

User Manual

NDS-WEB2
Cultivation

Published by: <www.swissmedic.ch>

Authors: Swissmedic Narcotics Division



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1 Basic principles of NDS-WEB Cultivation

The NDS-WEB2 system can be used to submit request to Swissmedic electronically.

A cannabis cultivation licence (CCL) needs to be granted by Swissmedic prior to cultivate cannabis for medical purpose with a single cultivation authorization (SCA).

The necessary notifications are part of the authorization and must be submitted within 10 working days to Swissmedic.

The import of seed and planting material needed for the cultivation of cannabis requires an import permit from Swissmedic. The receipt of the goods has to be reported to Swissmedic within 10 working days.

2 Registration and application

2.1 Self-registration

Employees of firms in possession of a cannabis cultivation licence (CCL) for the cultivation of cannabis for medical purposes may register for this system.

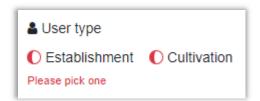
Schritt 1: Home page

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 "Cultivation".

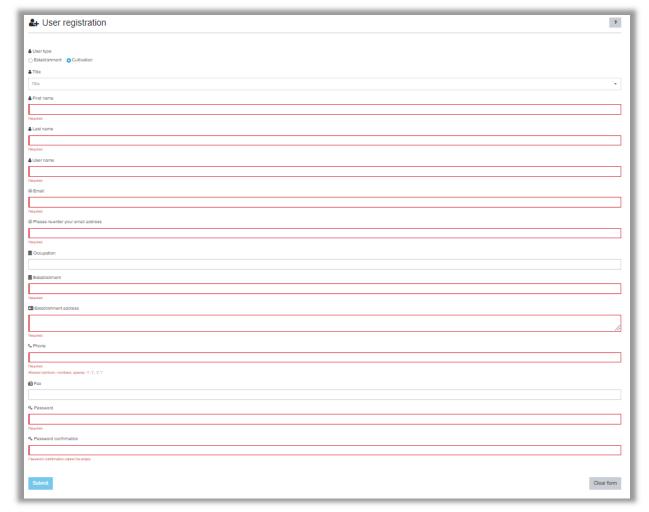


Fill out the red framed boxes <required> and the address box with your details.



Choose a user name and enter a password.

Confirm that you are not a robot.



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 this 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.

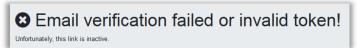
Validate

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:



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:



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 who is stated in the cannabis cultivation licence. By signing it, the responsible person confirms that the applicant is allowed to submit single cultivation authorization (SCA) requests and corresponding notifications as well as to upload the annual statistic (JARE) 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 via 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.

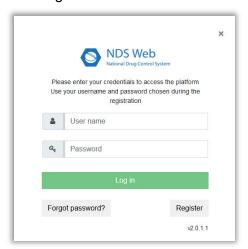


In case of a rejection from Swissmedic, you receive the following message:

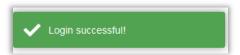
Your NDSWEB account/registration request has been rejected or cancelled.
Thank you.

2.2 Login

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



After the successful login, the following message appears:



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



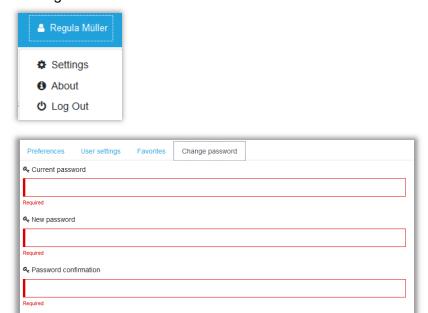
After the successful log out, the following message appears:





2.3 Change Passwort

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.



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

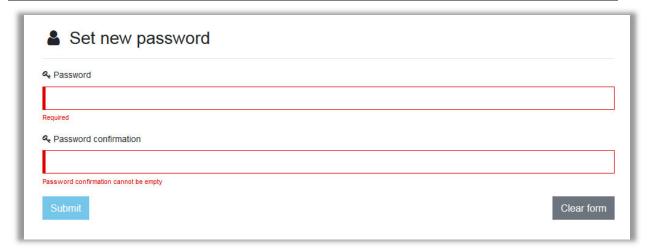
You have recently requested to reset your password. Please click the button below to continue.

Reset password In case you have not requested to reset your password, please click the following link: Cancel

Thank you.

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





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

Your password has been updated. Thank you.

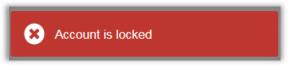
If you waited too long to use the link, you receive the following message:

❸ Unfortunately, this link is inactive!

Please repeat the steps <Forgot Password?>.

2.6 **Account locked**

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



Please send us an email via ndsweb@swissmedic.ch, so that we will 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.

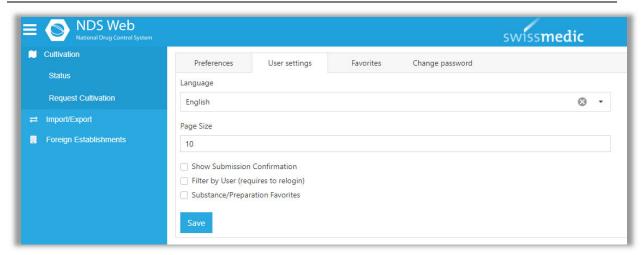
2.7 Settings

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

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



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Language: The system language available in Switzerland is English.

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

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

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

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

Process favourites



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 (resp. Cannabis-type) 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 keep the changes permanent, please click on <Save> (bottom left).

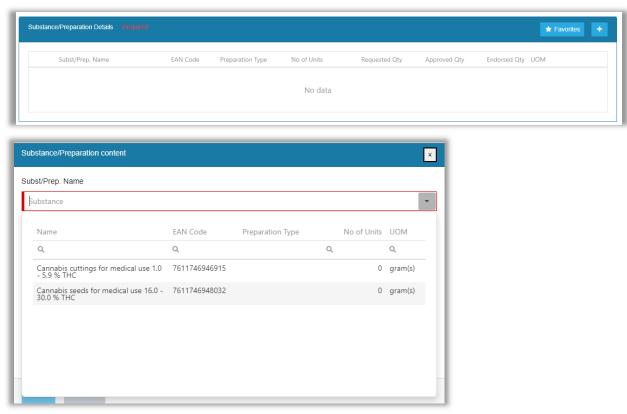
When creating a new request, the activated favourites are indicated with a star

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

Applying this selection, only favourites can be chosen.

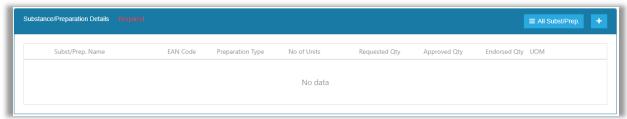


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If you would like to access all substances / preparations when entering a request, click on the star to remove the display of favourites.

This symbol indicates that it is again possible to select every substance/product.



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



3 Single Cultivation Authorization (SCA)

In the <Cultivation> menu, select <Status> for an overview of your requests.



3.1 Request und Notification Statuses

The following status types are enabled for a single cultivation authorization (SCA):

Draft

Requested

In Review

Approved

Closed

Cancelled

Expired

The following status types are possible for a Notification:

Requested

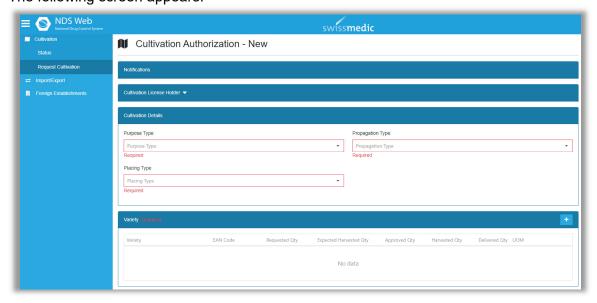
Acknowledged

Rejected

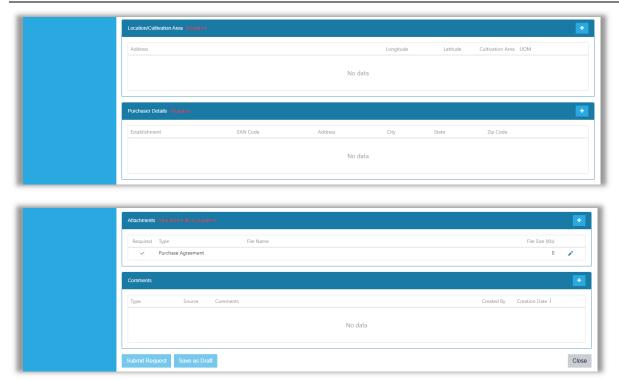
3.2 Creating a Single Cultivation Authorization (SCA)

Select Request Cultivation

The following screen appears:







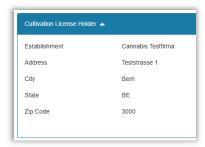
The red fields marked with <required> are compulsory.

Notifications

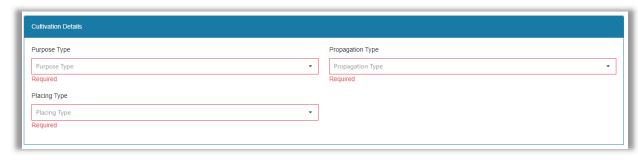
The section «Notifications» is not active as the single cultivation authorization (SCA) is not yet approved.

Cultivation License Holder

By clicking on the arrow Cultivation License Holder, the details of your establishment license for the cultivation of cannabis for medical purpose are shown.



Cultivation Details





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Purpose Type: Please choose «medical purposes» as Swissmedic is currently only

the competent authority for cannabis for medical purposes.

Propagation Type: Please choose the type of cannabis (seeds/stem cuttings) you intend

to cultivate.

Placing Type: Indicate if the cultivation takes place indoor or outdoor.

Variety

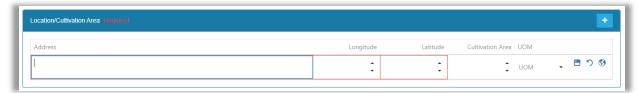
Via the details of the substance to be harvested can be entered.



Fill out the Requested Qty (Quantity) and the Expected Harvested Qty. Choose the Unit of Measurement (UOM) via drop-down which will be kept the same for notifications during the whole cultivation cycle. Please note that UOM "gram(s)" needs to be chosen for cannabis mother plants and cuttings whereas 1 gram(s) equals 1 piece plant.

Location/Cultivation Area

Please provide the physical address and in case this is not applicable, the latitude and longitude of the cultivation area. In addition, the size of the cultivated area must be indicated in hectares (ha) or square metres (m2) here.



By clicking on the globe, the cultivation address can also be selected via map.



Purchaser Details

Select the company from the drop-down list with which you concluded the purchase agreement and confirm the selection with the "save" button •.



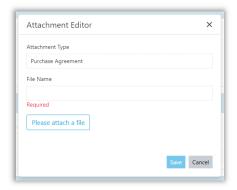


Attachments

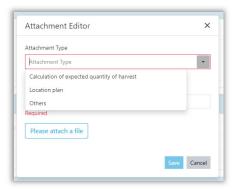
The document of traceability and the purchase agreement must be uploaded here. The individual document can be selected by clicking on ...



By applying Please attach a file the upload can be processed and has to be saved afterwards by pressing the <Save> button.



Additional attachments, i.e. explanation on the calculation of expected harvest, location plan etc. can also be uploaded.



Comments

To add a remark or additional information click on in the «Comments» filed. Please ensure to save these texts with the "Save" button, otherwise the "Comments" will not be transmitted.

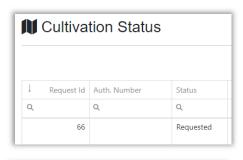


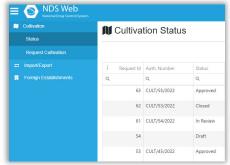
You can save the request as a draft by "Save as Draft", submit it via "Submit Request" or delete it with "Delete".





After saving as a draft ("Draft" status) or submitting the request, it appears in the overview (status "Requested").

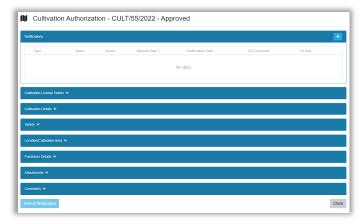




After Swissmedic has approved the single cultivation authorization (SCA), it appears with the status "Approved" and a number (CULT/xx/20xx) in the overview

3.3 Submission of Notifications

Click on on the right side and the screen below opens:



The possibility to enter notifications is only active in the "Approved" status.

The remaining information can be viewed by clicking on the white arrow, but can no longer be changed in this status.

Important information about Notifications:

- All fields marked in red which are labelled <required> contain mandatory data.
- > Entries always have to be saved by pressing the "Save" button (in the input field at the bottom right).





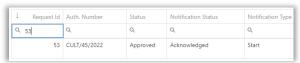
➤ To ensure that the notification is also sent to Swissmedic, it is essential to click on the "Submit Notification" button (at the very bottom after "Comments").



➤ The overview shows the transmitted message with the notification status "Reques-ted" and the notification type, e.g. "Start".



The confirmation of the notification by Swissmedic is indicated by the change of the "Notification Status" to "Acknowledged".



A message can also be rejected. In such a case, the status changes to "Rejected" and the message must be re-entered.



The reason for the rejection can be seen in the notification itself.

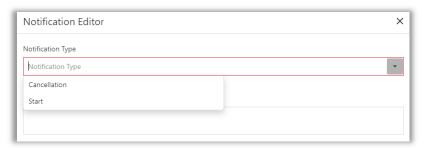


➤ To re-enter the notification, press the white plus • again.

By pressing the button • , the available message types appear. The first message that can be made after receiving the SCA, is to cancel or start the SCA.

You can select from the drop-down list:





3.3.1 Cancellation

Select "Cancellation" if the single cultivation authorization (SCA) cannot be started for any reason or if the validity of the SCA has expired without being "used".



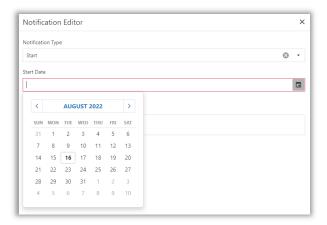
Save the date entry by pressing the "Save" button and submit the notification by pressing "Submit Notification".

3.3.2 Start

Select "Start" to report the start date of the single cultivation authorization (SCA).





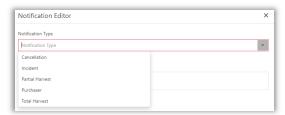


Save the entry by pressing the "Save" button. After saving, the notification appears as follows:



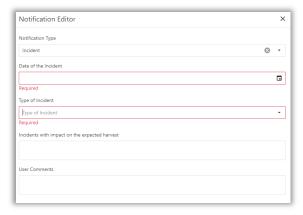
Submit the message via "Submit Notification".

After confirming the start date, several notifications can be selected, two of which "Total Harvest" and "Purchaser" are mandatory. "Incident" and "Partial Harvest" are optional and can be created several times.



3.3.3 Incident

Various incidents can be reported by an incident notification. After selecting "Incident" from the drop-down list, the date is required and the "Type of Incident" can be chosen from the drop-down list.



The following incidents can be chosen: Blackout



Others
Pest Infestation
Storm
Theft



In the field "Incidents with impact on the expected harvest" a more detailed description of the incident should be provided.

The "User Comments" are also available for further remarks. The entry must be saved using the "Save" button and then submitted using "Submit Notification".

3.3.4 Partial Harvest

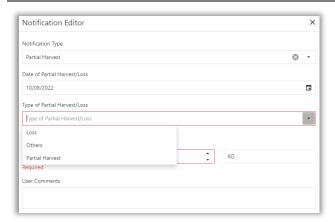
By using the notification type "Partial Harvest", partial harvests, losses or other notifications (e.g. mother plant) can be created.

Important: Even if partial harvest notifications are submitted, a "Total Harvest" notification still has to be submitted after the cultivation cycle.

The indication of date, type and quantity are mandatory. Additional information can be submitted in the section "Comments".





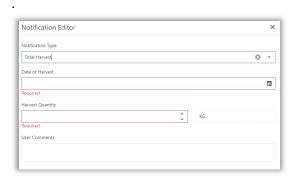


The entry must be saved using the "Save" button and then submitted using "Submit Notification".

3.3.5 Total Harvest

The notification of the total quantity must be reported via "Total Harvest", where the harvest date and the harvest quantity must be filled in.

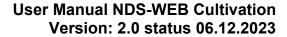
Attention: The unit of measurement (g, kg, t) is already pre-filled (as requested in the SCA) and the quantity must be reported accordingly.



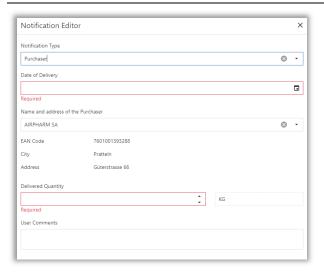
The entry must be saved using the "Save" button and then submitted using "Submit Notification".

3.3.6 Purchaser

A Single Cultivation Authorization (SCA) is completed by applying the notification type «Purchaser». The delivery date and the delivery quantity must be entered. The purchaser is automatically pre-filled by the system from the corresponding SCA.







The entry must be saved using the "Save" button and then submitted using "Submit Notification".

Once the purchaser notification has been approved by Swissmedic, the status of the SCA changes to "Closed" and is thus completed.



4 Import Requests

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



4.1 Creating an Import Request

Click on field Request Import Controlled Drugs

Step 1: Select request type

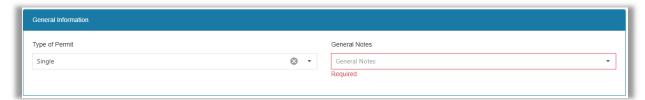
All fields marked in red, which are labelled <required>, contain mandatory data.

Type of permit:

Please keep the setting «Single».

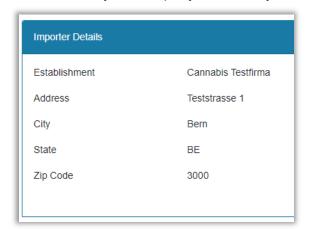
General Notes:

Choose <For Domestic Use>.



Importer Details:

The details of your company are already filled in.



Exporter Details:

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



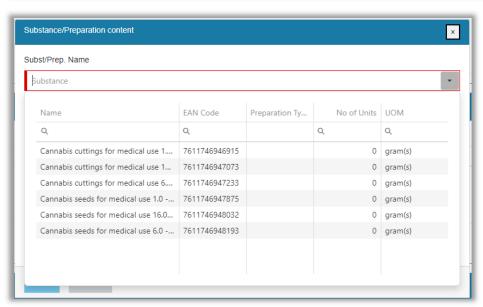


Substance/Preparation Details:

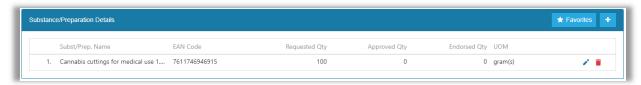
Details on the substance(s) can be entered here:

Note: Please choose UOM "gram(s)" for cannabis seeds and cuttings whereas 1 gram equals 1 piece.





To save the details, click Save



Attachments:

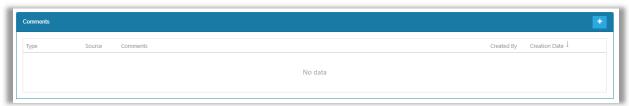
Attach pdf-files of documents necessary for issuing the permit. More than one attachment is possible.



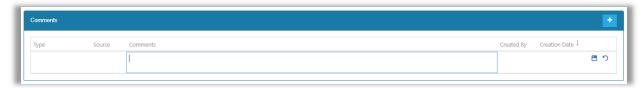


Comments:

Comments to Swissmedic can be made under <User comments>, e.g. additional information that should appear on your invoice, the number of seeds per kg.



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



If the foreign company address is not available in the selection, it can be requested via <Foreign Establishment>. See Chapter 7



Step 2: Submit Request

Click on Submit Request to submit the request to Swissmedic.

After successful submission, the following confirmation screens appear:



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 observations for Import Requests:

General:

- > Swissmedic will reject requests with incorrect information in the foreign address or the substance.
- Cancellation: You will receive an email informing you that the request has been cancelled. The reason for rejecting a request is shown at the top of the screen under Cancellation Reason.

4.2 Request Statuses

The statuses below are available:

Requested

In Review

Approved

Cancelled

Endorsement Submit.

Endorsed

Endorsement Cancel.

Expired

5 Endorsement Requests

5.1 Endorsement on an import

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

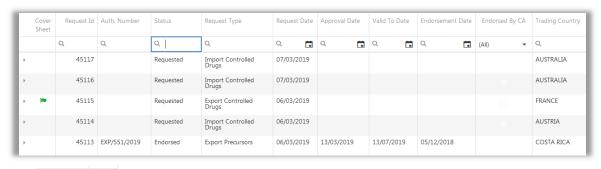


Step 1: Select Request

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



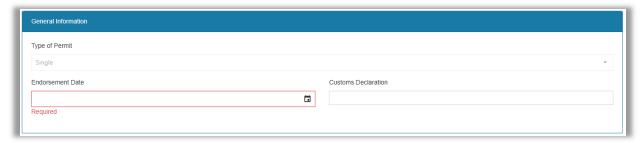
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Use to see details of the request.

Step 2: Enter the delivery date

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



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

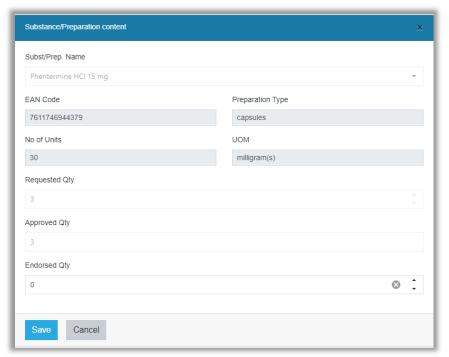
Proceed as follows to enter the delivered quantity:

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



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





3. Click on <Save> (bottom left) to save the entry



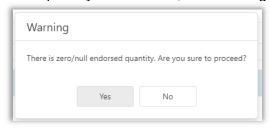
4. If necessary, attachments regarding the endorsement can be attached here.



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 douments.

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

5.2 Endorsements for imports within the time limit

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. Thereafter, 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 a reminder as an email, 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 respective decision is made by Swissmedic.

5.3 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 are no longer required to 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).

6 Cancellation of permits

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

- The whole set of original permits is 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 NDS-Web system".

7 Extension of permits

Our permits **CANNOT** be extended.

8 Various Filters, exports into EXCEL-format and Evaluations

8.1 Overview of the requests and view

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



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.



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.



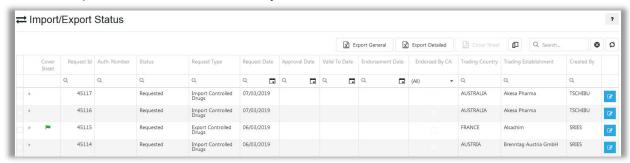


The column <Paper Required> is inactive and cannot be moved.

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.

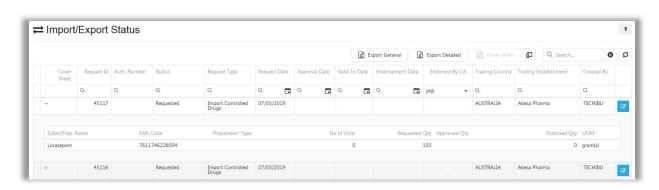
8.2 Filters for import requests

You can use the filter function Q to search for the relevant applications using various criteria, such as permit number, status, validity date, etc.



Click on to access the details of the application. You can also get a brief over-

view of the application details via <Expand>



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

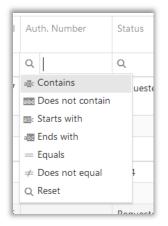
Use the button to activate/delete the filter.

Use the Refresh-button to update the overview.



The following filters are available:

Click on the filter button ^Q 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

Es kann nach folgenden Angaben gefiltert werden:

Request Id

Auth. Number

Status

Request Type

Request Date

Approval Date

Valid To Date

Endorsement Date

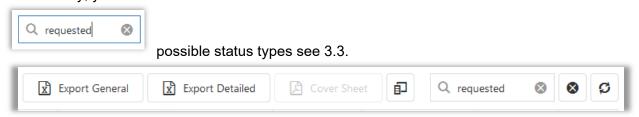
Endorsed By CA

Trading Country

Trading Establishment

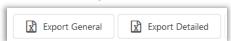
Created by

Alternatively, you can filter all columns via:



8.3 Export function into Excel-format for Import Requests

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>.



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.



Step 1: "Request New Foreign Establishment" function

Step 2: Request form

NDS Web National Drug Control System	swiss medic			
Cultivation Import/Export	Foreign Establishment Request Form - New	?		
Foreign Establishments	Country			
Foreign Establishment Requests	Country	•		
Register Foreign Establishment	Required Establishment			
	Establishment Required			
	Street Street			
	Required			
	City			
	Required State			
	State			
	Zip Code			
	Zip Code			
	Submit Request Save as Draft	Close		

ATTENTION: Please always leave the <State> field empty.

Schritt 3: Submit Request

Nach erfolgreicher Einreichung erscheint der Request in der Übersicht mit dem Status <Requested>

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 newly included company appears in the selection on the following working day.



10 Annual Statement - Cultivation of cannabis for medical purposes

10.1 Submission of Annual Statement (JARE) – Submit SPA Report

In the <SPA Cultivation> section, the <Submit SPA Report> menu takes you to the screen for entering the data for the annual financial statement for the reporting year and submitting it to Swissmedic.

Step 1: Function <Submit SPA Report>



Press to open the two sections Cannabis Cultivation and Cannabis Seeds and Seedlings to enter the relevant substances and add the appropriate data. Save the selection with the <Save>-button or delete an entire line of data with the "Delete" button If necessary, you can enter comments and explanations in the "Comments" field, which must be saved with the <Save>-button.

IMPORTANT: Substances with the same GTIN code (EAN code) may only be listed once per section, otherwise the error message < Substance code duplicate > will appear and it will not be possible to save the data. The data of every individual cultivation authorization for the same substance must therefore be combined for the same reporting year.

Step 2: Entering the data for the annual statement





Step 3: Submit Request

Press the button

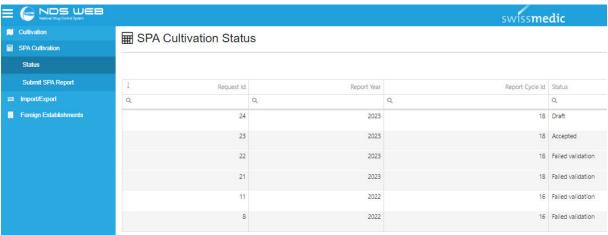
Submit Request

to submit your annual statement.

If the data record needs still to be edited, the draft can be saved by using

Save as Draft

10.2 Overview of Annual Statement – Status



The following statuses are shown below:

Draft Draft

Requested Annual statement submitted

Failed validation Annual statement failed technical validation and cannot be accepted.

Swissmedic will contact you.

Accepted Technical Validation of submitted annual statement successful.

Additional requests by Swissmedic are possible.