User guide for the narcotics web application

Federal Agency for Medicines and Health Products
Avenue Galilée 5/03
1210 BRUSSELS
Tel. + 32 2 528 40 00
Email: narcotics@fagg-afmps.be
Website: www.famhp.be

Table of contents

LIST OF ABBREVIATIONS AND TERMS

CoBRHA	**Common Base Registry for Healthcare Actor** The shared database of public institutions responsible for accreditation of healthcare actors in Belgium.
CSAM	Brings together a set of agreements, rules and services to organise identity and access management within e-government.
Domain	A group of applications managed by an access manager. 'Capacity' is the old term for domain.
e-Health	Belgian platform for information and communication technologies applied to health.
eID	The electronic identity card for Belgian citizens. The identity card is proof of registration in the national register.
FAMHP	Federal Agency for Medicines and Health Products.
HCO	**Health Care Organisation (HCO)** The HCO number is assigned to a healthcare facility by the accrediting authority. The HCO number is a unique designation for a healthcare facility within an accrediting authority. Therefore, in practice, there may be healthcare facilities with the same HCO number, but the combination of HCO number and accrediting authority will always be unique.
PAM	**Principal Access Manager** Principal access management officer of your enterprise who is able to delegate access management at any time by appointing access managers for each domain (application group). He/she may also designate a backup (co-chief access manager) to assist. The PAM is automatically an access manager, but is able to designate other access managers. Entity Access Manager (EAM) is the old term for PAM.
IAM	**Identity and access management** IAM solutions ensure that access to certain information and systems is limited to those who are identified (e.g. username or email), authenticated (e.g. verification via password or itsme) and authorised (e.g. for a particular application).
NISS	The unique identification number of a natural person with the Belgian social security system. For residents of Belgium, it is identical to the national register number. For non-residents of Belgium, it is their number in the BIS register (Source).
itsme	A mobile identification application that allows people with a Belgian identity card to access a wide range of online services, such as government platforms.
Crossroads Bank for Enterprises (CBE)	**Crossroads Bank for Enterprises** Central database that holds all identification data of all enterprises. The CBE therefore serves as an authentic source for all information about an enterprise.
LA	**Local administrator** An obsolete name for access manager (AM).
AM	**Access Manager** Is able to manage users and grant them access to various online services.

1. THE BASIS OF THE SYSTEM

Any delivery and receipt in Belgium of products containing substances listed in Annexes I, II and IV of the Royal Decree of 6 September 2017 may only be carried out on condition that they are registered in the digital system of the FAMHP (excluding preparations listed in Annexes Ic and IVc). This digital system replaces the paper narcotic order form.

The declaration in the system takes place after the event, as soon as possible after receipt or shipment of the goods. This can be done manually or integrated into management software. For each shipping note, a user must submit a separate declaration.

This chapter 'The basis of the system' applies both to manual (via the web application) and integration-based (via REST interface) entries. The rest of this document applies only to **manual entries**. A separate guide explaining the REST interface is available for integration.

1.1. DECLARATION

All market operators are expected to verify the delivery address and deliver only to licensed addresses. This is required not only by the aforementioned Royal Decree, but also by the Good Distribution Practices (GDP) rules. In addition, it is imperative that any change in a trading partner's data is reported in good time to the competent services (see Section 5.).

For pharmacies open to the public, it will largely concern **purchases**, i.e. receipts, of the narcotic drugs. Orders are repeatedly taken automatically by a server throughout the day and narcotic drugs are delivered immediately. The pharmacist must then record receipt via the web application after delivery. A sale is also possible, for example in the case of assistance between colleagues. This type of transaction must also be recorded, both by sender and recipient.

For its part, the **wholesaler/supplier** will mainly record **deliveries** to pharmacies. But receipts, in other words purchases from a manufacturer, other wholesalers, returns from a pharmacy etc. must also be recorded, of course.

1.2. CONTROL OF DECLARATIONS

The declaration of deliveries and receipts will be controlled by the FAMHP. Discrepancies between delivery and receipt will warrant further investigation. For this reason, where possible, it is important that declarants prepare and forward declarations of orders sent or received the previous day on a **daily** basis. The deadline for submitting a declaration is **30 days** from the date of receipt or shipping indicated on the declaration.

2. REGISTRATION – CONFIGURATION – LOGIN

Before the declaration can be made, the merchant must be **registered** (step 2.1.) and access to the application must be **configured** (step 2.2.). Steps 2.1. and 2.2. are executed once (see Figure 1).

After this has been done, the merchant can login (section 2.3.) and submit his declaration.

Important note for pharmacists
Pharmacists-in-charge and adjunct pharmacists with Belgian citizenship, both pharmacies open to the public and hospital pharmacies, can skip steps 2.1 and 2.2, since they are implicitly registered, and the application is already configured for them.

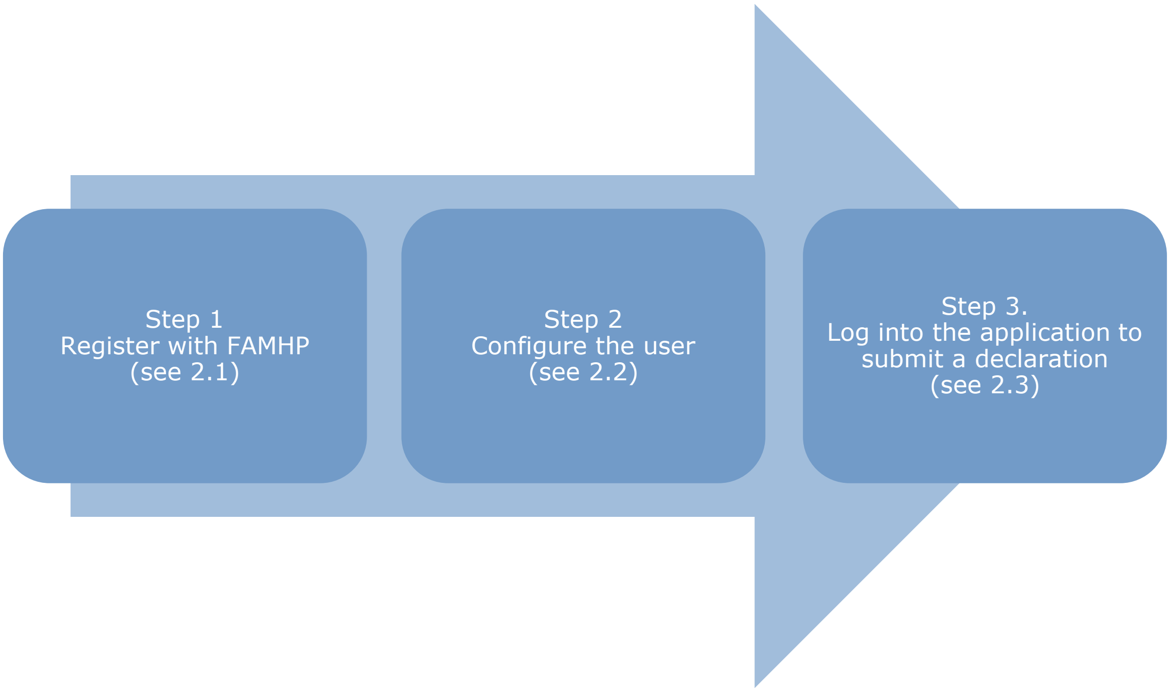


Figure 1: Steps to follow before submitting declarations

2.1. REGISTRATION WITH FAMHP (ONLY ONCE)

A trading partner that wishes to legally perform transactions involving narcotics must be licensed to do so (see section 4). The licence is issued by the FAMHP. For hospital pharmacists and pharmacists open to the public, the licence is granted implicitly.

2.2. USER ACCESS CONFIGURATION (ONLY ONCE)

The configuration of users for access (IAM) to the application must be done for:

1. merchants who are not pharmacists;
2. pharmacists-in-charge and adjunct pharmacists with foreign citizenship;
3. substitute pharmacists of a pharmacy open to the public.

Users must be configured by a statutory representative of the enterprise (see CBE) or by someone designated by that person as a representative.

Note for pharmacists-in-charge of a hospital pharmacy
In this version of the web application, only pharmacists-in-charge and adjunct-pharmacists have access to the web application. In the future, this will also be possible for substitute pharmacists and non-pharmacists.

2.2.1 TERMINOLOGY

The appointment of end users takes place through a number of government applications. This is quite complex as data from different databases are brought together and further updated (SME portal, national register, CoBHRA, etc.).

Keep in mind that old and new terms are used interchangeably in government applications. We prefer to use the new terms, although sometimes the application will show you the old term.

PAM Principal access manager [old term: EAM entity access manager or chief access manager]
The **principal access manager** is the main person responsible for access management for your enterprise. He/she may delegate the role to a co-PAM.
The PAM must appoint an access manager (him/herself or someone else) for a domain (group of applications). The PAM automatically becomes AM for each domain.

AM Access Manager [old term: LA Local Administrator]
The **access manager** performs user management. In this case, the AM provides access to various online services, e.g. to the services of FAMHP.
A co-access manager = person appointed as an additional AM [old term: co-local administrator].

Domain [old term: capacity]
A **domain** is a group of applications managed by an access manager.

Important note: the same person can take the role of PAM, AM, and user.

2.2.2. The steps

Configuring the end user is done once and involves several steps:

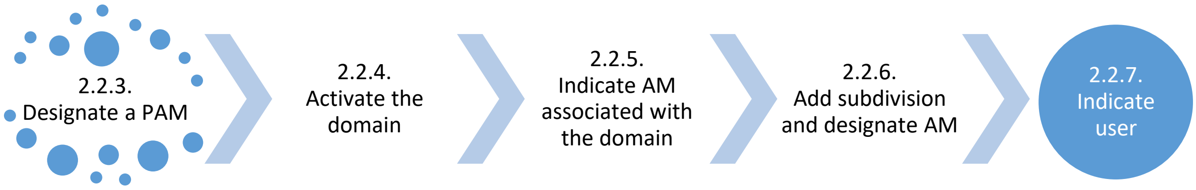


Figure 2: The steps for user configuration

Of course, if you have already performed a step, you can skip it.
If necessary, you can change the access data afterwards (Section 2.2.8.).

2.2.3. Designating a PAM

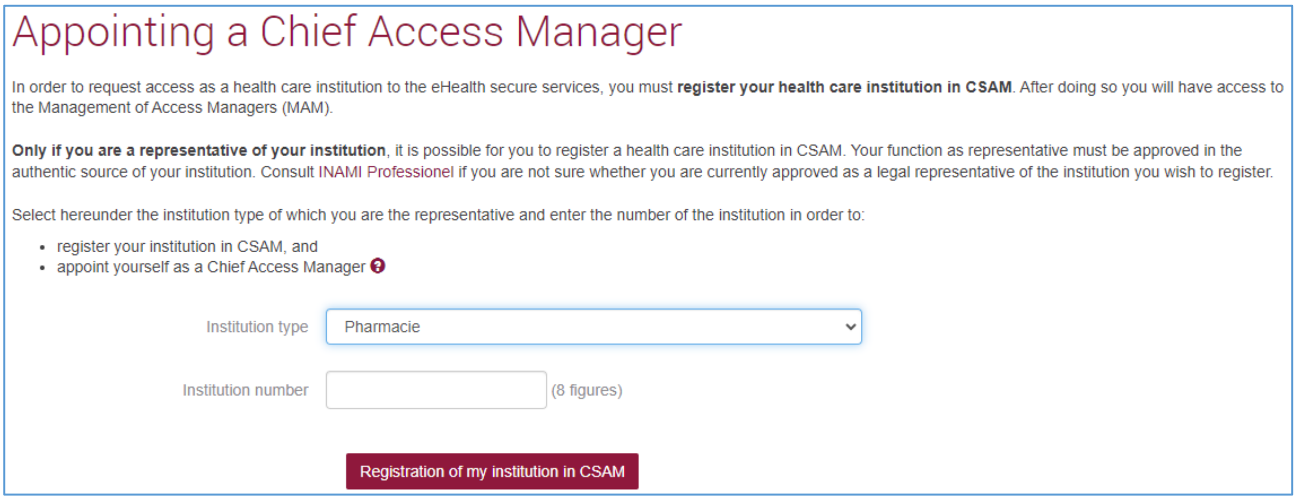
2.2.3.1. If this step has already been performed

You may have previously activated this person as a PAM on CSAM. For pharmacists-in-charge, this should be the case. The pharmacist-in-charge can then proceed to step 2.2.7.1.
Other PAMs can continue to step 2.2.4.

2.2.3.2. Designating the PAM if this step has not yet been carried out

2.2.3.2.1. For pharmacists of a pharmacy open to the public

1. Log in to this link;
2. Select "Pharmacie" under Institution type;
3. Enter the institution number (consisting of eight digits, i.e. the APB number and two control digits) of your pharmacy (see figure 3).
   The institution number corresponds to the RIZIV number of the pharmacy.
   The pharmacist-in-charge will find this number as follows:
   a. log into the web application
   b. click on "Submit a declaration"
   c. the number next to "Declarant ID" corresponds to the institution number


Appointing a Chief Access Manager

In order to request access as a health care institution to the eHealth secure services, you must **register your health care institution in CSAM**. After doing so you will have access to the Management of Access Managers (MAM).

Only if you are a representative of your institution, it is possible for you to register a health care institution in CSAM. Your function as representative must be approved in the authentic source of your institution. Consult INAMI Professionel if you are not sure whether you are currently approved as a legal representative of the institution you wish to register.

Select hereunder the institution type of which you are the representative and enter the number of the institution in order to:

- register your institution in CSAM, and
- appoint yourself as a Chief Access Manager

Institution type: Pharmacie

Institution number: (8 figures)

Registration of my institution in CSAM

Figure 3: Appoint a chief access manager.

4. Click on 'Registration of my institution in CSAM';
5. The pharmacist-in-charge further completes the requested details (email, phone number,...) to finalise the registration.

2.2.3.2.2. For other companies

Log into CSAM and follow the steps described in the CSAM manual (step-by-step guide for businesses).

- For persons with a Belgian identity card: item I = page 4 'Een Hoofdtoegangsbeheerder (HTB) aanstellen [Appointing a Principal Access Manager (PAM)].'
- For persons without a Belgian identity card: item II = page 17 'Een Hoofdtoegangsbeheerder (HTB) aanstellen – Uitzonderingsprocedure [Appointing a Principal Access Manager (PAM) – Exception procedure]'.
  ➔ If the legal representative does not have a national register number or bis number o.w.v. domiciliation abroad, the steps below should be followed to obtain a bis number:
  - Surf to www.limosa.be;
  - Select the preferred language;
  - At the bottom of the page, under Limosa, click on "More information";
  - Create an account;
  - Submit and send the required data.

If you have any questions about the CSAM manual, please contact CSAM directly on 02 511 51 51 or by using this contact form.

2.2.4. Activating the domain

2.2.4.1. For pharmacists of a pharmacy open to the public

Pharmacists-in-charge do not need to activate the domain [Hoedanigheid] themselves. It is activated automatically once the principal access manager is registered in CSAM. The pharmacist-in-charge can proceed to §2.2.7.1 to add users.

2.2.4.2. For other companies

1. Click on 'Toegangsbeheer' [Access Management] via [this link](), and log in via eID or itsme;
2. Select the company you want to sign in to the social security portal for;
3. Double-click on 'Benaming ... (Verantwoordelijke Toegangen Entiteit)' [Entity Access Manager' (see Figure 4);

Figure 4: Activate the domain [Hoedanigheid] (1)

4. At the bottom of the list, select: 'eHealth Gezondheidszorg' [eHealth Healthcare] and click 'Volgende' [Next] (see figure 5).

Figure 5: Activate the domain [Hoedanigheid] (2)

5. Add another e-mail address for the domain, preferably a generic e-mail address of the users of the domain.
   Proceed to step '2.2.5. Designating an AM'.

2.2.5. Designating an AM

2.2.5.1. If this step has already been performed or if you are a PAM

You can proceed to step 2.2.6.

A PAM is automatically an AM for each domain. Thus, if you as the PAM also take on the role of AM, you can skip this step.

2.2.5.2. Designating an AM

From here, you can follow the steps in this guide instead of the CSAM guide.

1. Choose (see Figure 6):
   a. Either 'Ik wens zelf in te staan voor het beheer van de hoedanigheid' [I wish to be responsible for managing the domain myself]. The PAM is then designated as AM.
   b. Or 'Ik wil een lokale beheerder aanstellen om de hoedanigheid te beheren' [I want to appoint a local administrator[1] to manage the domain]. The PAM then delegates the work to a (different) AM.

Figure 6: For the option 'I wish to be responsible for managing the domain myself': click 'Next'

[1] Local administrator (LA) is an obsolete name for access manager.

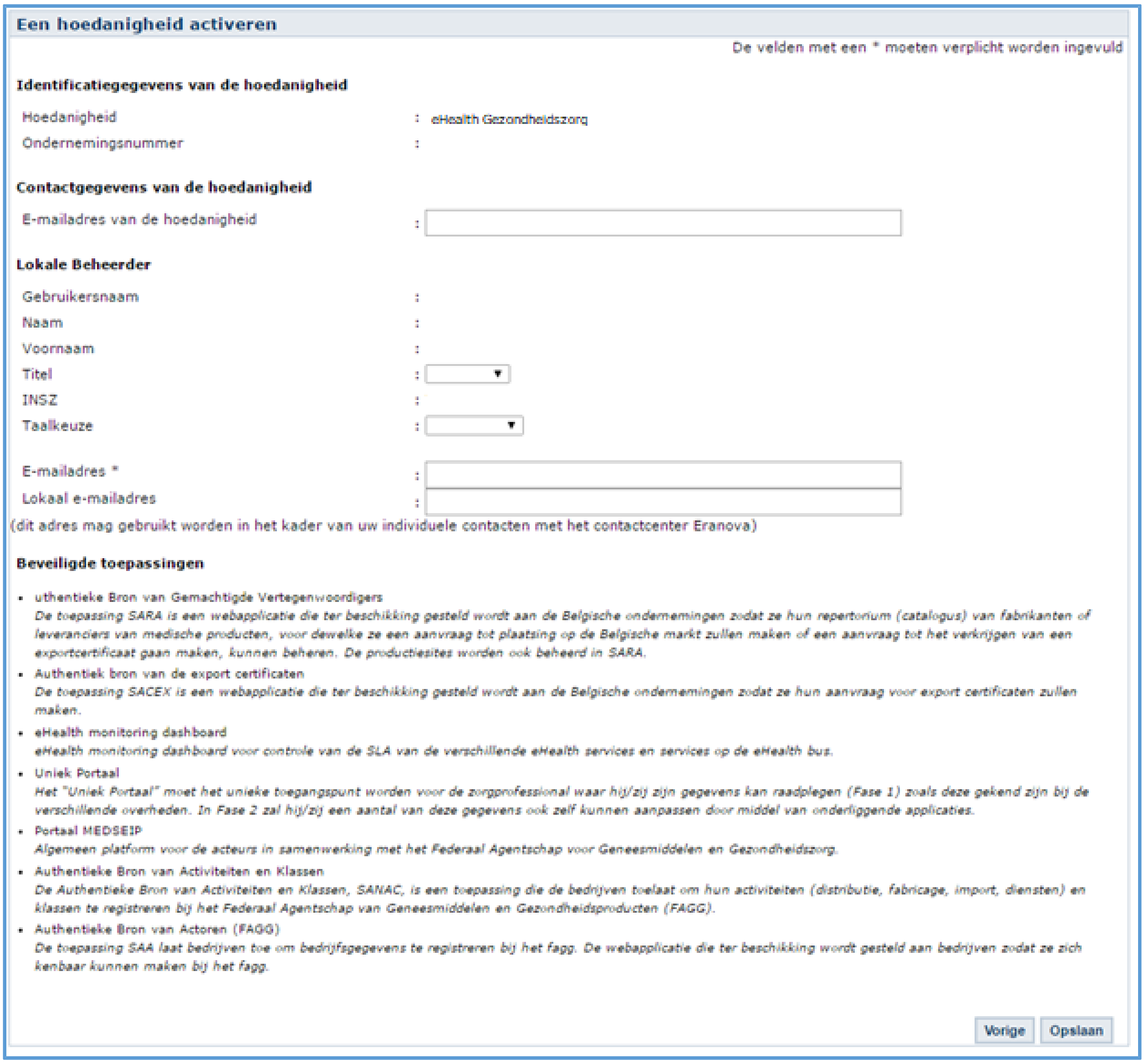


Figure 7: Confirm the data entered by clicking 'Opslaan' [Save].

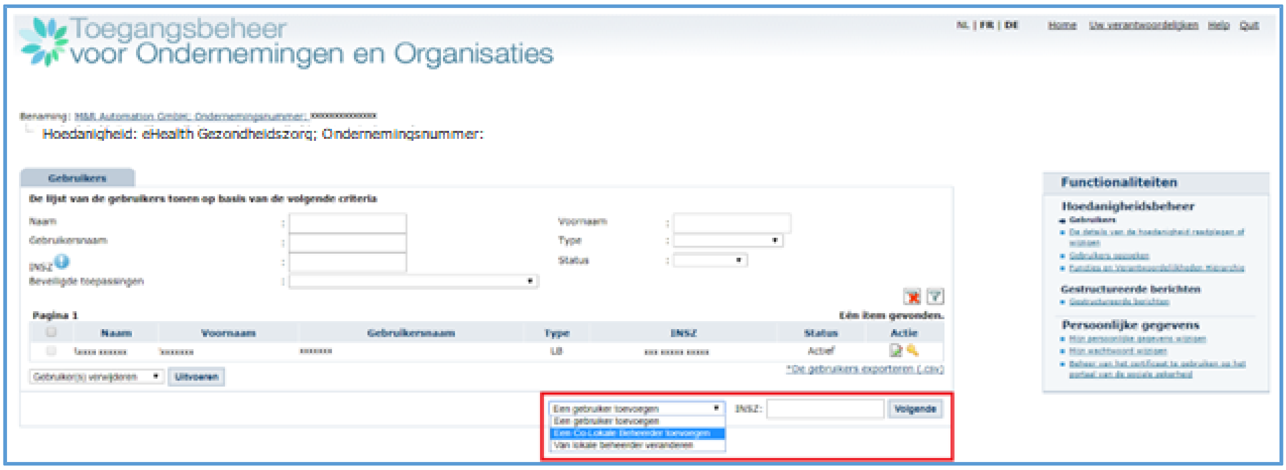


Figure 8: For the option 'I want to appoint a local administrator to manage the domain':

a. *Select the 'Een Co-Lokale beheerder toevoegen' [Add a Co-Local Administrator] function. Enter the Co-local administrator's NISS number, and click 'Next'.*

b. *In this step you can:*
   - *add a new user (see 2.2.7.);*
   - *change the AM;*
   - *delete a user;*
   - *(un)block a user.*

2.2.6. Adding a subdivision

This section applies to all companies under the *hoedanigheid* [domain] "eHealth Gezondheidszorg", regardless of the number of branches or establishments.

2.2.6.1. If this step has already been performed or does not apply

You can proceed to step 2.2.7.

2.2.6.2. Adding a subdivision and appointing a manager

1. Select your enterprise;
2. Select the *hoedanigheid* [domain] 'eHealth Gezondheidszorg' (see Figure 9).

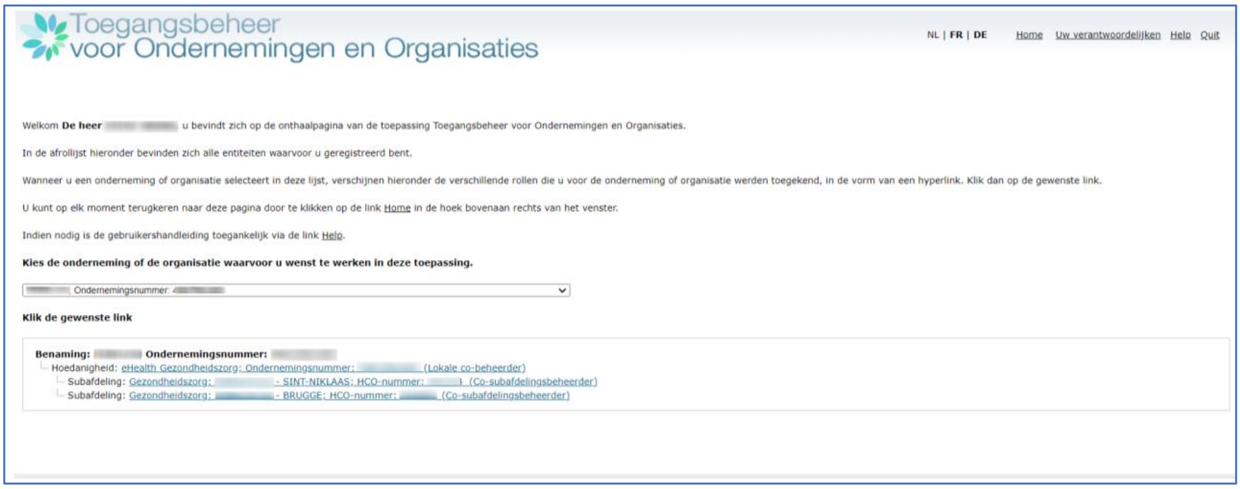


Figure 9: Adding a subdivision and appointing a manager

3. Select the 'gebruikers' [users] menu (see Figure 10) and then click on the 'subafdeling' [subdivision] tab (see Figure 11).

Figure 10: Select the 'users – subdivisions' menu.

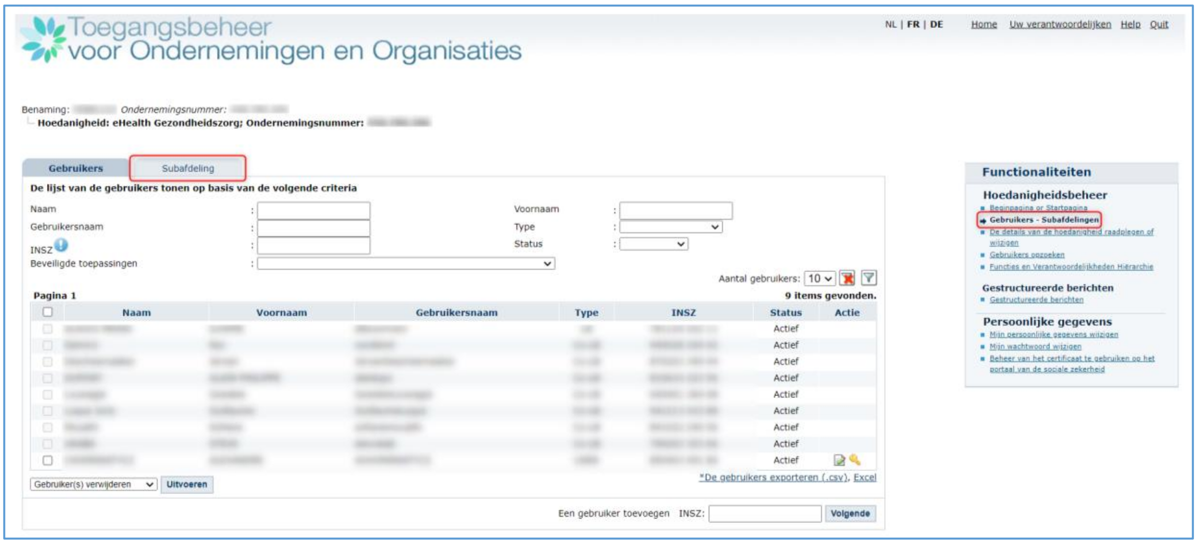


Figure 11: Next, click on the 'subdivision' tab.

4. Select the 'een subafdeling toevoegen' [add a subdivision] tab, choose ‘Gezondheidszorg’ [Healthcare], and click 'Volgende' [next] (see Figure 12).
5. Complete the form with the institution's HCO number and email address. Finally, select whether you want to manage the subdivision yourself or entrust it to another person. For the latter option, you will be asked to enter the person's NISS number (see Figure 13);

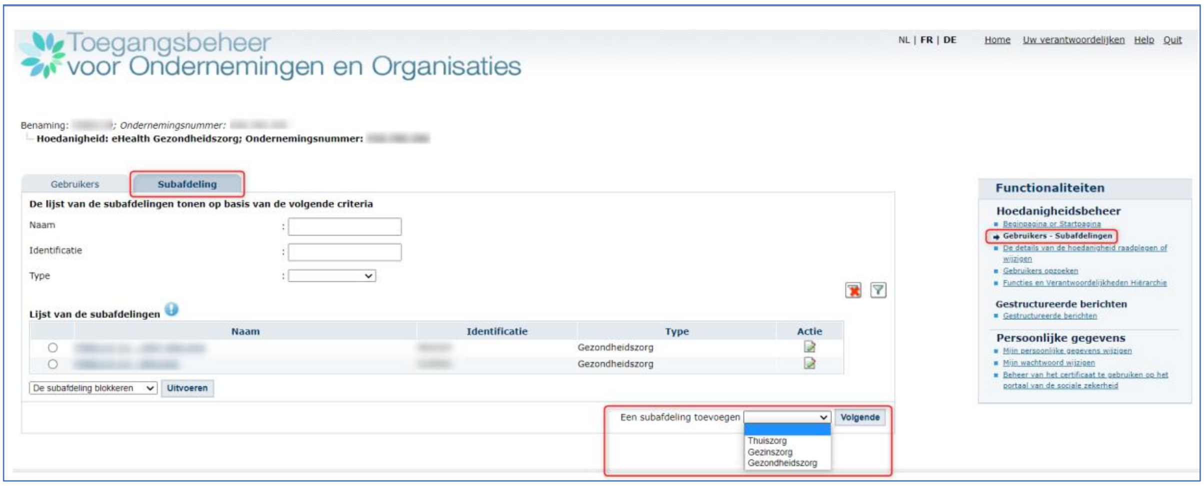


Figure 12: Select the 'subdivision' tab and then click 'next'.

Figure 13: Complete the form.

6. Select the 'Online aangifte voor de overdracht van verdovende middelen' [Portal of Online aangifte voor de overdracht van verdovende middelen] service to add the subdivision (see Figure 14).
7. Click 'Opslaan' [Save].
8. Click 'Bevestigen' [Confirm].

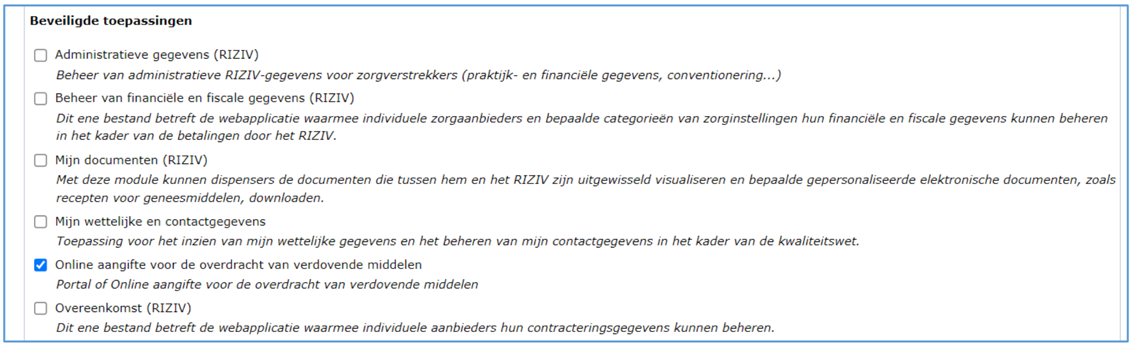


Figure 14: Select the 'Portal of Online aangifte voor de overdracht van verdovende middelen' application.

2.2.7. Designating users

2.2.7.1. For pharmacists of a pharmacy open to the public

1. Click on 'Toegangsbeheer' [Access Management] via this link, and sign in via eID of itsme
2. Once signed in, select your pharmacy (figure 15)

Figure 15: selecting your pharmacy.

3. The *hoedanigheid* [domain] 'Apotheek' under which users can be added now appears, click on it (Figure 16).

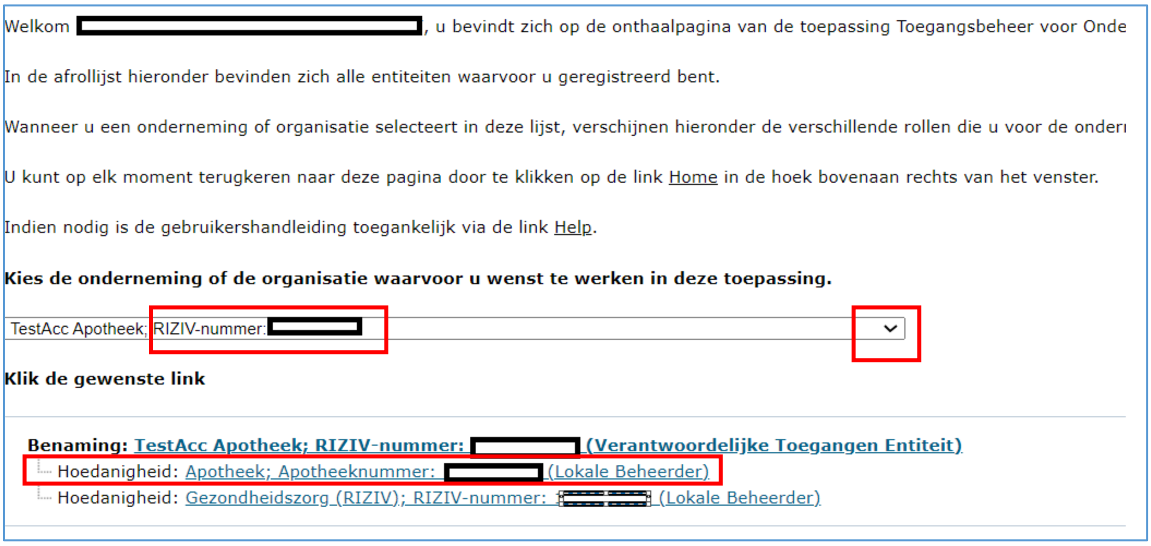


Figure 16: Select the 'hoedanigheid' [domain].

4. Click on 'Gebruikers' [users] on the right-hand side of the screen.

5. At the bottom, enter the user's INSZ number (social security number) and click 'Volgende' [Next] (Figure 17).

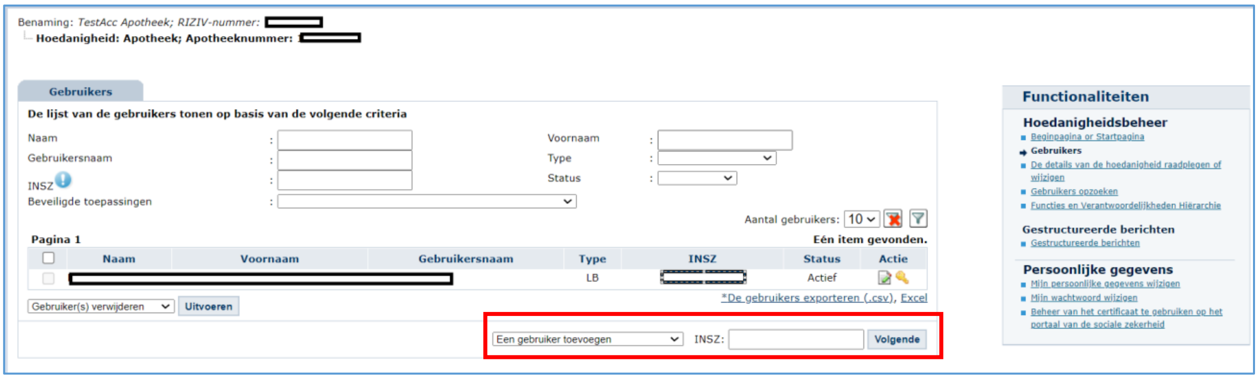


Figure 17: adding a user.

6. After completing the user details and assigning a password, you will be able to select the online application 'Online aangifte voor de overdracht van verdovende middelen' at the bottom [Portal of Online aangifte voor de overdracht van verdovende middelen] (Figure 18).

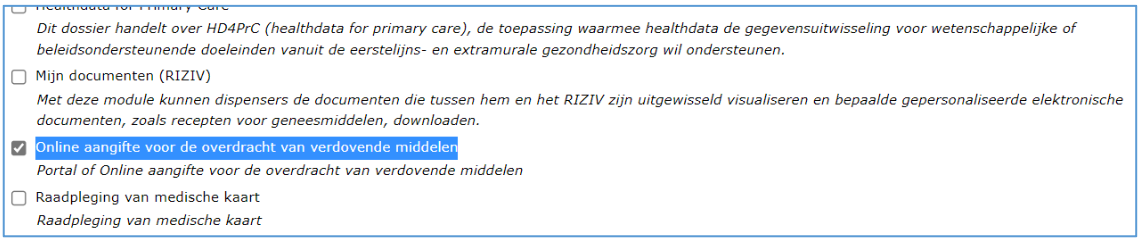


Figure 18: Select the 'Online aangifte voor de overdracht van verdovende middelen' application.

7. Click on 'opslaan' [save] and 'bevestigen' [confirm].

2.2.7.2. For other companies

2.2.7.2.1. If starting from this step

Make sure you are logged into the Social Security 'access management for businesses and organisations' portal.

1. Click on this link.
2. Click on 'Toegangsbeheer' [access management] (see Figure 19) and sign in.
3. Select the enterprise, and subdivision if applicable, for which you want to create a user.
4. Now proceed from figure 22 in step 2.2.7.2.

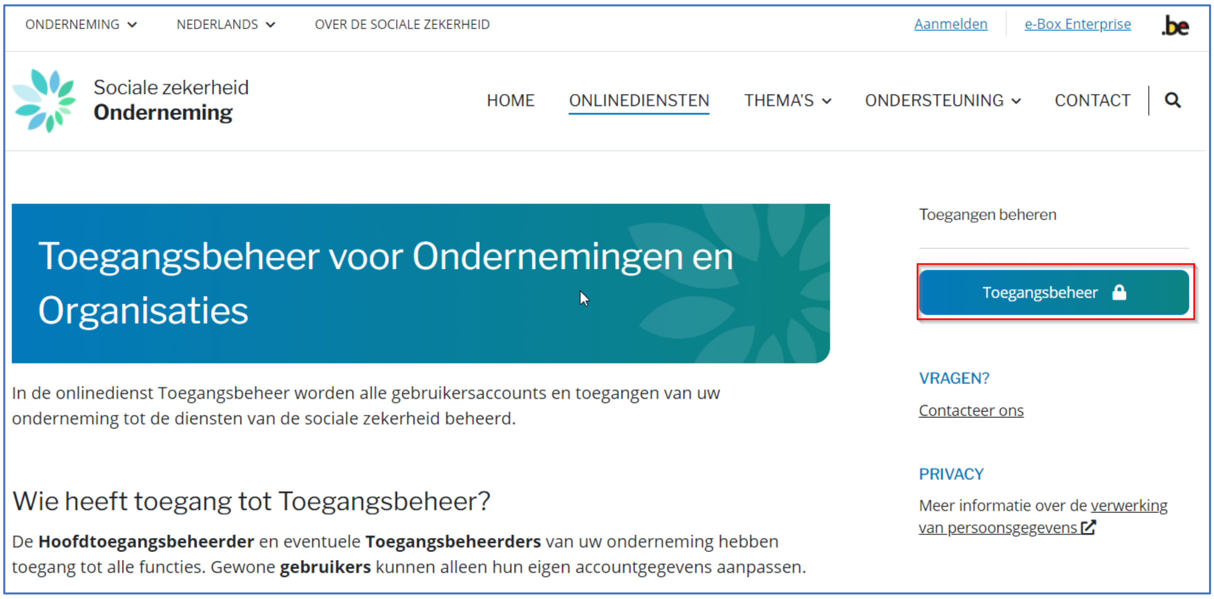


Figure 19: Accessing the social security portal.

2.2.7.2.2. If you arrive here from a previous configuration step

1. Click on the 'Home' menu at the top right of the screen (see Figure 20).

Figure 20: Click on 'Home'.

2. Select the *hoedanigheid* [domain] 'eHealth Gezondheidszorg' or subdivision of the domain (see Figure 21). A user added at the domain level is given access to all the data of the enterprise. **Note** that the user added at domain level, gets access to all the company's data. The user added at subdivision level, only gets access to the subdivision’s information/application.

Figure 21: Select the domain or subdivision of the domain.

3. Click on the 'Gebruikers' [Users] menu (see Figure 22).

Figure 22: Click on 'users'.

4. Enter the user's NISS number (see Figure 23).
5. Click 'Volgende' [Next].

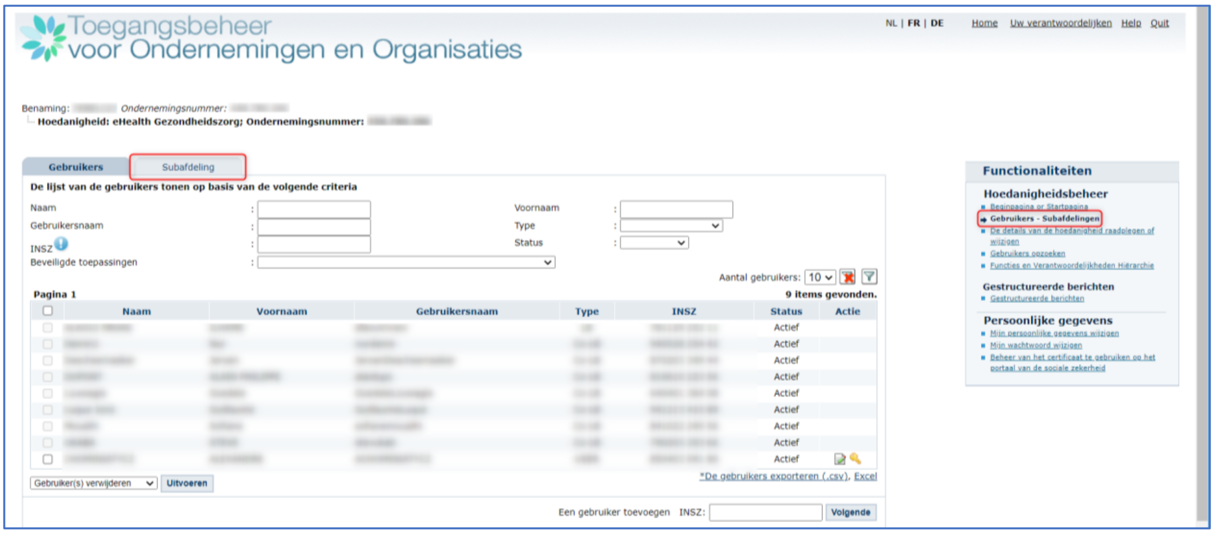


Figure 23: Enter the user's NISS number.

6. After completing the user details and assigning a password, you will be able to select ‘Online aangifte voor de overdracht van verdovende middelen’ [Portal of Online aangifte voor de overdracht van verdovende middelen] at the bottom of the screen (see Figure 24).
7. Click on the box ‘**Online aangifte voor de overdracht van verdovende middelen**’ [Portal of Online aangifte voor de overdracht van verdovende middelen].
8. Click 'Opslaan' [Save].
9. Check the information and click 'Bevestigen' [Confirm].

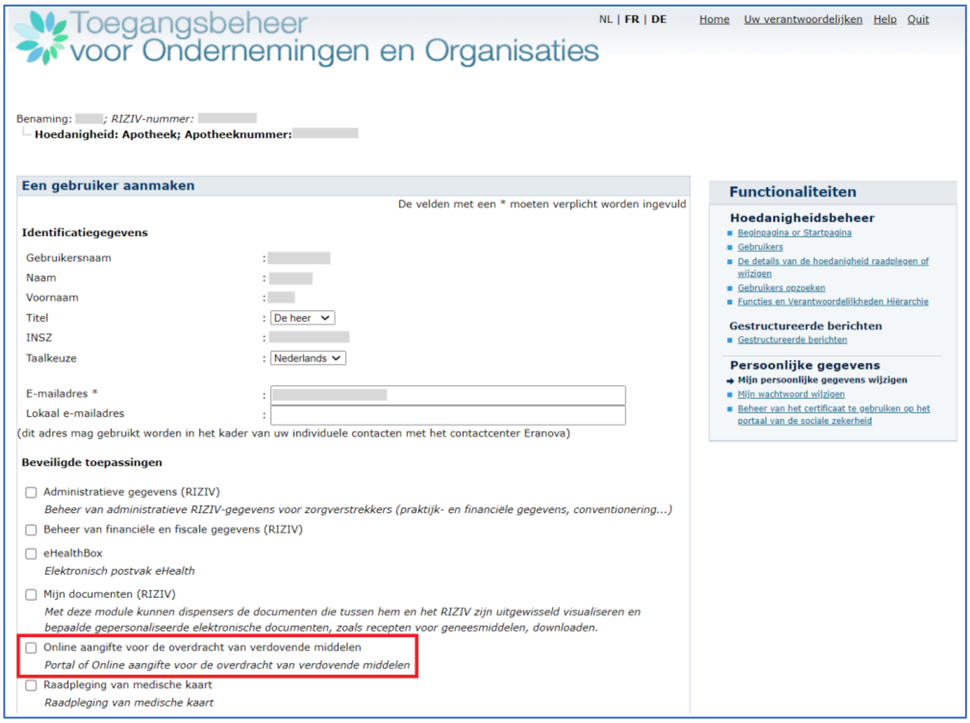


Figure 24: Enter the user's details.

2.2.8. Changing access data
It is possible to edit the access data later.

2.2.8.1. Logging in
Make sure you are logged into the social security portal 'Toegangsbeheer voor ondernemingen en organisaties' [access management for businesses and organisations] by clicking on this link, and then clicking on 'Toegangsbeheer' [access management] (see Figure 19).

2.2.8.2. Actions by role
The following roles can perform the following actions.

- As PAM:
  - Add, delete, (un)block or modify user or AM data;
  - (de)activate or change a domain.

- As AM:
  - Add, delete or (un)block an existing user;
  - Export user list to CSV or Excel format;
  - Add, delete or (un)block a subdivision;
  - Cannot remove PAM.

- As a user:
  - edit personal data.

2.3. LOGGING INTO THE APPLICATION
After registration (step 2.1.) and configuration (step 2.2.), you can log into the web application.

1. The link first takes you to a government platform, where you can securely log in (see Figure 25).

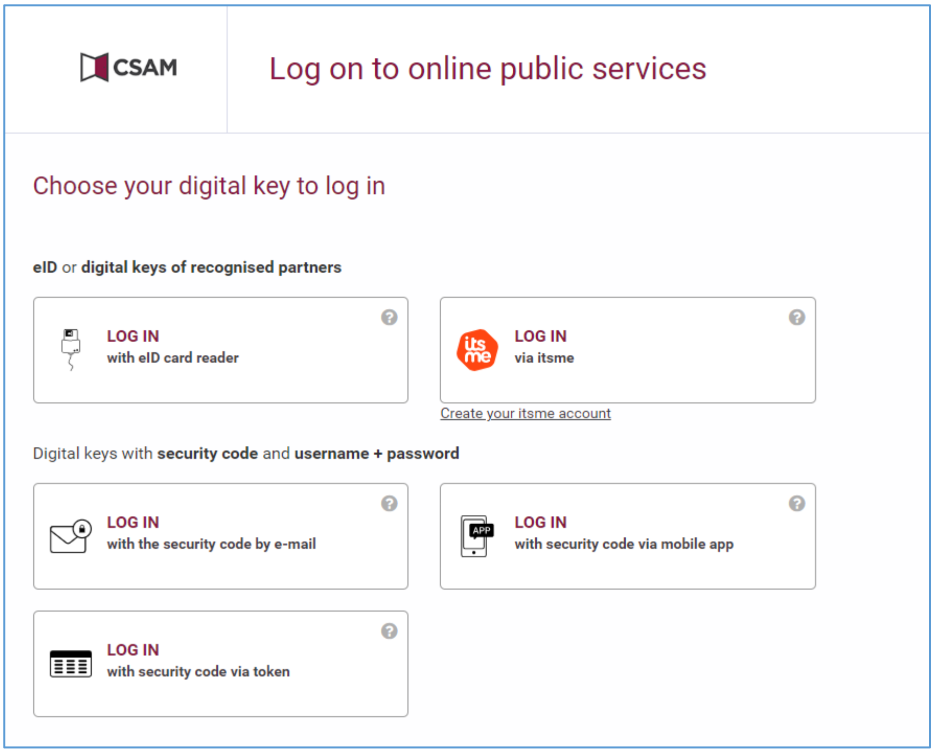


Figure 25: CSAM login platform

2. Next, select the enterprise and subdivision if applicable for which you wish to submit a declaration (see Figure 26).

Figure 26: Select the enterprise and subdivision if applicable.

Note for pharmacists

If you can only select the profile of your former employer, even though you now work for another pharmacy, this can be changed through the following procedure:
Please contact the NIHDI at dossierpharma@riziv-inami.fgov.be stating that you are no longer employed by your former employer. This will allow the NIHDI to change your data in coBRHA. After all, our application gets its data from coBRHA.

If the address of your pharmacy is incorrect in the system, it can be changed through contacting the NIHDI at dossierpharma@riziv-inami.fgov.be. Don't forget to mention your APB number.

3. SUBMITTING DECLARATIONS THROUGH THE WEB APPLICATION

3.1. SUBMITTING A DECLARATION

▪ SUBMITTING DECLARATIONS INDIVIDUALLY

The user must first log in to the web application (see Section 2.3.).

The web application offers two ways to submit the declaration:

- by submitting the declarations individually (see 'Submitting declarations individually');
- by bulk upload using a CSV file (see 'Declaration via bulk upload').

Follow the steps below.

1. Select the type of transfer from the drop-down menu.
   - Purchase
   - Sale

Please note: Users working in a lab can only choose the 'Sale' type for now. This will be changed in the future.

2. Enter the trading partner's ID. To do this, refer to the list of trading partners in the 'Information' section, or click on the magnifying glass to search for the name of the trading partner.

3. Enter the ID of the narcotic code. Please refer to the product list in the 'Information' section.
   A magnifying glass will also be added here in the future for ease of use.
   The 'CNK code' field is optional. Please refer to the product list in the 'Information' section.
   Note that it is sufficient to enter either the narcotic code or the CNK code.

4. Enter the quantity of product received/shipped (fractional quantities are possible for bulk goods).
   - Unit for raw materials in bulk = grams
   - Unit for medicines and pharmaceutical raw materials = per package

5. Enter the order date (format: DD/MM/YYYY).

6. Enter the date of the incoming shipment (format: DD/MM/YYYY). This is the date of shipment (for a sale) or receipt (for a purchase) of the product.

7. Save the declaration.

▪ DECLARATION VIA BULK UPLOAD

Users can also send declarations via bulk upload using a CSV file.
The CSV file template can be downloaded by clicking on 'Example CSV' on the 'Upload a list of declarations' page. Then a screen appears with the following information:

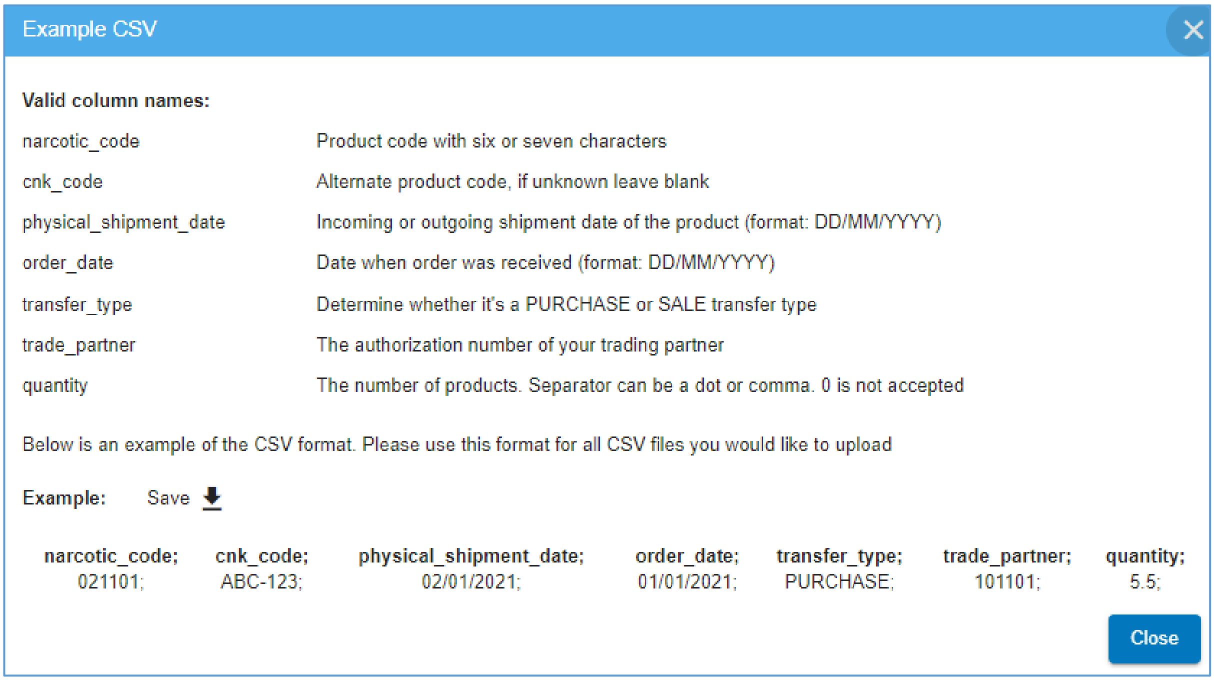


Figure 27: The template for the CSV file.

The template file is automatically downloaded after clicking the ↓ arrow.

Follow the steps below for the bulk upload :

1. Click 'Select the CSV file' and select the CSV file you want to upload. The declarations to be sent will then appear on the screen.
2. Click 'Submit'.
3. Confirm the declaration by clicking 'YES'.
4. You will be notified that the declarations have been successfully uploaded.

Note that data not recognised by the system or declarations with SALE type submitted by lab staff are indicated in red. The reason for the error message can be viewed by clicking on the v symbol.
Correct or delete these declarations if necessary by clicking on the pencil or bin icon respectively.
After correcting, click submit again. You will be notified that the declarations have been successfully uploaded.

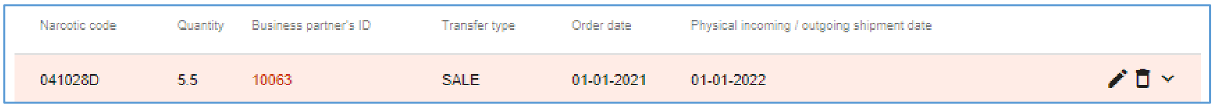


Figure 28: Declarations with SALE type.

You can download the declarations you submitted by clicking 'Export'. The CSV file is downloaded automatically. This option is especially useful if you have had to modify your initial upload.

- VIEWING DECLARATIONS

Declarations can be viewed in the 'Consult your declarations' section. You can access both your own declarations and those of your colleagues.
Then click 'Search' to view the list of all your declarations. It is possible to sort the data in the columns in ascending or descending order. The details of the declaration can be accessed by expanding the declaration. To do this, click on the v symbol.

You can also perform an advanced search by completing the fields provided below and then clicking 'Search'.

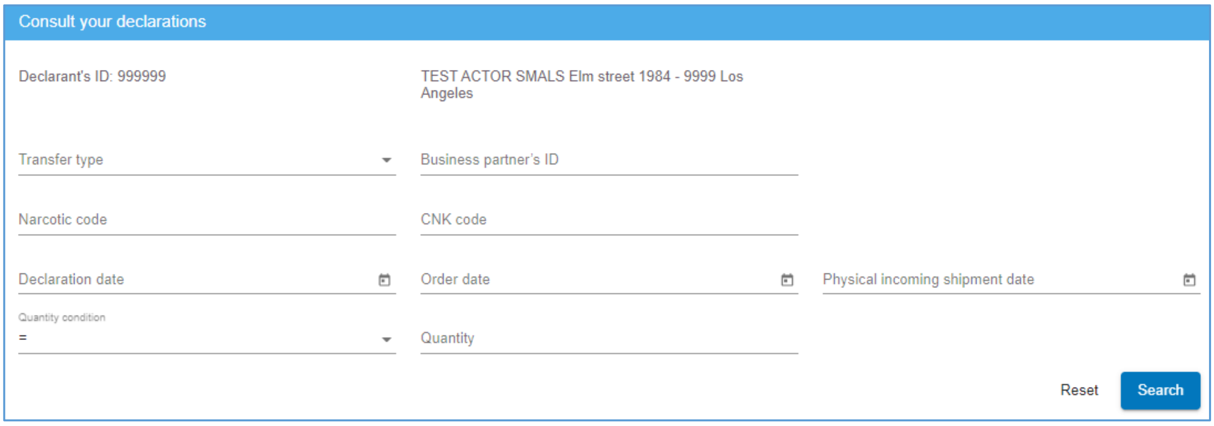
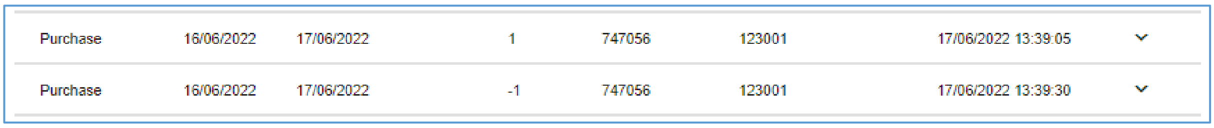


Figure 29: Viewing declarations.

3.2. EDIT OR CANCEL A DECLARATION

In this version of the web application, it is not yet possible to edit or delete submitted declarations. If a declaration needs to be corrected or cancelled, the declaration must be deleted in its entirety. This is done by means of a 'minus declaration'. The declarant must re-submit the same declaration, but with a negative quantity. The correct declaration can be submitted.



Purchase	16/06/2022	17/06/2022	1	747056	123001	17/06/2022 13:39:05
Purchase	16/06/2022	17/06/2022	-1	747056	123001	17/06/2022 13:39:30

Figure 30: Edit or cancel a declaration

3.3. DEADLINE FOR SUBMITTING A DECLARATION

The deadline for submitting a declaration is a maximum of 30 days from the date of receipt or shipment of the product, as stated on the declaration. Declarations cannot be sent after this time.

Nevertheless, it is recommended to report a delivered/received shipment as soon as possible, so that possible errors would be detected faster and registrations would not be forgotten.

Additionally, enterprises that receive (multiple) small deliveries daily, such as pharmacies, are advised to submit what they have physically received into the system, rather than merely copying the data that appears on a shipping note.

4. APPLICATION FOR REGISTRATION OF NEW TRADING PARTNERS

Article 6 of the Royal Decree of 6 September 2017 regulating narcotics and psychotropic substances stipulates that a prior activity licence is required for **all those who import, export, transport, manufacture, produce, sell or offer for sale, supply or deliver, or purchase narcotics and this permit applies for the place where the activities involving these narcotic drugs are performed.**

In practice, this means that anyone who wants to legally conduct activities involving narcotics must be licensed to do so by the FAMHP. These include, for example:

- manufacturers and distributors of narcotic drugs, Investigational Medicinal Products (IMPs) and Active Pharmaceutical Ingredients (APIs);
- wholesaler-distributors;
- laboratories that analyse narcotic drugs.

For more information about the legislation behind the licence, more specifically an activity licence, we recommend thoroughly reading the elements concerning this aspect in the Royal Decree.
Applications can **only** be made using the application form on the FAMHP website.

Article 7 of the Royal Decree provides for an alternative to the activity licence, namely the **end user licence** as applicable, for example, to toxicology laboratories and to police and customs services. More information is available on the website of FAMHP.

Article 8 of the Royal Decree further stipulates some **exemptions** from the activity licence such as for pharmacists and veterinarian-depot holders.

5. CHANGE DATA OF TRADING PARTNERS

For all trading partners, it is extremely important that any change (holder, person in charge, address, etc.) are reported in time to the competent services.

- **In the case of a pharmacy open to the public,** changes must always be reported to the 'Registration of Pharmacies' service using the form, available on this page: Pharmacy for the public – Human Use – FAMHP.

- **In the case of a hospital pharmacy**, changes must be reported to hospital pharmacy inspectors (contact details see: Hospital Pharmacies – Human Use – FAMHP).

- **In the case of wholesalers,** changes must be reported via a request for amendment to the narcotics licence to the FAMHP (Narcotics team). Remember to also report the changes at the WDA licence level (contact eudragmdp@fagg-afmps.be).

- **Trading partners who hold an activity licence or end user licence** are required by law to notify the FAMHP (Narcotics team) of any change in the data listed on the licence within fifteen days.

6. APPLICATION FOR REGISTRATION OF NEW NARCOTIC DRUGS

The term 'narcotic drugs' is derived from the UN conventions and includes either a solid or liquid mixture of narcotic substances, such as a licensed drug (preparations) or a pure substance.
These types of applications cannot currently be submitted through the digital system.

The application must be submitted by email to narcotics@fagg-afmps.be and must include the following information:

- the name of the preparation/substance;
- the pharmaceutical form;
- the name of the narcotic drug;
- the amount in anhydrous substance;
- pack size (number of units per pack).

Applicants are also asked to attach an official document (copy of the MA, extract from the IMP File, foreign import licence in case of an export of these preparations, etc.) that can substantiate the above data.