

User manual for Client Portal

- 1. How to register? 1
 - 1.1. Marketing authorisation holder’s representative 1
 - 1.2. Pharmacy / wholesale distributor / manufacturer (Estonian activity license) 2
 - 1.3. Physician / veterinarian 4
 - 1.4. State agency..... 5
 - 1.5. Other natural person 6
 - 1.6. Other company 7
- 2. Logging in 8
 - 2.1. Logging in with an ID card. 8
 - 2.2. Logging in with a user ID and password..... 9
 - 2.3. Logging in as a physician or a veterinarian..... 10
- 3. Filling in document forms and submitting documents 10
 - 3.1. Filling in a document form 10
 - 3.2. Adding enclosed documents..... 11
 - 3.3. Verifying a document 11
 - 3.4. Signing and submitting a document 12
- 4. Searching for submitted and unfinished documents 13
 - 4.1. Searching for a document..... 13
 - 4.2. Document statuses 14
- 5. Continuing an unfinished document 15
- 6. Making a copy of an old document for starting a new document 15
- 7. Changing the password and user account data 15
 - 7.1. Changing the password 15
 - 7.2. Changing account data (contact data, etc)..... 16
 - 7.3. Restoring a forgotten password..... 16
- 8. Subscribing to notices and unsubscribing from notices 17
- 9. Administrating sub-users..... 18
- 10. Didn’t find the answer in the user manual?..... 19

1. How to register?

1.1. Marketing authorisation holder’s representative

Marketing authorisation holder’s representative can sign up as a company or as a natural person.

Type of user account

Registry code
 Register of state institutions
 Person
 Foreign company
 Foreign person

Code

Name

To sign up as a company it is preferred that a Board Member of the enterprise uses his or her Estonian ID card for signing up. The Client Portal sends a query to the Commercial Registry and provides an option to select which enterprise related to that person will be the enterprise on behalf of which the user account will be created. After creating the user account, logging in takes place with the username and password; the ID card cannot be used for logging in.

A foreign enterprise can create an account without an ID card and can log in with the username and password.

To sign up as a natural person is it necessary to use an ID card. After creating the user account, logging in takes place with the username and an ID card or with the username and password. A foreign natural person can create an account without an ID card and log in with the username and password.

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

Groups

Pharmacy Manufacturer Wholesaler
 Marketing authorisation holder/applicant Clinical trials Handler of cells, tissues and organs
 Central blood bank Blood bank at the health care provider

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account.

1.2. Pharmacy / wholesale distributor / manufacturer (Estonian activity license)

In case of medicine handlers with an activity license it is recommended that the user account is created by a Board Member of the enterprise **having the activity license**, using an ID card. The Client Portal sends a query to the Commercial Registry and provides an option to select

which enterprise related to that person will be the enterprise on behalf of which the user account will be created.

In case the board member does not have an Estonian ID-card, s/he can create an account without an ID card and can log in with the username and password.

→

Type of user account

Registry code

Register of state institutions

Person

Foreign company

Foreign person

Thereafter the Client Portal sends a query to the Registry of Activity Licenses of Handling Medicines and binds the activity licenses of the enterprise to the user account. The enterprise becomes the main user, and **one sub-user is created per each activity license**. In the Client Portal, the main user sees the documents of all its sub-users, whereas a sub-user sees only its own documents.

The data of sub-users, i.e. the related activity licenses are displayed as links at the end of the sign up form (see the picture below) – please fill in the data of sub-users by clicking those links.

Activity licences

675

After creating the user account, logging in takes place with the username and password; the ID card cannot be used for logging in.

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

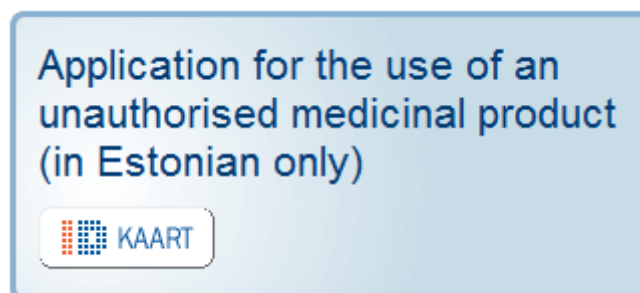
Groups

<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Wholesaler
<input type="checkbox"/> Marketing authorisation holder/applicant	<input type="checkbox"/> Clinical trials	<input type="checkbox"/> Handler of cells, tissues and organs
<input type="checkbox"/> Central blood bank	<input type="checkbox"/> Blood bank at the health care provider	

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account. A message stating the username and password will be sent to each sub-user, using the e-mail address stated in the application.

1.3. Physician / veterinarian

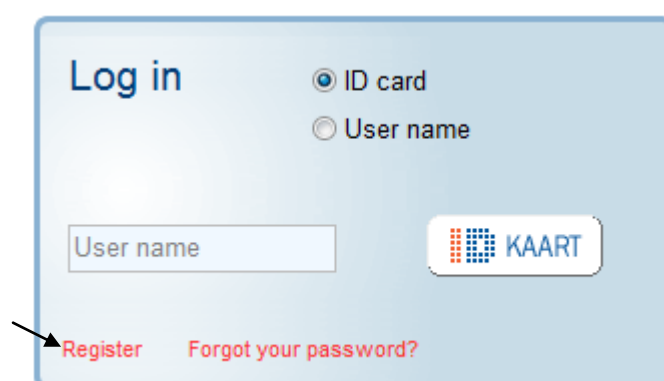
It is not necessary to sign up for filling in applications for medicines without a Marketing authorisation, but an ID card is required for that. Start filling in the document by making the selection “Physician’s application for using medicines w/o Marketing authorisation” on the home page:



When logging in with an ID card, your data will be verified in state registries, and if you are a practicing physician/veterinarian then you are logged in without a user account. You can also view applications submitted earlier and also replies to those applications if logging in with an ID card.

Four types of applications can be submitted this way: an application for use of medicines without a Marketing authorisation (for human treatment), an application of a professional organisation for use of medicines without a Marketing authorisation (for human treatment), an application for use of medicines without a Marketing authorisation for veterinary treatment, and an application of a professional organisation for use of medicines without a Marketing authorisation for veterinary treatment.

If you also want to use other forms of the Client Portal, then you should create a user account. For this, click the link **Sign up**:



Use the ID card for signing up. When selecting the type of user account, we recommend using the selection “Natural person”. If you are a Board Member of an enterprise, then you will also be given the choice of creating a user account on behalf of an enterprise.

Type of user account

→ Registry code

→ Register of state institutions

Person

Foreign company

Code

Name

Foreign person

After creating the user account, logging in takes place with the username and an ID card or with the username and password.

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

Groups

Pharmacy Manufacturer Wholesaler

Marketing authorisation holder/applicant Clinical trials Handler of cells, tissues and organs

Central blood bank Blood bank at the health care provider

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account.

1.4. State agency

This allows you to sign up as an Estonian state institution. Use the ID card when signing up for a user account. In the sign-up form, select the user account type as “Register of State Agencies/Institutions”.

Then enter the registry code and the name of the agency.

After creating the user account, logging in takes place with the username and password; the ID card cannot be used for logging in.

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

Groups

<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Wholesaler
<input type="checkbox"/> Marketing authorisation holder/applicant	<input type="checkbox"/> Clinical trials	<input type="checkbox"/> Handler of cells, tissues and organs
<input type="checkbox"/> Central blood bank	<input type="checkbox"/> Blood bank at the health care provider	

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account.

1.5. Other natural person

To sign up as a natural person is it necessary to use an ID card. After creating the user account, logging in takes place with the username and an ID card or with the username and password.

A foreign natural person can create an account without an ID card. For this, make the selection “Sign up” in the login window on the home page and make the selection “No ID card” on the next page.



In the sign-up form, select a suitable user account type:

Type of user account

Registry code
 Register of state institutions
 Person
 Foreign company
 Foreign person

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

Groups

Pharmacy Manufacturer Wholesaler
 Marketing authorisation holder/applicant Clinical trials Handler of cells, tissues and organs
 Central blood bank Blood bank at the health care provider

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account.

1.6. Other company

To sign up as a company it is necessary that a Board Member of the enterprise uses his or her ID card for signing up. The Client Portal sends a query to the Commercial Registry and provides an option to select which enterprise related to that person will be the enterprise on behalf of which the user account will be created. After creating the user account, logging in takes place with the username and password; the ID card cannot be used for logging in.

A foreign enterprise and a Board Member without an ID card can create an account without using an ID card. For this, make the selection “Sign up” in the login window on the home page and make the selection “No ID card” on the next page.

Log in

ID card
 User name

[Register](#) [Forgot your password?](#)



In the sign-up form, select a suitable user account type:

Type of user account

→ Registry code

→ Register of state institutions

Person

Foreign company

Code

Name

Foreign person

When filling in the sign-up form for a user account, you can get help by clicking the link **“Form instructions”** at top right.

Roles of other user groups can be added to the user account if necessary – **select the suitable user groups** when filling the form:

Groups

<input type="checkbox"/> Pharmacy	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Wholesaler
<input type="checkbox"/> Marketing authorisation holder/applicant	<input type="checkbox"/> Clinical trials	<input type="checkbox"/> Handler of cells, tissues and organs
<input type="checkbox"/> Central blood bank	<input type="checkbox"/> Blood bank at the health care provider	

After submitting the application for a user account, the application is sent to the administrator of the Client Portal for approval. You will be sent an e-mail message confirming the activation of the user account.

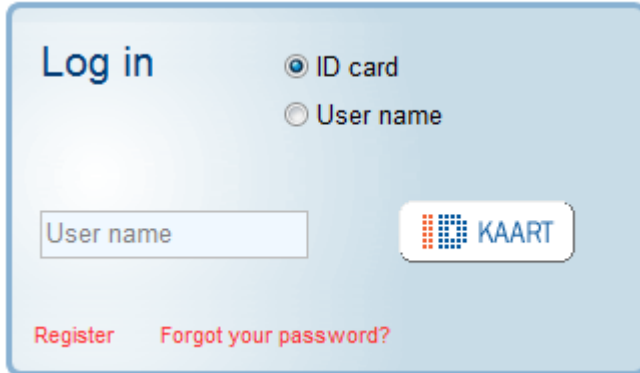
2. Logging in

There are three ways to log in. A legal person can log in with a user ID and a password; a natural person can log in with a username and an ID card or a username and a password; a practicing physician/veterinarian can log in with an ID card.

2.1. Logging in with an ID card.

In the login window, select “With an ID card”, enter the username and click the button „ID CARD“, then enter the PIN1 code.

A prerequisite for logging in with an ID card is a user account (you need to sign up). A physician/veterinarian can log in without a prior sign-up, see the description in section 2.3. A legal person can log in only with a username and a password.



The screenshot shows a light blue login window titled "Log in". At the top right, there are two radio buttons: "ID card" (which is selected) and "User name". Below the radio buttons, there is a text input field labeled "User name" and a button with the KAART logo. At the bottom left, there are two links: "Register" and "Forgot your password?".

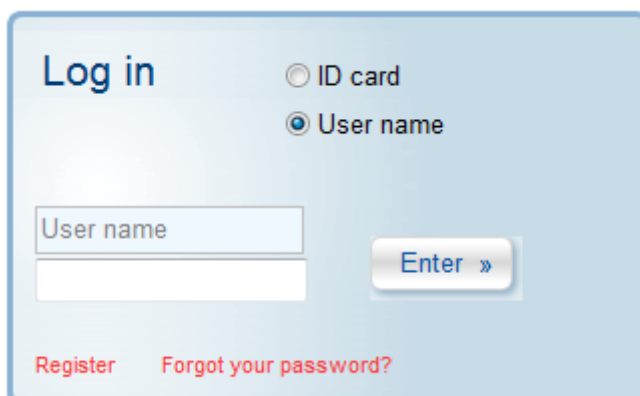
If login fails, then verify that you entered the username correctly, close and reopen the browser, and try again. If the problem persists, then verify that the ID card software is functioning properly. If necessary, contact the Estonian Agency of Medicines where your user ID for the Client Portal can be checked.

After logging out, it is a recommended secure practice to close the browser window – the ID card software will remember your PIN1 code until the end of the browser session. Thus, if you don't close the browser window, the Client Portal (and other systems allowing login with an ID card) may not ask for the PIN1 code again.

2.2. Logging in with a user ID and password.

In the login window, select “With a user ID”, enter the username and password, and click the button “Enter”.

A prerequisite for logging in with a username and a password is a user account (you need to sign up).



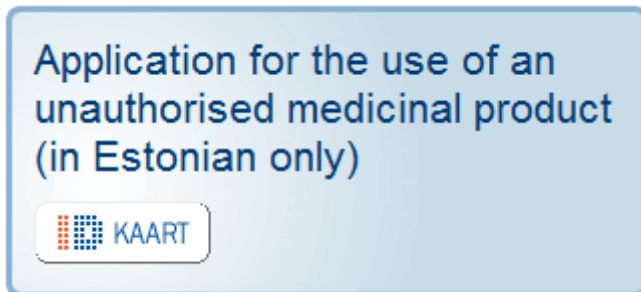
The screenshot shows a light blue login window titled "Log in". At the top right, there are two radio buttons: "ID card" and "User name" (which is selected). Below the radio buttons, there are two text input fields, the first labeled "User name". To the right of the input fields is a button labeled "Enter »". At the bottom left, there are two links: "Register" and "Forgot your password?".

The procedure for restoring a forgotten password is described in section 7.3 of this manual.

2.3. Logging in as a physician or a veterinarian.

A user account or prior sign-up is not required for logging in as a physician or a veterinarian.

Insert the ID card into the card reader and click the button “ID CARD”. Then enter the PIN1 code and wait until the authentication is verified in the state registries.



If the verification in the state registries is successful, then you are logged in under your name.

If login fails, then close and reopen the browser and try again. If the problem persists, then verify that the ID card software is functioning properly. If necessary, contact the Estonian Agency of Medicines where the functioning of the state registries can be checked.

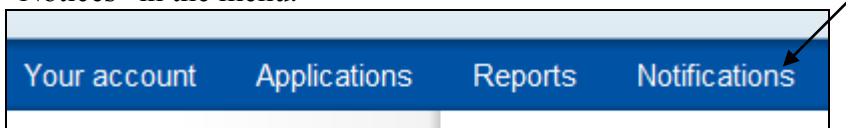
3. Filling in document forms and submitting documents

3.1. Filling in a document form

Document forms can be filled in after logging in.

After a successful login, a window opens with a top menu listing the following selections: “Your account”, “Applications”, “Reports” and “Notices”. Select the suitable document type from among the last three.

For example, if you wish to submit an import notice to the Agency of Medicines, then select “Notices” in the menu.

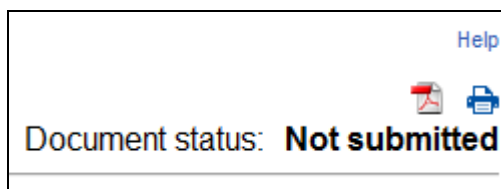


A list opens with forms for notices that can be submitted via the Client Portal. Select the suitable type of notice.

Notifications

- » Suspect adverse reaction report (CIOMS)
- » Notifications of import
- » Notifications of export
- » Notification of import of cells, tissues and organs
- » Notification of export of cells, tissues and organs
- » Notification of placement of medicinal product on the market

An empty form of the selected type of document opens. When filling in the document form, you can get help by clicking the link “Form instructions” at top right. A small red icon allows viewing the document and to save it in PDF format; a small blue icon allows opening the document in printable version.

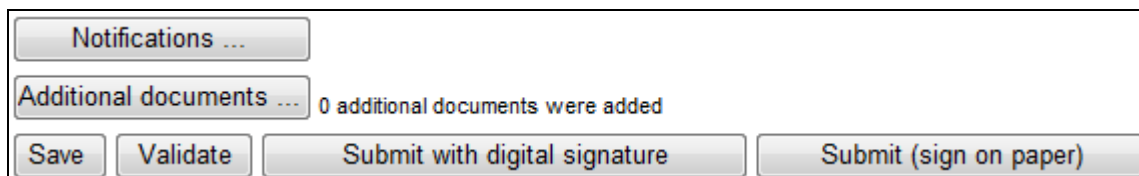


While the document has not been submitted yet, the top right corner of the document form shows the document status as “Not submitted”. If you wish to suspend the filling of the document form in order to continue it later, click the button “Save”; later you can open the document again via document search (see section 4 of this manual).

You can also start filling in a document form by selecting a copy of a previous document (see section 6 of this manual). This saves time if the document contains many fields and majority of them are identical to what was submitted earlier.

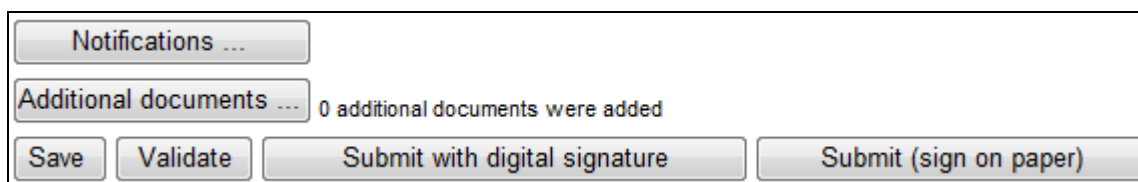
3.2. Adding enclosed documents

You can add enclosed documents to the document being submitted, by clicking the button “Enclosed documents”. It is recommended to save the filled-in document before that. After the button “Enclosed documents” there is a line indicating the number of enclosed documents already added to the document form.



3.3. Verifying a document

When the document has been filled in, it is recommended to pass it through an automatic verification by clicking the button “Verify”.

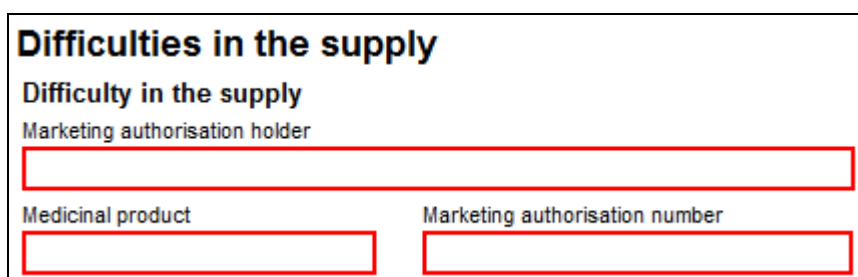


Notifications ...

Additional documents ... 0 additional documents were added

Save Validate Submit with digital signature Submit (sign on paper)

If the verification finds errors, then the Client Portal indicates the problematic fields with a red outline (see the picture below). By selecting such a field, an error message is shown beside the field, indicating whether it is a required field that was left empty or a logical error was made there.



Difficulties in the supply

Difficulty in the supply

Marketing authorisation holder

Medicinal product Marketing authorisation number

After correcting the errors, click the button “Save” and “Verify” again.

If no errors are found, then the Client Portal displays a message “Document verified”. After that, the document is ready for signing (if necessary) and submitting.

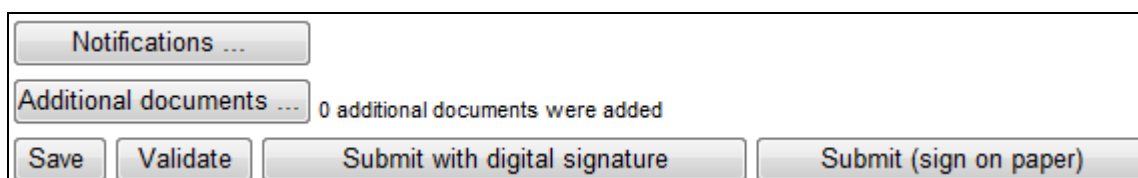
Checked for errors

3.4. Signing and submitting a document

After verifying (see section 3.2) the document is ready for signing and submitting.

If the document is not required to be signed, then you can click the button “Submit” immediately and the Client Portal will not ask for a signature.

If the document is required to be signed, then only the button “Submit with digital signature” or also the button “Submit with paper signature” is displayed, depending on the document form. If possible, we strongly recommend using a digital signature.



Notifications ...

Additional documents ... 0 additional documents were added

Save Validate Submit with digital signature Submit (sign on paper)

Upon digital signing, the PIN2 code is required. After entering the code, the document is signed and is submitted to the Agency of Medicines. The Agency of Medicines will verify the validity of the digital signature and the representation rights of the signatory (for this reason, a letter of authorisation is required in case of authorised signing).

Only one person with an Estonian ID card can digitally sign a document. If a document is required to be signed by several persons or if it is signed by a foreigner having no Estonian ID card, then the selection “Submit with paper signature” can be used.

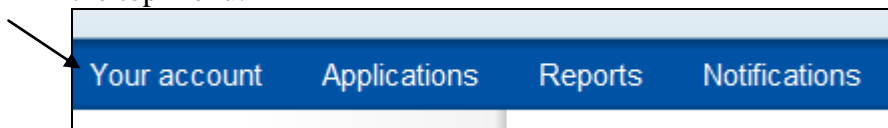
By clicking the button “Submit with paper signature”, an intermediate window opens, warning that the document cannot be changed anymore after continuing. If you are convinced that the document is correct, then click the button “Next” – a letter of confirmation is displayed which you can print out and supplement by hand if necessary. Add your signature and if necessary then also the letter of authorisation to the letter of confirmation and send it by regular mail to the Agency of Medicines. It’s not necessary to print out and enclose the filled-in document – it is sent to the Agency of Medicines via the Client Portal. The time limit of processing of the document will start from the moment of receiving the letter of confirmation in the Agency of Medicines.

You can search documents submitted earlier (see section 4 of this manual). The letter of confirmation can be printed out again from a document if necessary.

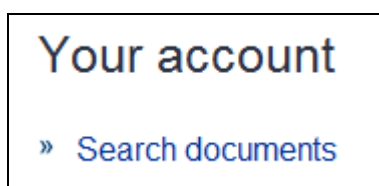
4. Searching for submitted and unfinished documents

4.1. Searching for a document

You can search for documents filled in earlier. For this, open the selection “Your account” in the top menu.



In the list opening thereafter, click the selection “Search documents”.



A document search window opens, allowing you to search for documents on the basis of several parameters. The main user of a user account can search from among all documents related to this user account (incl. those entered by sub-users); sub-users can search only from among the documents entered/submitted by themselves.

By selecting multiple parameters, you can search for documents conforming to both of them at once.

Click the button “Search” to start the search.

Type of the document	All
Status of the document	All ▼
Period of the last change	27.01.2012 ... 27.02.2012
<input type="button" value="Search"/>	

The document search window will display one line for each document found. There are buttons “View” and “Edit” at the end of each line. The former of those opens the document for viewing, and the latter opens it for editing (if the document is not yet submitted and is allowed to be changed). After submitting a document, it cannot be changed anymore, but an editable copy can be made of the document (see section 6 of this manual).



After opening the document, it can be printed out (small blue printer icon) or downloaded in PDF format (small red icon), and a DigiDoc container can be downloaded or a new letter of confirmation can be printed out for signing on paper (links “Print a confirmation” and “Download DigiDoc” at top left).

4.2. Document statuses

The different document statuses have the following meanings:

Not submitted – the document has not been submitted to the Agency of Medicines yet, it can be edited.

Submitted – the document has been submitted to the Agency of Medicines, but it has not reached processing yet.

Sent – the document has been sent to the Agency of Medicines by e-mail; the status of this document in the Client Portal will no longer change. You will be contacted if necessary.

Procedure ongoing – the document has been forwarded to the main database for processing by specialists.

Processing suspended – the processing of this document have been suspended for some reason; the submitter of the document will be notified about the reasons.

Awaiting corrections – errors have been found in the document and those need to be corrected; the submitter of the document will be notified separately about the need to correct errors.

Rejected – the document has not been accepted into processing; the submitter of the document will be notified about the reasons.

Withdrawn – the document has been withdrawn by the submitter.

Refused to issue activity license – the activity license was refused; the submitter of the document will be notified about the reasons.

Annulled – the document has been cancelled.

5. Continuing an unfinished document

Use the document search (see section 4 of this manual) for finding an unfinished document.

In order to edit an unfinished document, click the link “Edit” corresponding to the relevant document in the document search window. A partially filled-in document form is opened and you can continue filling it in according to section 3 of the manual.

If the document is already submitted to the Agency of Medicines, but needs to be changed later, then a copy has to be made of the submitted document, because the submitted document itself cannot be edited anymore (see section 6 of this manual).

In order to permanently delete an unfinished document, click the button “Delete” at the bottom of the document form. A deleted document cannot be restored again.

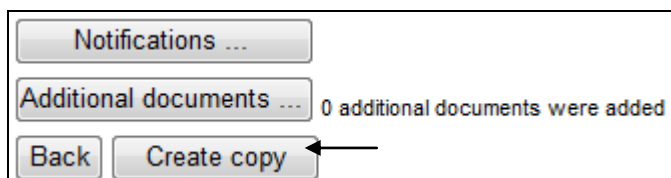


6. Making a copy of an old document for starting a new document

A submitted document cannot be changed anymore, but a copy can be made of it if necessary, to be used as a starting point for filling in a new document. If you want to withdraw a submitted document, then immediately send a free-text notice to that effect to the Agency of Medicines.

Use the document search for finding a submitted document (see section 4 of this manual).

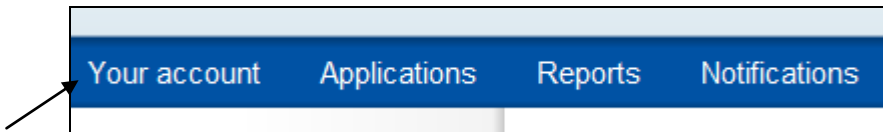
To make an editable copy of a submitted document, click the link “View” corresponding to the relevant document in the document search window, and then click the button “Create copy” at the end of the opened document. The software will ask whether you want to make a copy of the document together with its enclosed documents or not – make that selection according to your needs.



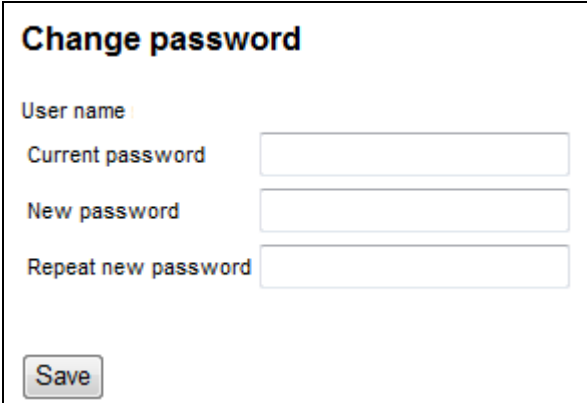
7. Changing the password and user account data

7.1. Changing the password

In order to change the account data, log into the Client Portal and open the selection “Actions” in the top menu.



The next window displays a list of actions. Make the selection “Change password”. In order to change the password, you are required to enter the old password and then twice the new password. A password must contain at least 8 symbols and must include capital letters, small letters and numbers.

A screenshot of the 'Change password' form. The title is 'Change password'. Below the title are four input fields: 'User name', 'Current password', 'New password', and 'Repeat new password'. At the bottom left of the form is a 'Save' button.

If you can't remember your password, then you can restore it according to the procedure described in section 7.3 of this manual.

It's not required to regularly change the password. Still, it is a recommended secure practice to change your password from time to time. Never give your password to others!

7.2. Changing account data (contact data, etc)

You can change your contact data (e-mail, telephone, address) via the top menu selection “Your account”, sub-selection “Change contact data”. In the next window, enter your new contact data.

The procedure for changing the data of sub-users is described in section 9 of this manual.

To change other account data, you will need to send a free-text letter to that effect to the administrator of the Agency of Medicines via the Client Portal.

7.3. Restoring a forgotten password

If you have forgotten your password, then you cannot change it to a new one via the Client Portal itself, because a password change requires that you enter the old password first. In this case, the password restoration procedure needs to be started from the home page – click the link “Forgot the password?” in the login box.

This opens a window where you can enter your e-mail address that is related to your user account. Further instructions will be sent to that e-mail address.

If no message is received at the entered e-mail address within reasonable time, then look into the spam mail folder of your e-mail software (Junk Folder, Spam, etc.). Automatic messages can sometimes end up erroneously filtered into spam.

If a password change fails, then you can ask for help from the administrator of the Client Portal who can change your password for you.

The password automatically generated by the Client Portal is complex and not easy to remember. You should change it at the first opportunity (see section 7.1 of this manual).

8. Subscribing to notices and unsubscribing from notices

You can subscribe for notices about document statuses, by clicking the button “Notices” at the bottom of the document form.

You can subscribe for notices to be sent to maximum three e-mail addresses simultaneously, and you can select whether you wish to receive the automatic notices in Estonian or English language.

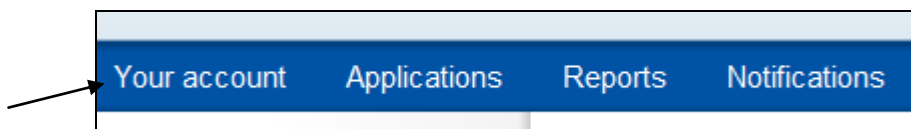
Notifications about the document status on your e-mail

1. e-mail	<input type="text"/>	English
2. e-mail	<input type="text"/>	Estonian
3. e-mail	<input type="text"/>	Estonian

Sometimes the Client Portal sends several notices within a single message. Don't be alarmed because of this. A status change doesn't always mean that the processing of the document has ended – by subscribing to document status notices, you will be notified about e.g. the document having moved from the Client Portal to the processing environment of the State Agency of Medicines or if errors are found in the document that need to be corrected.

If you don't want to receive automatic notices anymore, then you can also monitor the status of submitted documents via the document search. Unless you have agreed otherwise, you will be notified about the final decision of the processing or about a need for additional information via a personal message from the State Agency of Medicines in any case.

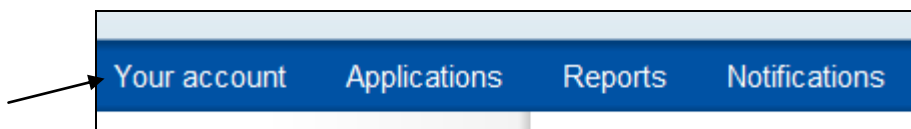
You can view, add, change and remove subscriptions to notices via the selection "Your account" in the top menu.



In the list that opens, select "Subscribing to notices". A search window for notice subscriptions opens, where all notice subscriptions related to your user account are displayed by default. You can unsubscribe from notices by clicking the link "Delete" in front of the relevant line.

9. Administrating sub-users

If your user account allows creating sub-users, then you can view and change their data via the selection "Your account" in the top menu.



Choose "Administrate sub-users" to block a sub-user, change sub-user's password or data.

If you have problems with changing the data of sub-users or deleting sub-users, then send a free-text message to that effect to the administrator of the Agency of Medicines.

10. Didn't find the answer in the user manual?

Every document form has a link "Help" at top right; this opens a comprehensive help text about filling in the form. The instructions give both technical and content advice for correct filling in and submitting of the form. The instructions may also provide a link at the bottom, leading to additional information on the website of the State Agency of Medicines and/or a reference to a legal act on the basis of which the document form has been prepared.



You can also get general advice from the frequently asked questions on the homepage of the Client Portal (the button FAQ in the left-hand menu).

You can also always get advice from the State Agency of Medicines, by sending a message via the Client Portal, writing to the e-mail address kliendiportaal@ravimiamet.ee or calling the phone number +372 737 4140.