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EDQM DCEP Sharing Tool - How to manage your account

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Revision history of the documentl

| Revision N°	Date	Reason
Initial version	01/2022	Implementation of tool
1 R	09/2022	Clarifications and introduction of additional information to assist the user in interactions with the tool including a section of frequently asked questions.
2 R	06/2024	Update of screenshots according to new system layout
3R	10/2024	Update of screenshots following slight change of layout, removal of expiry notification and addition of Q&A about the sharing of documents from the applicant to the EDQM

1. Scope

The EDQM DCEP Sharing Tool is an IT tool used to ensure that EDQM documents related to Certificate of Suitability (CEP) applications are shared securely by the EDQM with the CEP dossiers' applicants/holders during the lifecycle of a CEP application. This tool requires the use of a defined and dedicated account by the company. The instructions below are intended for CEP dossiers' applicant and/or authorised representative and address the use and management of their **EDQM DCEP Sharing Tool** account.

2. Managing an account

CEP dossiers' applicants and authorised representatives are requested to always ensure that the EDQM Certification of substance Department (DCEP) has been provided with the details and the valid e-mail address of the appropriate contact person. Any changes to this information should be communicated immediately to the DCEP i.e. using both documents published on the EDQM website, namely "Change in Contact Details: Notify the EDQM (PA/PH/CEP (10) 86)" and the form "Change of contact details for a CEP application". Failure to inform EDQM of a change in contact may result in a holder not receiving important communications about the CEP or application.

An account is automatically created by the **EDQM DCEP Sharing Tool** for the contact person defined in the most recent Application Form (in Contact person section) when a new application, revision, renewal or notification is submitted to the (DCEP) as part of a procedure linked to a CEP dossier.

The designated contact person will receive a notification from the **EDQM DCEP Sharing Tool** which informs them of the automatic creation of their account, with their username, and invites them to choose a password. The **username** is by **default the email address** of the contact person and can be found in the first sending made by the **EDQM DCEP Sharing Tool**.
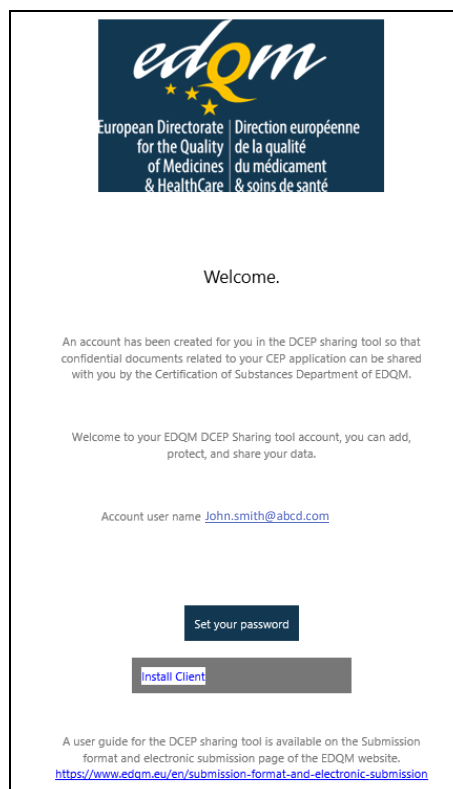
3. Setting the password

A valid **password** can be created by clicking on the button "Set your password". _It is important to take action as soon as possible and set the password, since the **link provided expires within four days.**_

In order to be valid any password in the EDQM DCEP Sharing Tool must be:

- a minimum of 10 characters
- a mix of capital letters and lower-case letters
- at least one numerical digit
- "common" passwords are not accepted (i.e. very easy to break passwords, for example "12345678", "qwerty", "password")

4. Setting password when the link has expired

When the link to set the password has expired, the error message "Could not reset password because the token is invalid" as shown below will appear.
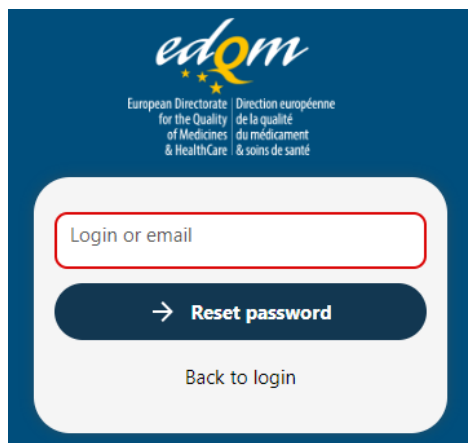
In this case, click on the **EDQM DCEP Sharing Tool** hyperlink, on the bottom-left of the window:(highlighted in a red circle on the screenshot above).
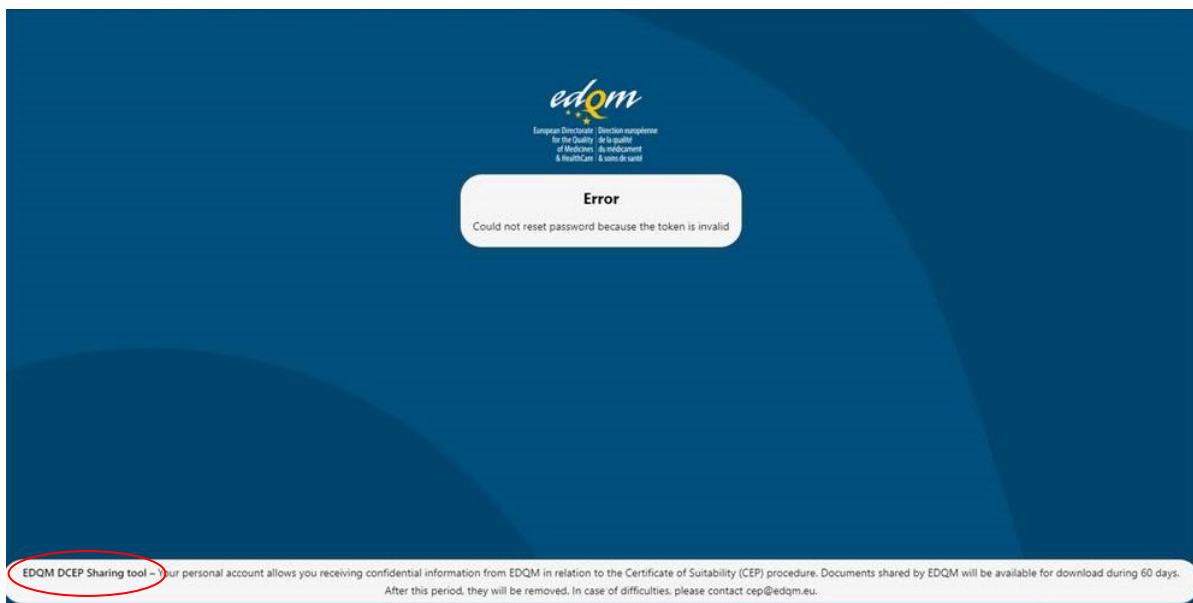
The window below will appear: click on "Forgot Password?"
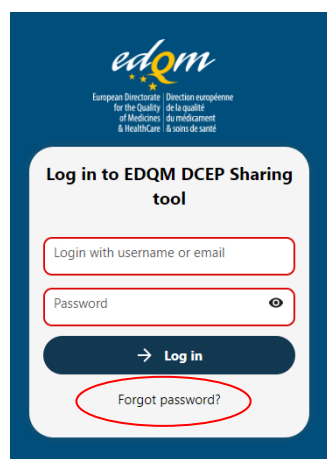
The window below will appear:

Fill-in the username (your email address as declared, see section 2) and click on "Reset Password".

Use the rules given in section 3 to set the new password.

5. Accounts and email addresses

For technical reasons to ensure security, EDQM documents are shared by the DCEP only with one e-mail address, the one indicated in the Application Form for the assigned Contact person. It is strongly advised to choose **one** email address per contact person (and only one).

> 1 Valid e-mail address = 1 Account

If more than one email address is given for a same contact person, EDQM documents related to a CEP dossier application may be shared with either email, resulting in the creation of one **EDQM DCEP Sharing Tool** account for each e-mail address, which could generate confusion to the user and lose traceability, and result in important communications being missed.

An email account must be linked to only one account, for technical reasons, it is not possible to have the email address linked to multiple accounts. The sending of information using the tool will not work correctly if the same email address is used for multiple accounts.

Users should not edit their accounts (e.g. change the email address) in the DCEP sharing tool. They must inform EDQM using the form available on the EDQM website and the account details will be updated. If users edit their account details directly in the DCEP sharing tool, then there will be issues with the sharing of communications and there is the likelihood that important communications may be missed.

For any issues or difficulties encountered, EDQM DCEP should be contacted by e-mail (mailbox for general communication indicated on the letters issued by DCEP), in which case the requester should indicate the e-mail address used to connect to the **EDQM DCEP Sharing Tool**, and provide as many details and screenshots as possible to illustrate the issue they are reporting.

6. Period of availability of documents in the EDQM DCEP Sharing Tool

The designated contact person will receive a notification from the **EDQM DCEP Sharing Tool** which informs them of the sharing of a document by EDQM.

It is important to <u>download the EDQM documents shared in a timely manner</u>, as they are available for a maximum period of 60 days in the **EDQM DCEP Sharing Tool**.

The share will expire automatically for the documents after the 60 days and the documents will not be available anymore in the user's inbox.

7. Frequently asked questions about the EDQM DCEP sharing tool

Q. When I open the link to set the password for my account, I get the message "Couldn't reset password because the token has expired". How do I proceed?

A. The link to set the password is valid for 4 days and this period has passed. See section 4 for how to proceed.

Q. I have not yet received a link to set a password for my account in the **EDQM DCEP sharing tool** even though I am the authorised contact for a CEP, what should I do to get an account?

A. The accounts are created at the reception of a new request (as described in section 2) or when EDQM first needs to share something with you using the **EDQM DCEP sharing tool** if the account has not yet been created. If you have not submitted something, or EDQM has not yet had something to share, since the tool is in use, then the account will not yet have been created. Do not worry; the account will be created automatically when needed.

Q. I have forgotten my password for my account in the **EDQM DCEP sharing tool**, what should I do?

A. There is a link on the login page "Forgot password", use it to reset your password.

Q. When I tried to login I received a message "We have detected multiple invalid attempts from your IP. Therefore your next login is throttled up to 30 seconds" (I had tried to login unsuccessfully a few times). What should I do?

A. The system will be blocked for a short time. Try again a little later and provided the login and password are correct, it should allow you to connect.

Q. I received a notification about some activity at the **EDQM DCEP sharing tool** but when I click on link to share the file, the file cannot be found in my account?

A. It is likely that you have more than one account and you are logged into the **EDQM DCEP sharing tool** with the incorrect account. Please check which account the notification email was sent to, and if appropriate, log out of the tool, then log in with the other account and if you click on the link in your notification email, you should see the document.

When you are finished using the DCEP sharing tool, it is highly recommended to log out before closing the browser window, if you do not, then the next time you open the DCEP sharing tool you may still be logged in.

Q. As an applicant, can I share a document with EDQM via the DCEP Sharing tool?

A. No, the EDQM Sharing tool is only a one-way tool, to share documents from the EDQM to the applicants. The upload of documents by applicants is deactivated. If you wish to share documents regarding your CEP application with the EDQM, you need to use the CESP portal (guidance for [submissions](#) on EDQM website).

Q. I have a problem which is not described in these FAQs?

A. Please contact EDQM using the email address included in the correspondence sent to you about the CEP.