menu, select <Status> for an overview of your requests.



Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45117		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCMBU
	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCMBU
	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE	Alcachim	SRIES
	45114		Requested	Import Controlled Drugs	06/03/2019					AUSTRIA	Brenntag Austria GmbH	SRIES
	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA	Laboratorios Barly, S.A.	AIWEYE
	45112	IMP/237/2019	Endorsement Submitted	Import Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		COSTA RICA	Cefa Central Farmaceuticos S.A.	AIWEYE
	45111		Cancelled	Export Controlled Drugs	06/03/2019					COSTA RICA	Laboratorios Barly, S.A.	AIWEYE
	45110	IMP/238/2019	Endorsement Submitted	Import Controlled Drugs	06/03/2019	06/03/2019	03/07/2019	14/03/2019		COSTA RICA	Chemo Centroamericana S.A.	AIWEYE
	45109	EXP/550/2019	Endorsed	Export Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		AUSTRALIA	Anspec Pty Ltd	TSCMBU
	45108		Requested	Import Precursors	06/03/2019					AUSTRALIA	Akesa Pharma	TSCMBU

Depending on your display resolution you may not see all rows/columns. By moving the bar (at the right hand side of the display and below the chart) you can scroll.

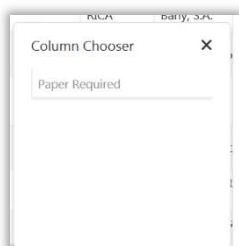


Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45111		Cancelled	Export Controlled Drugs	06/03/2019					RICA	Farmaceutico S.A.	
	45110	IMP/238/2019	Endorsement Submitted	Import Controlled Drugs	06/03/2019	06/03/2019	03/07/2019	14/03/2019		COSTA RICA	Laboratorios Barly, S.A.	
	45109	EXP/550/2019	Endorsed	Export Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		AUSTRALIA	Anspec Pty Ltd	
	45108		Requested	Import Precursors	06/03/2019					AUSTRALIA	Akesa Pharma	

By using the <Column Chooser> you can remove columns you do not need. The changed view cannot be saved and will be set to the original view once you leave the overview.



Click on this symbol and drag the column to be removed in the box. To show the column again, drag the column in the overview again.



The column <Paper Required> is inactive and cannot be moved.

You can also arrange the columns with drag and drop. The changed view cannot be saved and will be set to the original view once you leave the overview.

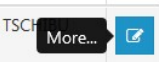

7.2 Filters for import/export requests

Über die Filterfunktion können Sie die entsprechenden Gesuche über verschiedene Kriterien, wie beispielsweise Bewilligungsnummer, Status, Gültigkeitsdatum etc. suchen.

Import/Export Status

Export General Export Detailed Cover Sheet Search...

Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By
	45117		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCHIBU
	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCHIBU
	45115		Requested	Export Controlled Drugs	06/03/2019					FRANCE	Alsachim	SRIES
	45114		Requested	Import Controlled Drugs	06/03/2019					AUSTRIA	Brenntag Austria GmbH	SRIES
	45113	EXP/551/2019	Endorsed	Export Precursors	06/03/2019	13/03/2019	13/07/2019	05/12/2018		COSTA RICA	Laboratorios Barly, S.A.	AWEYE
	45112	IMP/237/2019	Endorsement Submitted	Import Precursors	06/03/2019	06/03/2019	06/07/2019	01/07/2019		COSTA RICA	Cefa Central Farmaceuticos S.A.	AWEYE
	45111		Cancelled	Export Controlled Drugs	06/03/2019					COSTA RICA	Laboratorios Barly, S.A.	AWEYE

Über  gelangen Sie zu den Angaben des Gesuchs. Eine Kurzübersicht zu den Gesuchsangaben erhalten Sie auch über <Expand> .

?

Import/Export Status

Export General

Export Detailed

Cover Sheet

Q Search...

Cover Sheet	Request Id	Auth. Number	Status	Request Type	Request Date	Approval Date	Valid To Date	Endorsement Date	Endorsed By CA	Trading Country	Trading Establishment	Created By	
	Q	Q	Q	Q	Q	Q	Q	Q	(All)	Q	Q	Q	
	45117		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCHIBU	

Subst/Prep. Name

EAN Code

Preparation Type

No of Units

Requested Qty

Approved Qty

Endorsed Qty

UOM

Lorazepam

7611746228004

0


100

0 gram(s)

	45116		Requested	Import Controlled Drugs	07/03/2019					AUSTRALIA	Akesa Pharma	TSCHIBU	
--	-------	--	-----------	-------------------------	------------	--	--	--	--	-----------	--------------	---------	--

If a filter is active, **(FILTERED)** is shown in red.

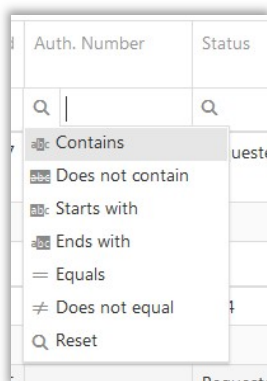
Import/Export Status (FILTERED)

Use the button  to activate/delete the filter.

Use the Refresh-button  to update the overview.

The following filters are available:

Click on the filter button  to choose from the following filter options:



Contains: All permits containing the inserted number/letter combination are shown.

Does not contain: All permits not containing the inserted number/letter combination are shown.

Starts with: All permits starting with the inserted number/letter combination are shown.

Ends with: All permits ending with the inserted number/letter combination are shown.

Equals: All permits matching exactly the inserted number/letter combination are shown.

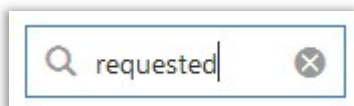
Does not equal: All permits not matching the inserted number/letter combination are shown.

Reset: filter is reset to its original position

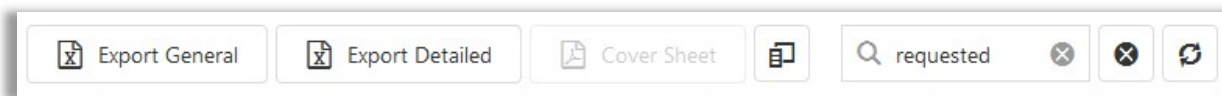
The following information can be filtered:

Request Id
 Auth. Number
 Status
 Request Type
 Request Date
 Approval Date
 Valid To Date
 Endorsement Date
 Endorsed By CA
 Trading Country
 Trading Establishment
 Created by

With the following filter function you can alternatively filter over all columns:

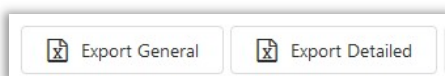


possible status types see 3.3.



7.3 Exporting Import / Export Requests to Excel

If a filter is needed to obtain other information that is contained in the request, all requests can be exported using the two buttons <Export General> or <Export Detailed> in order to be processed using Excel.



<Export general> exports only the information in the overview to Excel. <Export detailed> also includes the information available under <Expand>.

8 Registering new preparations

8.1 Creating a request for the registration of new preparations

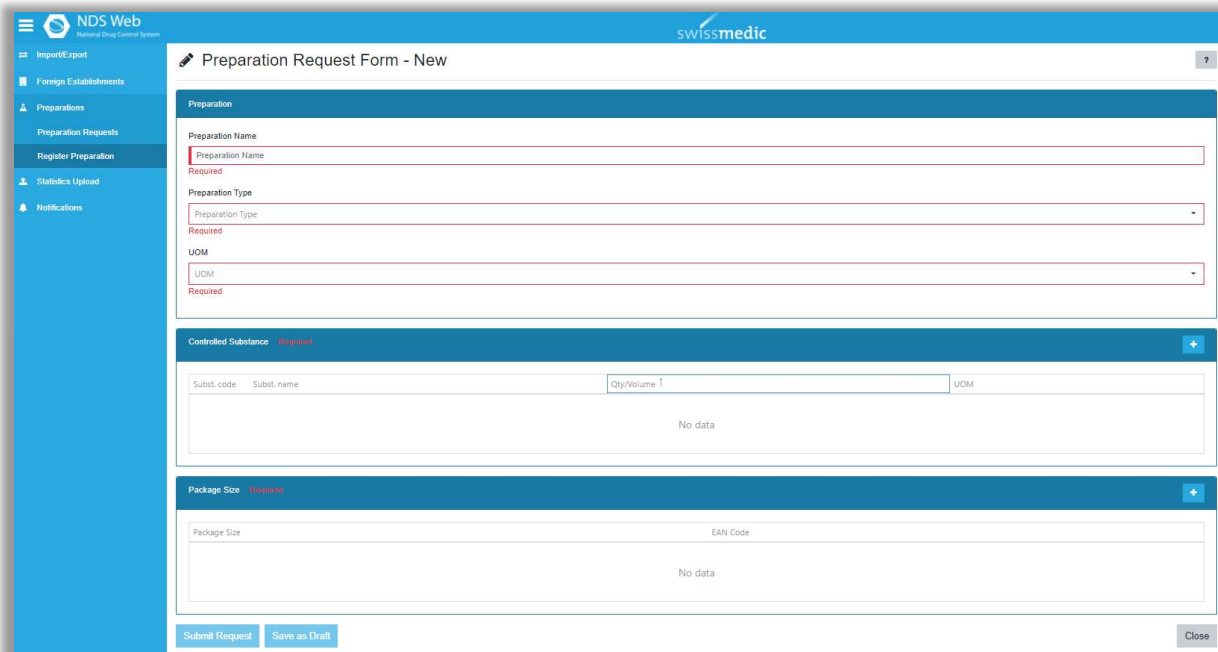
Use the <Preparations> menu, then <Preparation Requests> for an overview of preparations, for which you have already submitted requests.



Request Id	Status	Request Date	Approv./Cancel Date	Preparation Name	Preparation Type	UOM	Comments	Created By
186	Cancelled	02/05/2014		Test	ampoules	package(s)	test	MUO
3	Approved	30/11/2011		Pia Special 10mg/1ml	ampoules	package(s)		PMOSE
1	Cancelled	30/11/2011		Pia's Special 10 mg	tablets	package(s)	not under control	PMOSE

Step 1: <Preparations>/<Register Preparation>

Step 2: Preparation



Preparation

Preparation Name
Preparation Name
Required

Preparation Type
Preparation Type
Required

UOM
UOM
Required

Controlled Substance

Subst. code Subst. name Qty/Volume UOM

No data

Package Size

Package Size EAN Code

No data

Submit Request Save as Draft Close

Preparation Type:

Use the drop-down list to select the corresponding dosage form / pharmaceutical form.


Preparation Name:

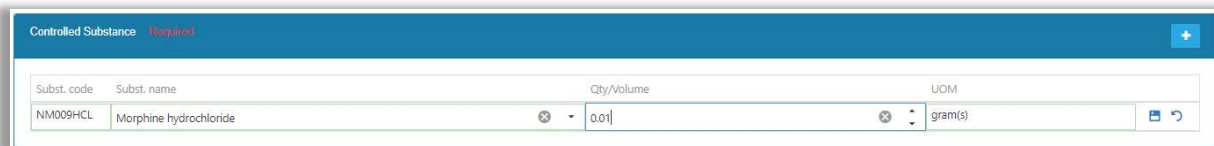
Enter the correct name of the preparation (using the name specified in the authorisation).

UOM, Unit of Measurement:

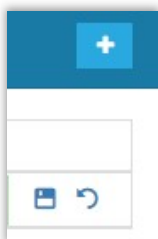
Select either "package(s)" or "bottles" as the UOM. The other options do not apply to Switzerland because the dosage form / pharmaceutical form is already stated under "Preparation Type".

Step 3: Controlled Substance

Use the  function to enter information on the substance (substance name and quantity in grams)




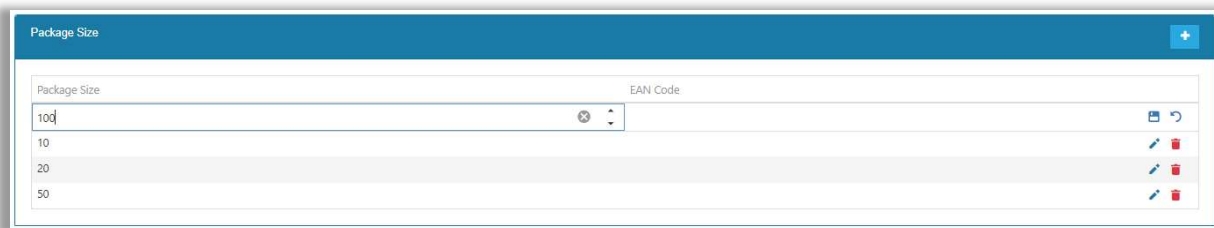
Use the <Save> button to save the information entered. Modifications can still be made until the request is submitted.



Step 4: Package Size

If more than one package size is needed, they must all be included in the same request.

Use  to enter the package sizes and if available the GTIN/EAN code. Confirm the information entered using <Save>.



Step 5: Submit Request

When a request has been submitted successfully, it appears in the overview with the status <Requested>.

As soon as Swissmedic approves the request, the user receives an e –mail confirmation. The new preparation appears in the selection on the following day and the status changes to <Approved>.

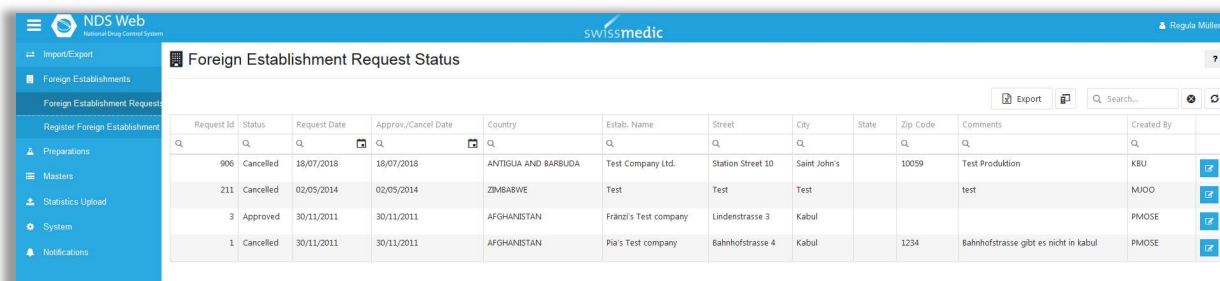
Substances **cannot** be applied for using this method.

IMPORTANT: If you only wish to request a new package size for an existing preparation, please send us an e-mail at ndsweb@swissmedic.ch .

9 Requests for the inclusion of foreign companies

9.1 Creating a request for the inclusion of foreign companies

In the "Masters" menu, select "Register Foreign Establishment" for an overview of those companies for which you have already requested inclusion.



Request ID	Status	Request Date	Approv./Cancel Date	Country	Estab. Name	Street	City	State	Zip Code	Comments	Created By
906	Cancelled	18/07/2018	18/07/2018	ANTIGUA AND BARBUDA	Test Company Ltd.	Station Street 10	Saint John's		10059	Test Produktion	KBU
211	Cancelled	02/05/2014	02/05/2014	ZIMBABWE	Test	Test	Test			test	MUJO
8	Approved	30/11/2011	30/11/2011	AFGHANISTAN	Fränzi's Test company	Lindenstrasse 3	Kabul				PMOSE
1	Cancelled	30/11/2011	30/11/2011	AFGHANISTAN	Pia's Test company	Bahnhofstrasse 4	Kabul		1234	Bahnhofstrasse gibt es nicht in kabul	PMOSE

Step 1: "Request New Foreign Establishment" function

Step 2: Request form



Foreign Establishment Request Form - New

Country: Required

Establishment: Required

Street: Required

City: Required

State:

Zip Code:

The full information must be identical to that stated on the foreign permit.

Step 3: Submit request

After the request has been submitted successfully, the request is shown in the overview with the status "Requested".

As soon as Swissmedic approves the request, the user receives an e-mail confirmation. The new company appears in the selection on the following day.

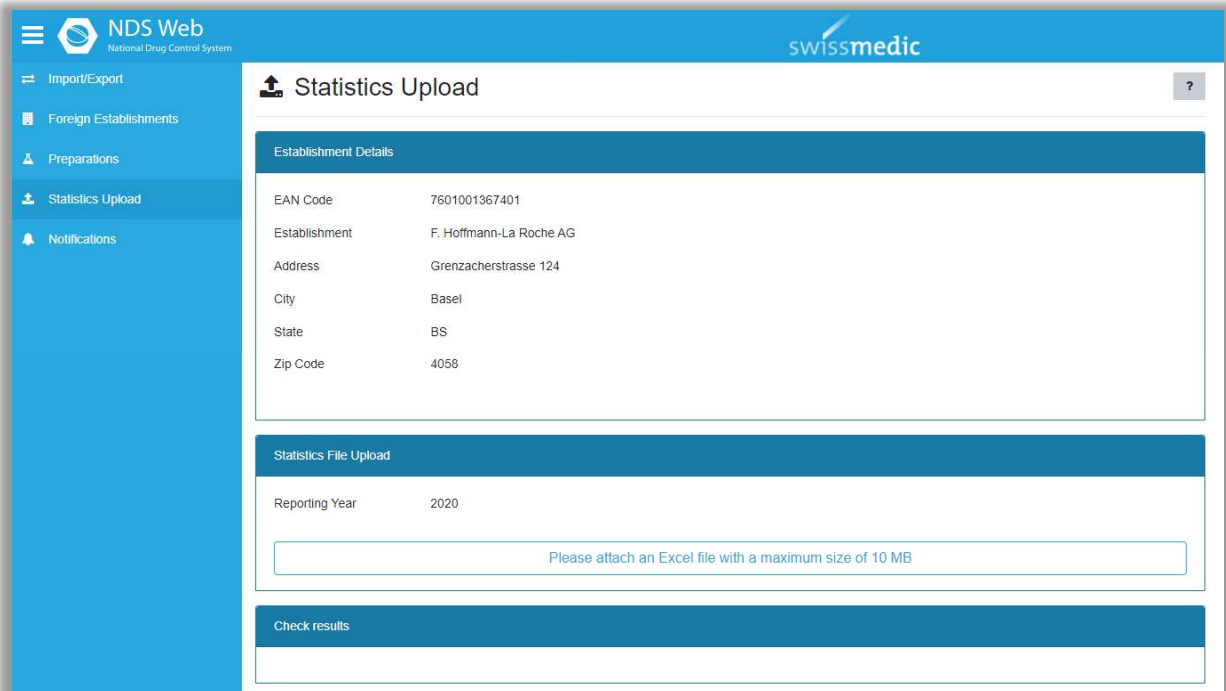
9.2 Important information regarding the inclusion of foreign companies

For minor differences in comparison with existing addresses, please send an email to ndsweb@swissmedic.ch in order for them to be verified in advance. In some cases, it is preferable for the change to be made to the existing address. In this case, the change is made directly by Swissmedic.

10 Statistic Upload

In this menu, you can upload the excel file of the annual statistic. Use the “Select” button to choose the right file and upload it with a double click.

Unter <Statistic Upload>/<Upload> können Sie die Excel-Liste für die Jahresrechnung direkt rauploaden. Mit der Schaltfläche Please attach an Excel file with a maximum size of 10 MB können Sie die entsprechende Datei aussuchen und mit einem Doppelklick rauploaden.

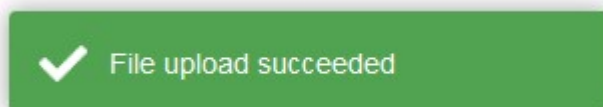


The screenshot shows the 'Statistics Upload' page in the NDS Web interface. The left sidebar contains a menu with 'Import/Export', 'Foreign Establishments', 'Preparations', 'Statistics Upload' (selected), and 'Notifications'. The main content area is titled 'Statistics Upload' and contains three sections:

- Establishment Details:** A table with the following information:

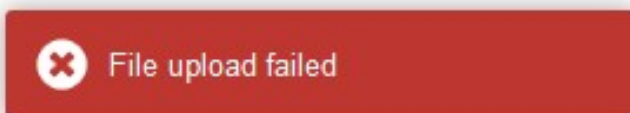
EAN Code	7601001367401
Establishment	F. Hoffmann-La Roche AG
Address	Grenzacherstrasse 124
City	Basel
State	BS
Zip Code	4058
- Statistics File Upload:** A section with a 'Reporting Year' field set to '2020' and a large text box containing the message: 'Please attach an Excel file with a maximum size of 10 MB'.
- Check results:** A section with a table for displaying the upload status.

You will then see under “Check Results” the message
 War das Hochladen erfolgreich, erhalten Sie folgende Meldung:



Zudem erhalten Sie ein Bestätigungsemail.

Falls die Datei nicht hochgeladen werden konnte, erhalten Sie folgende Fehlermeldung:



Unter <Check results> erhalten Sie noch zusätzliche Angaben zum Grund des Fehlers.

Check results

Check Results.
Errors summary. : 1. Empty Establishment Responsible Person
Report Upload Failed.

Check results

Check Results.
Protection key is invalid
Report Upload Failed.

Check results

Check Results.
Protection key doesn't exist
Report Upload Failed.