THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

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How to communicate efficiently with the EDQM on CEP applications

Webinar 29/03/2022

Certification of Substances Department

EDQM/Council of Europe

Programme of the Webinar

1. **New application forms** (AF)

   How to complete it in order to facilitate the treatment of your application.

2. **New DCEP sharing tool**

   How to use the new IT system to download documents related to your application, shared by EDQM-DCEP in a secure way.

New application forms

- The following forms have been updated:
  - Change of contact details form
    - change_of_contact_details_for_a_certificate_of_suitability_application.doc
  - New application form
    - application_form_request_for_new_certificate_of_suitability.doc
  - Sister file form
    - application_form_request_for_a_certificate_of_suitability_via_the_sister_files_procedure.doc
  - Revision/Renewal form
    - application_form_request_for_revision_or_renewal_of_a_certificate_of_suitability.doc
- Implementation date: 1st April 2022

Change of contact details

Change of contact details

- Policy PA/PH/CEP (10) 86, 2R
  - Ensure **timely and efficient communication** with EDQM by keeping the details of the official contact person up to date
  - Details **can be updated at any time during the lifecycle** of a CEP application
  - Option 1:
    - Include new details in table 2.2 of the application form (e.g. Revision/Renewal)
    - Mention in cover letter if change is for one CEP dossier or for several/all dossiers and list the impacted dossiers
  - Option 2:
    - Notify EDQM by using form “Change of contact details for a CEP”
    - Option to be used when the assessment procedure has aleady started or there is no ongoing procedure

Change of contact details form

CHANGE OF CONTACT DETAILS
FOR A CERTIFICATE OF SUITABILITY APPLICATION

Date of notification: ...../...../.....

1. General Information

Dossier number and substance

CEP: .....

[Substance name]: .....

Name of the Certificate holder: .....

In case the change concerns several CEPs, please list the dossier numbers and substances here:
NB: if needed, an annex with list of all affected dossiers might be provided

CEP	[Substance name]

- CEP dossier number:
  - Example: CEP 2000-125

Change of contact details form

Title* (Ms, Mr, Dr)	
First name*	
FAMILY NAME*	CAPITAL LETTERS
Job title/Department	
NAME OF THE COMPANY*	CAPITAL LETTERS
Recommended: **ORG_ID[1]**	
Recommended: **LOC_ID[1]**	
Address for correspondence*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

- Fields marked * are mandatory
- [1] see SPOR - Organisation Management Services (OMS) on the EMA website
- [2] no PO box, only physical address
- [3] please provide one email address. Shared mailboxes are strongly preferred.

Change of contact details form

Does the contact person mentioned above belong to the CEP holder's group :

☐ Yes

☐ No
→ please provide an *authorisation letter (see Annex 1)*
→ please provide details of a contact person within the CEP holder's group:

Title* (Ms, Mr, Dr)	
First name*	
FAMILY NAME*	
Job title/Department	
NAME OF THE COMPANY*	
Recommended: **ORG_ID**[1]	
Recommended: **LOC_ID**[1]	
Address for correspondence*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

➢ When contact person is not belonging to CEP holder group, a contact person within the CEP holder group must be provided

New application form

New application form: General information

Application Form
REQUEST FOR
NEW CERTIFICATE OF SUITABILITY

(to be completed for each request for a new Certificate of Suitability to the monographs of the European Pharmacopoeia, in accordance with Resolution AP-CSP (07) 1)

Date of submission: ……/……/……

Please note that the format of the submission should be eCTD.
NB: exceptions are for substances for veterinary use only (VNeeS or eCTD accepted) or for TSE risk assessment (PDF required).

1. General Information:

1.1. Type of application for a new Certificate of Suitability:

☐ *Chemical*	☐ *Chemical and sterile*	☐ *TSE*
☐ *Double (Chemical and TSE)*	☐ *Double and sterile*	☐ *Herbal*

1.2 Name of the substance using the Recommended International Nonproprietary Name (rINN):

1.3 *If needed* **(subtitle):** specify any subtitle requested such as 'micronised', 'process B', …:
NB: acceptability of the proposed subtitle will be confirmed during assessment

1.4 Monograph(s) you are referring to:
(*Name, Number, Year of publication*)

1.5 Re-test period requested: *(not applicable for TSE Certificate of Suitability)*

Proposed re-test period (in months)	
If applicable: required storage conditions (e.g. T°, nitrogen atmosphere, others, …)	
Tick this box if you do **not** wish a re-test period	☐

New application form: Intended certificate holder

2.1 Intended certificate holder:	
NAME OF THE COMPANY*	CAPITAL LETTERS
Recommended: **ORG_ID**[1]	
Recommended: **LOC_ID**[1]	
Address*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

- Fields marked * are mandatory
- [1] see SPOR - Organisation Management Services (OMS) on the EMA website
- [2] no PO box, only physical address
- [3] please provide one email address. Shared mailboxes are strongly preferred.

New application form: Contact person

Follow same instructions as on previous slide and slides 8 and 9

2.2 Contact person authorised for communication on behalf of the intended holder. This person will be the main contact point with EDQM:	
Title* (Ms, Mr, Dr)	
First name*	
FAMILY NAME*	
Job title/Department	
NAME OF THE COMPANY*	
Recommended: **ORG_ID**[1]	
Recommended: **LOC_ID**[1]	
Address for correspondence*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

Does the contact person mentioned above belong to the intended CEP holder's group :

☐ Yes

☐ No

→ please provide an *authorisation letter (see Annex 1)*

→ please provide details of a contact person within the intended Certificate holder's group:

Title* (Ms, Mr, Dr)	
First name*	
FAMILY NAME*	
Job title/Department	
NAME OF THE COMPANY*	
Recommended: **ORG_ID**[1]	
Recommended: **LOC_ID**[1]	
Address for correspondence*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

New application form: Manufacturing sites

3. Manufacturing site(s): detailed name and address of all sites° involved in the manufacture of this substance

° All sites involved in the manufacture of the substance after the introduction of starting material(s), including quality control / in process testing sites, intermediate manufacturers, milling, micronisation and sterilisation sites should be listed in separate boxes and their role should be specified.

Role of the manufacturing site*	
NAME OF THE COMPANY*	
Recommended: **ORG_ID**[1]	
Recommended: **LOC_ID**[1]	
Address*[2]	
City/Town*	
Postcode*	
State/Province	
Country*	
Telephone*	
E-mail*[3]	

➢ Follow same instructions as on slide 8

GPS (WGS 84) coordinates of the site*:
Latitude (+ or -) and Longitude (+ or -) expressed in Degrees to at least 5 decimal places

	+ or -										
Latitude:		NA			.						
Longitude:					.						

GPS coordinates:

- Policy PA/PH/CEP (10) 118, 2R
- Provide GPS coordinates only as per the internationally recognized WGS 84 system.
- Latitude (North or South) and longitude (East or West), only expressed in Degrees to at least 5 decimal places (DD.DDDDD)
- Numeric only (no N, S, E, W), with positive and/or negative symbols:
  - Latitude: North="+" or blank, South="-"
  - Longitude: East ="+" or blank, West ="-"

New application form: List of approved/marketed products

Country of registration	Evaluation procedure number by which the medicinal product containing this source of substance was approved	Brand name of medicinal product	List of countries where the medicinal product is commercialised

- Please provide key information regarding accepted marketed medicinal products within the European Union, EEA, Switzerland, the UK, Australia, or Canada containing the substance manufactured by your company according to the manufacturing process presented in this CEP dossier.

New application form: List of accepted ASMFs/DMFs

Country of registration	ASMF/DMF registration number	Latest ASMF/DMF holder's version	Approval date

- Please provide information concerning ASMFs/DMFs which have been accepted after October 2012.

Has this source of substance already been evaluated by WHO after October 2012 in the context of the pre-qualification programme?

Yes (please specify WHO ref No.): WHOAPI-…… APIMF Version No. ……

No

New application form: Declarations

Annexes	Yes	N/A
1) Letter of Authorisation	☐	☐
2) Letter of agreement • In cases where the manufacturer is not the intended holder of the Certificate of Suitability	☐	☐
3a) Letter of declaration that the manufacture of the drug substance is according to the presented dossier and to GMP • For each manufacturing site	☐	☐
3b) Letter of declaration that the manufacture of the substance is according to the presented dossier and to GMP rules / quality assurance system (applies to TSE risk substances or excipients) • For each manufacturing site	☐	☐
4) Letter of declaration of willingness to be inspected • For each manufacturing site	☐	
• For holder (if different from manufacturers)	☐	☐
5) Declaration on the use of substances of animal/human origin (not applicable for applications for TSE risk assessment)	☐	
6) Letter of commitment to provide samples upon request by the EDQM (not applicable for applications for TSE risk assessment)	☐	
7) Declaration of Holder's commitments	☐	

➢ Please indicate in the list which annexes are part of your application

Sister file form

Sister file form:

Application Form
REQUEST FOR
A CERTIFICATE OF SUITABILITY
VIA THE 'SISTER FILES' PROCEDURE

➢Follow instructions new application

Date of submission: ……/……/……

Please note that the format of the submission should be eCTD.
NB: exceptions are for substances for veterinary use only (VNeeS or eCTD accepted) or for TSE risk assessment (PDF required).

1. General Information:

1.1. Type of application:

☐ *Chemical*
☐ *Double (Chemical and TSE)* ☐ *Herbal*

CEP dossier referred to:

- **CEP: ……**
- **[Substance name]: ……**

Proposed Subtitle for the sister file: …….

➢CEP dossier number:
➢Example: CEP 2000-125

Revision/renewal form

Request for revision/renewal form: General information

1.2 **Type of application** *(please tick one box only)*

☐ Notification *(may include several changes)*

☐ Minor revision *(may include several changes including notifications)*

☐ Major revision (*may include notifications and minor changes)*

☐ Renewal *(notifications and minor changes may be included)*

☐ Transfer of holdership

☐ Grouped revision *(several dossiers affected by the same change[s])*
Please list the dossier numbers and substances below:
NB: if needed, an annex with list of all affected dossiers may be provided

CEP	[Substance name]

Request for revision/renewal form: Section 2

- Only to be complete for parts that have changed

- Company details
- Contact person
- Manufacturing sites

- Follow instructions as for New Application

Request for revision/renewal form: Comparative table

Annexes	Yes	N/A
7) Comparative table	☐	

- The comparative table should highlight the differences between the approved and proposed text of module 3, together with the correct classification of each change according to the EDQM Guideline for revisions. The justification for the changes should be fully developed in the cover letter.

Request for revision/renewal form: Declarations

Annexes	Yes	N/A
1) Updated letter of Authorisation	☐	☐
2) Updated letter of agreement • In cases where the manufacturer is not the intended holder of the Certificate of Suitability	☐	☐
3a) Updated letter of declaration that the manufacture of the drug substance is according to the presented dossier and to GMP • For each manufacturing site	☐	☐
3b) Updated letter of declaration that the manufacture of the substance is according to the presented dossier and to GMP rules / quality assurance system (applies to TSE risk substances or excipients) • For each manufacturing site	☐	☐
4) Updated letter of declaration of willingness to be inspected • For each manufacturing site	☐	☐
• For holder (if different from manufacturers)	☐	☐
5) Updated declaration on the use of substances of animal/human origin (not applicable for applications for TSE risk assessment)	☐	☐
6) Updated declaration of Holder's commitments	☐	☐

- In case of a change affecting a declaration, an updated declaration should be provided.
- For renewal applications, updated declarations of manufacture according to the presented dossier and to GMP (annex 3a or 3b) and of willingness to be inspected (annex 4) should be provided.

Request for revision/renewal form: List of approved/marketed products

➢ Only to be complete for renewals

Country of registration	Brand name of medicinal product	Date of commercialisation

➢ Please provide a list of marketed medicinal products within the European Union, EEA, Switzerland, the UK, Australia, or Canada containing the substance manufactured by your company according to the manufacturing process presented in this CEP dossier.

New DCEP Sharing Tool

New EDQM DCEP sharing tool

- In October 2021, the Certification of Substances Department (DCEP) of the EDQM implemented a new IT application for the **management of its activities** and **communication with CEP applicants**.

- The IT application is used to share **confidential** documents in a **secure** way between DCEP and CEP holders/applicants during the CEP lifecycle => no longer shared by e-mail.

- This tool requires the use of a defined and **dedicated account** for each holder/applicant.

- **IMPORTANT**: CEP holders/applicants need to maintain details of **contact person up-to-date**!

EDQM DCEP sharing tool account

DCEP sharing tool **accounts are created by EDQM** (not by CEP holders/applicants themselves):

2 cases:

1. **NEW applicants**

   - Companies sending a CEP request to EDQM-DCEP for the first time => companies which were not registered in the former EDQM-DCEP database.

   - The account will be created by DCEP **at reception of the CEP application**. The Application form should be clear regarding contact person details !

   => The contact person will **immediately** receive a notification from the EDQM DCEP sharing tool to inform about the creation of the account (even if NO document has yet been shared by DCEP in relation to the CEP application).

EDQM DCEP sharing tool account

2. EXISTING applicants

- Companies already registered in the EDQM-DCEP former database => they had already submitted CEP application(s) in the past.

- The account will be created by DCEP at the moment **when DCEP sends a document** in relation to the CEP application(s). The Application form should be up to date regarding contact person details !

⇒The contact person will **not immediately receive a notification** from the EDQM DCEP sharing tool until DCEP has shared a document in relation to the CEP application.

Creation of your account in the EDQM DCEP sharing tool

The designated contact person will receive a **notification e-mail** from the EDQM DCEP Sharing Tool which informs about the automatic creation of the account:

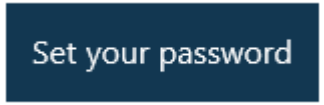
USERNAME: PROVIDED BY EDQM (by default the email address of the contact person)

PASSWORD: NOT PROVIDED BY EDQM (to be set by the contact person)

Creation of your account in the EDQM DCEP sharing tool

Setting the password:

Click on the button (link) in the notification email:



Set your password as soon as possible after receiving this notification, since the link provided expires within four days

Rules to set a valid password:

- minimum of 10 characters
- mix of capital letters and lower-case letters
- at least one numerical digit

Note: “easy” passwords are not accepted (e.g. "12345678”, “qwerty”, “password”)

How to manage your EDQM DCEP account

- Companies should ensure that the application form is clear and up to date with respect to the contact person details and provide **ONE valid e-mail address** of the appropriate contact person.
- **Invalid/obsolete e-mail** => the company will not receive communication from EDQM => delayed response or absence of response from the company => potential closure of a CEP application or cancellation of a CEP.

1 Valid e-mail address = 1 Account

ONE SINGLE EMAIL ADDRESS can be registered in the new DCEP sharing tool and thus:

ONE SINGLE EMAIL ADDRESS should be declared for the contact person in the application form!

How to manage your EDQM DCEP account

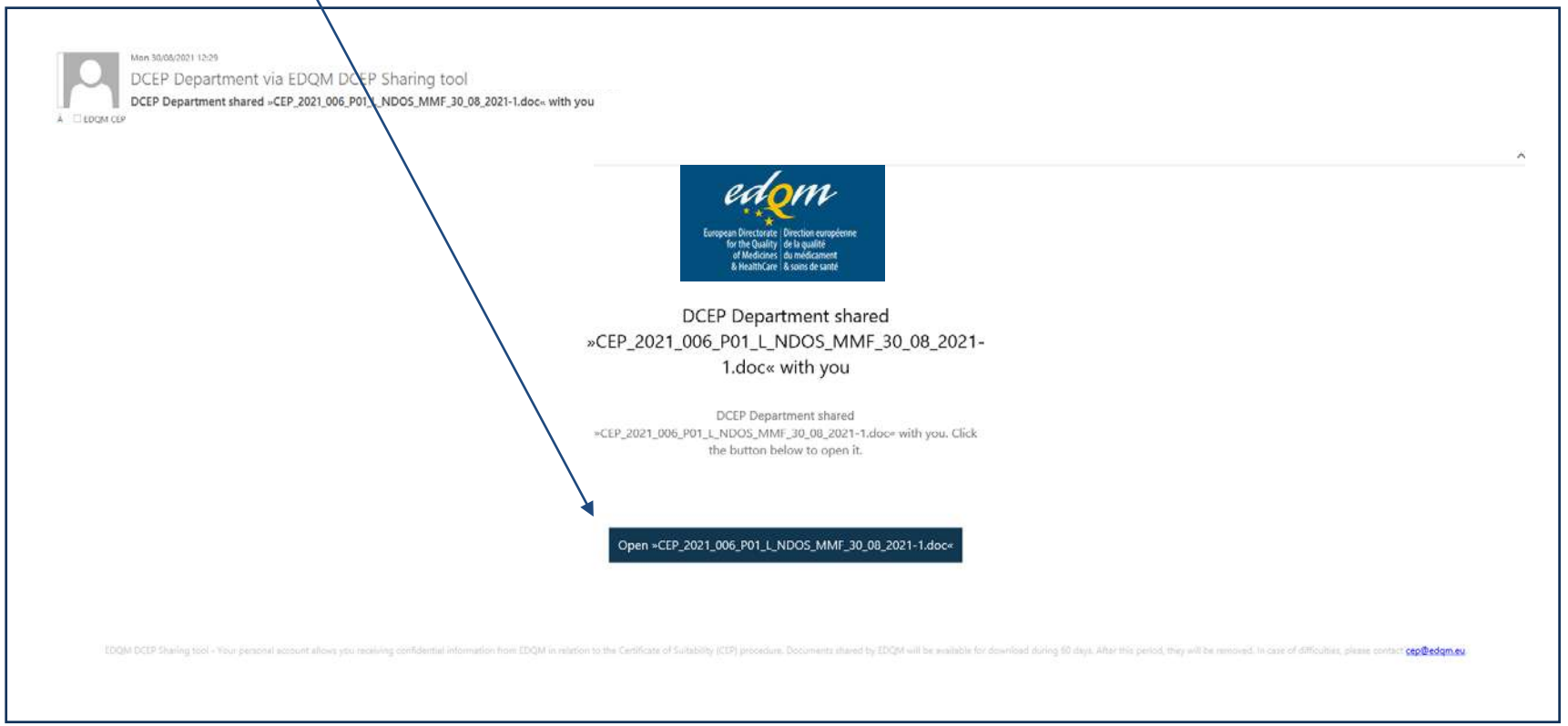
- **Changes in contact details** should be immediately communicated to DCEP.

- Change of contact details is free of charge.

Please read Document “Change in Contact Details: Notify the EDQM (PA/PH/CEP (10) 86)” available on the EDQM website

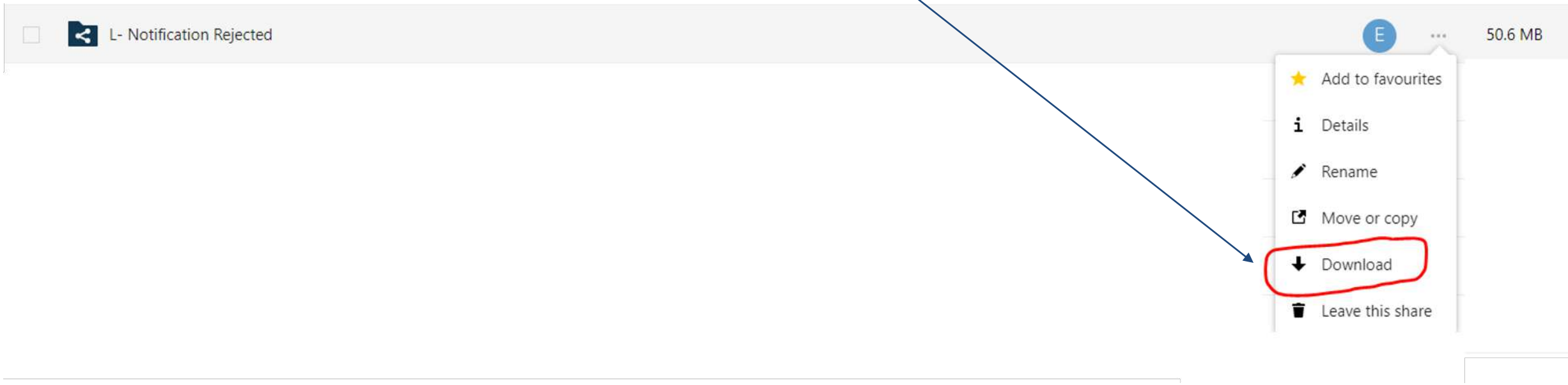
EDQM DCEP sharing tool

At the moment when DCEP shares a document via the EDQM DCEP sharing tool, the contact person will receive an e-mail with a **link** which allows downloading the document:



EDQM DCEP sharing tool

After entering your username and password, you can **download** the shared document:



EDQM DCEP sharing tool

Availability of documents

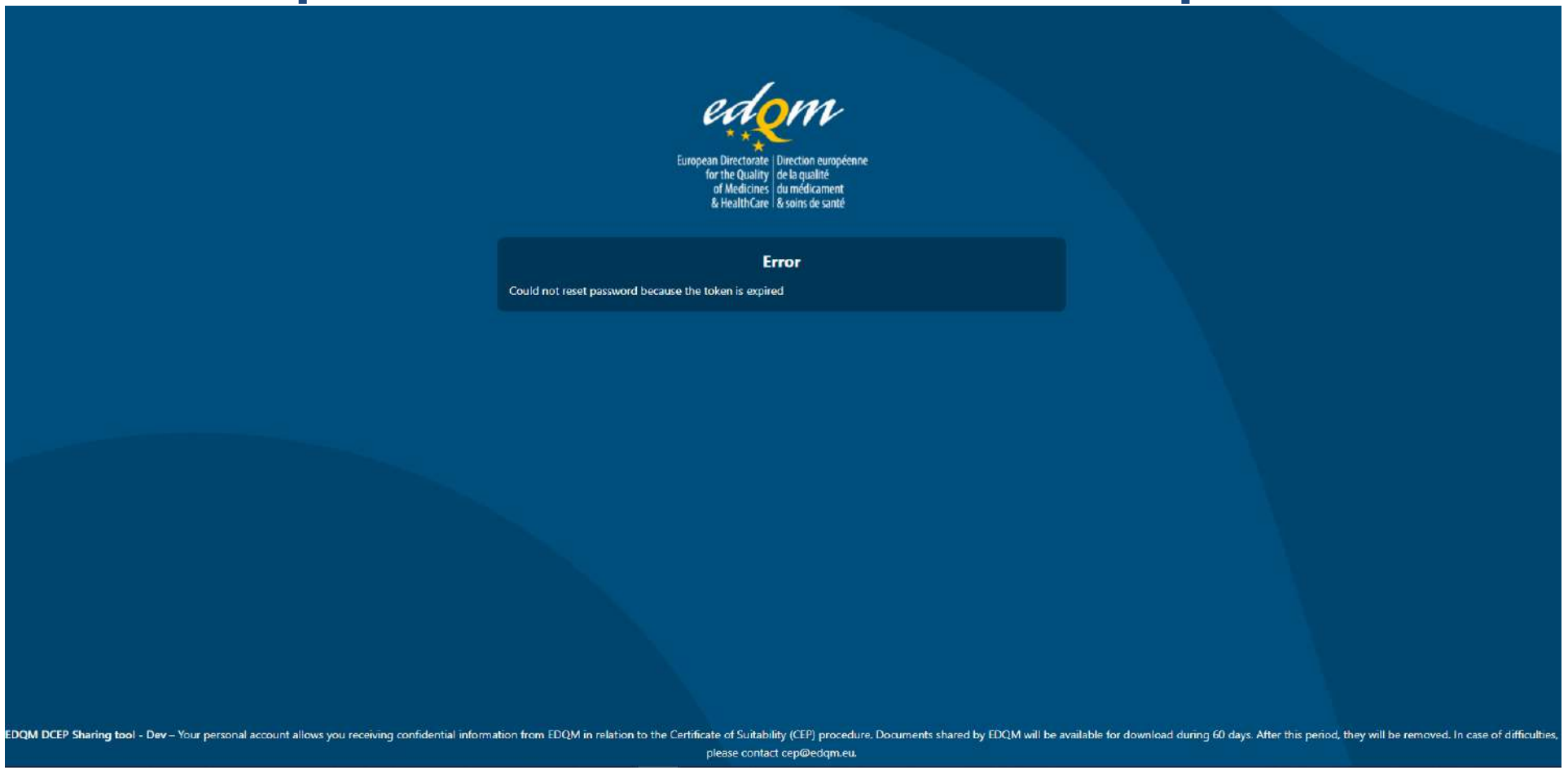
- Documents shared via the EDQM DCEP Sharing Tool are available for download for a maximum period of **60 days.**
- After this period they will be removed.

It is important to download the documents as soon as possible

3 common problems encountered by users

1) Error message received:

« Could not reset password because the token is expired »



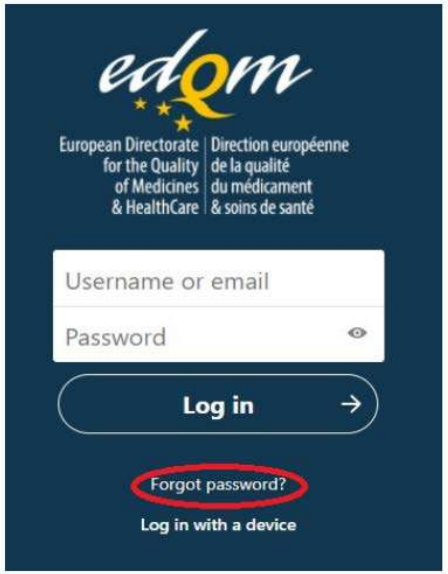
3 common problems encountered by users

Reason: **LINK** to set the password has **EXPIRED**

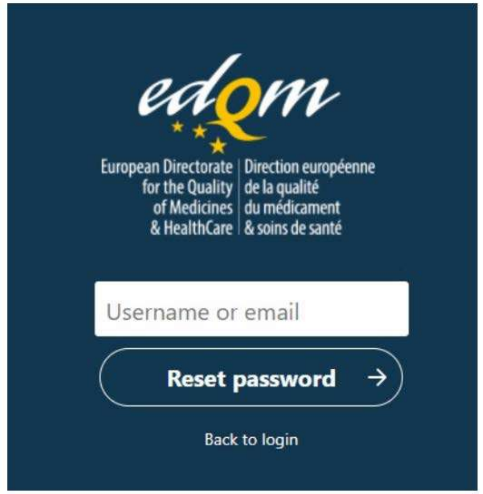
- The company did not set a password shortly after receiving the notification from the DCEP Sharing tool at the creation of their account.

1-Click on the **hyperlink** “EDQM DCEP Sharing Tool” on the bottom-left corner of the window

2-Click on “**Forgot Password?**

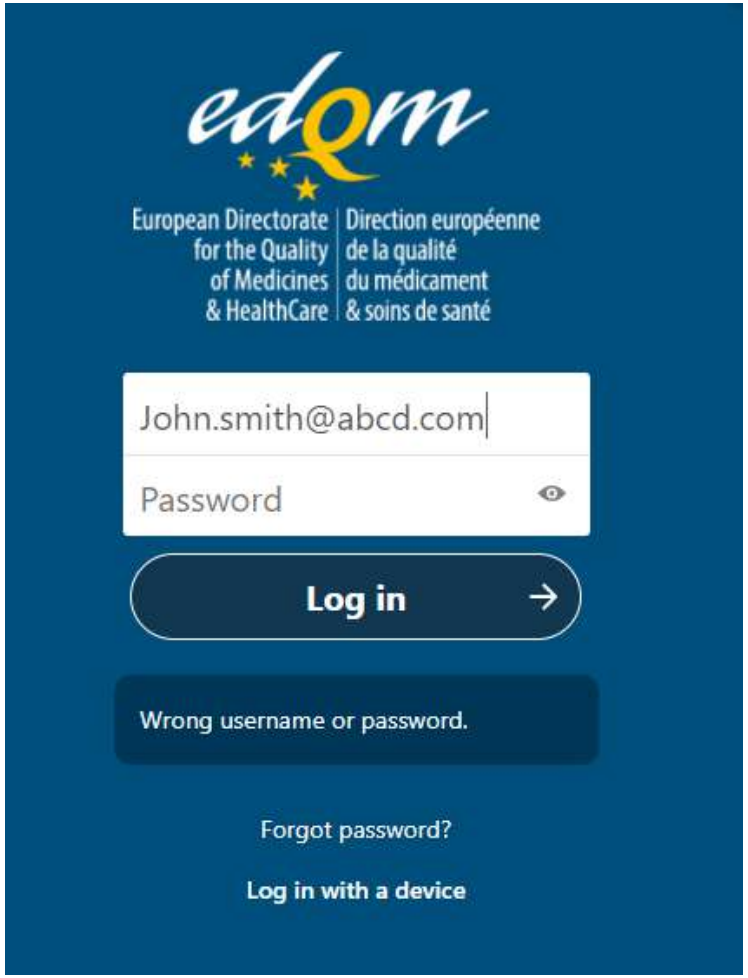


3-Fill-in the username (your email address) and click on “**Reset Password**”



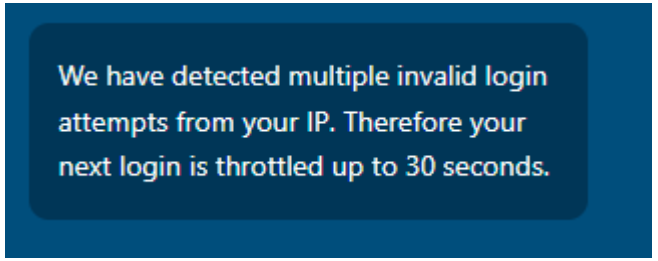
3 common problems encountered by users

2) Error message received: **« Wrong username or password »**



After multiple unsuccessful attempts, the system is blocked for a while, you need to re-try a little bit later with the correct password (if you remember it)

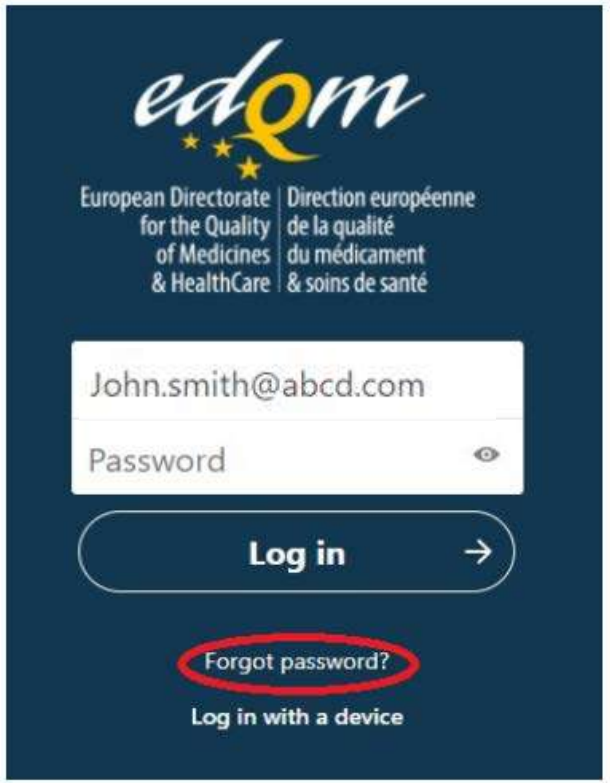
No need to contact EDQM immediately



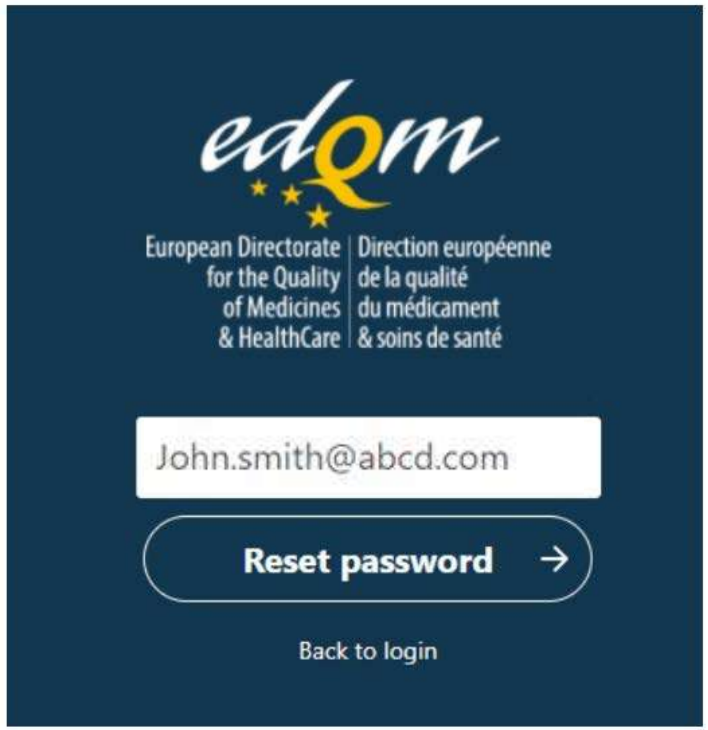
3 common problems encountered by users

Reason: the contact person forgot the PASSWORD (I)

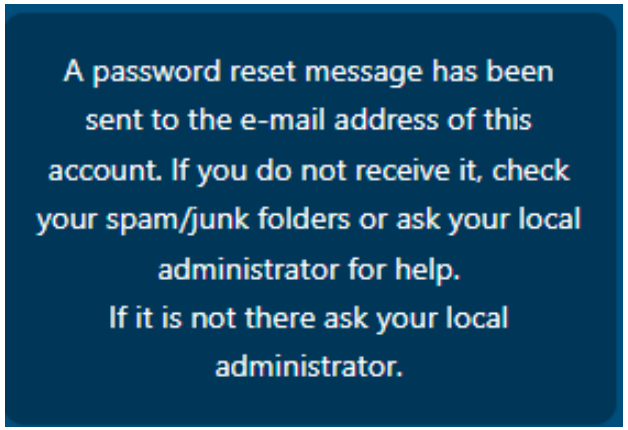
1-Click on
"**Forgot Password?**



2-Fill-in the username (your email address) and click on
"**Reset Password**"



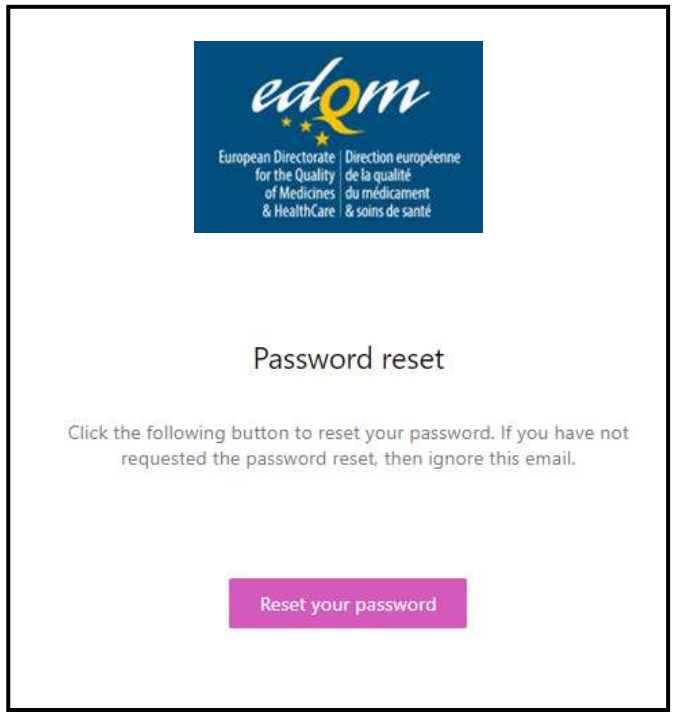
3-The following message is displayed. Check you e-mail box (also spam box) for a link to reset password



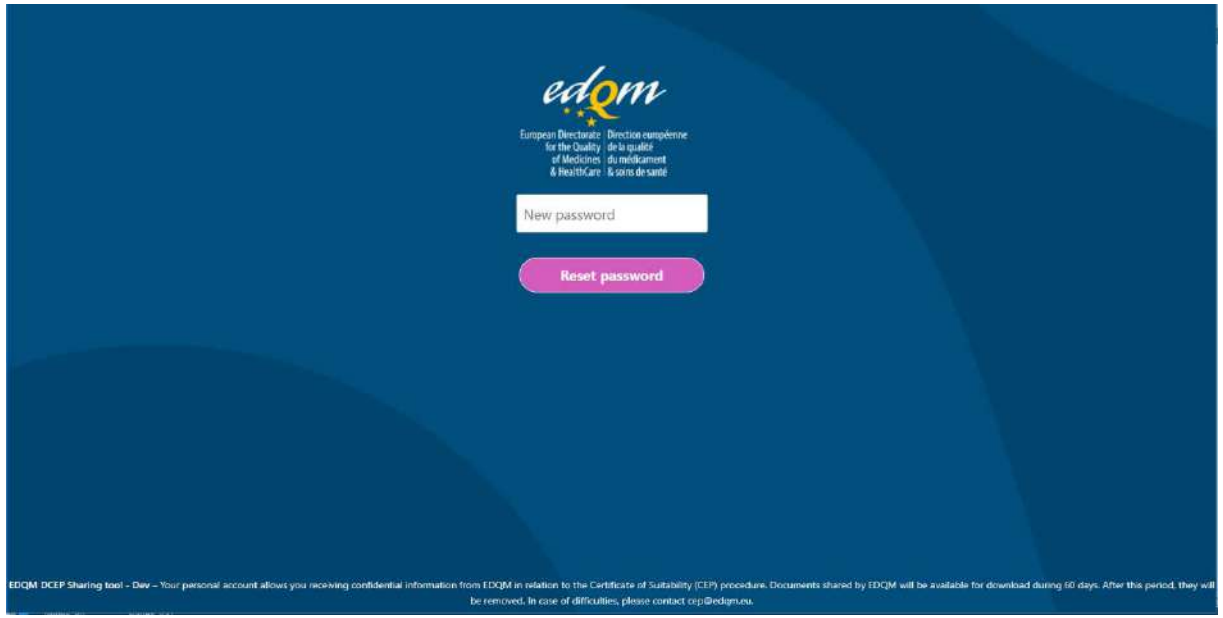
3 common problems encountered by users

Reason: the contact person forgot the PASSWORD (II)

4-You will receive an email
« Password reset »



5- you will be able to enter a
New password



3- Document availability period exceeded (60 days)

Not possible to download the document anymore.

⇒ Please contact EDQM-DCEP **by e-mail** at cep@edqm.eu

⇒ EDQM-DCEP will **share again** the same document with the same contact person (or with a new contact person, provided that changes have been duly communicated to DCEP)

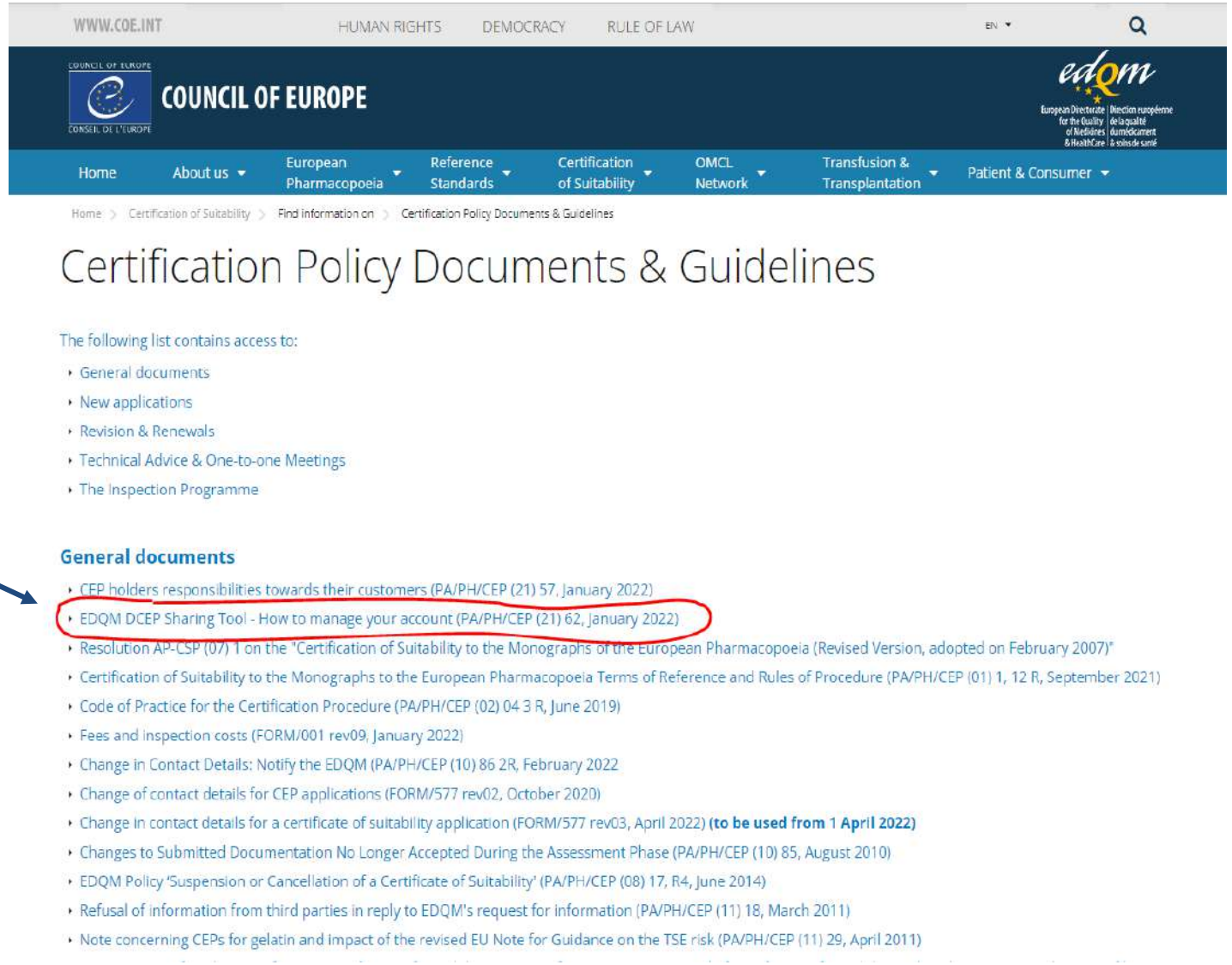
Other problems

For any other issues or difficulties encountered, EDQM DCEP should be contacted by e-mail (cep@edqm.eu) and provide the following information:

1. The name of your **company**
2. The **e-mail address (=account)** used to connect to the EDQM DCEP Sharing Tool
3. As many **details** as possible (e.g. date, what you were trying to do in your account e.g. connect, reset password, download document)
4. **Screenshots** of the error messages received

How to manage your EDQM DCEP account

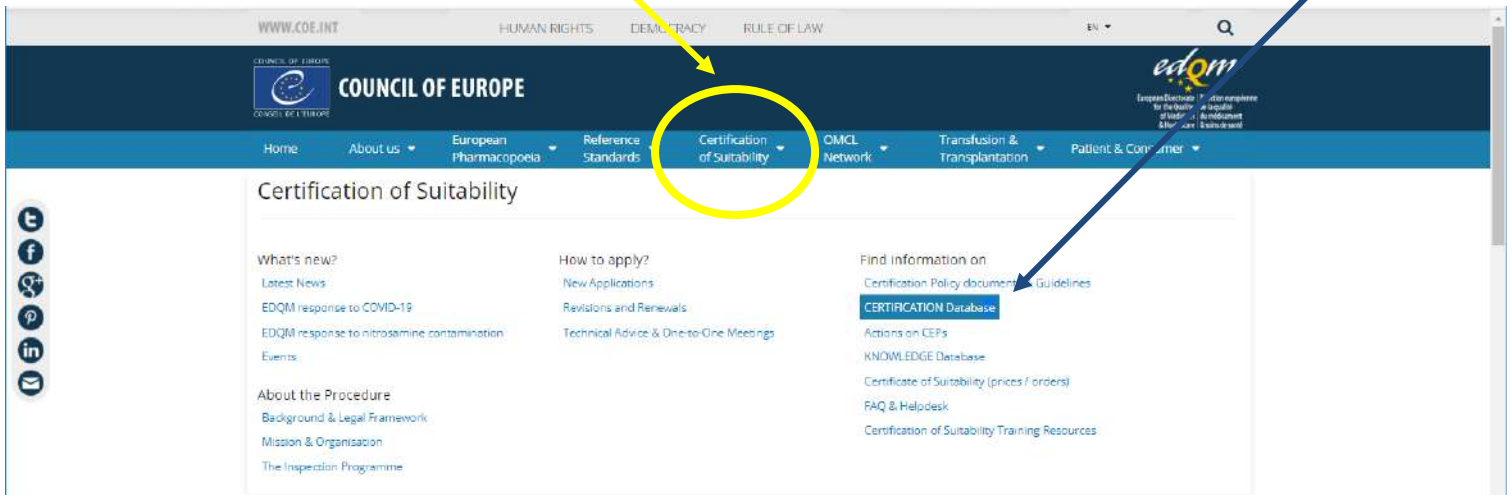
Specific instructions are available on the EDQM website under « Certification Policy Documents & Guidelines » for the maintenance of your account in the EDQM DCEP sharing tool

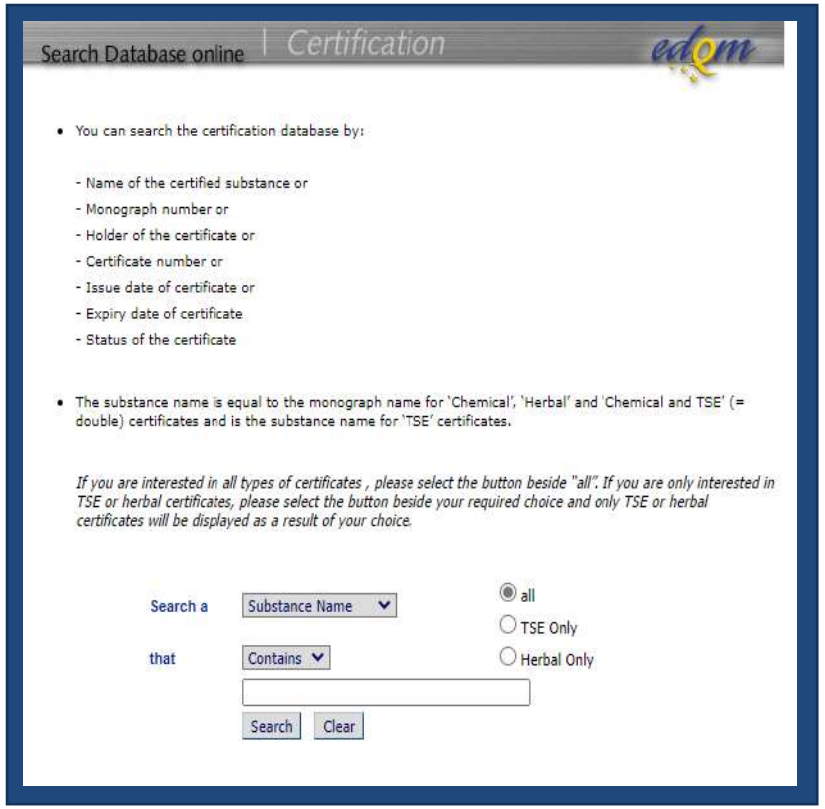


Please note that as from 1st April 2022, the EDQM website interface will change !

New features on the Certification on-line database

- The Certification on-line database is accessible from the EDQM website, under "**Certification of Suitability**".





- You can check if a **CEP is valid** (updated daily).

https://extranet.edqm.eu/publications/recherches_CEP.shtml

New features on the Certification on-line database

8 possible CEP statuses (compared to 4 before):

- **Valid**
- **Expired**
- **Withdrawn:** the reason is now more explicit
  - Withdrawn by Holder
  - Withdrawn by EDQM GMP non-compliance
  - Withdrawn by EDQM Failure to CEP procedure

NEW

- **Suspended:** the reason is now more explicit
  - Suspended by Holder
  - Suspended by EDQM GMP non-compliance
  - Suspended by EDQM Failure to CEP procedure

NEW

Thank you for your attention

Stay connected with the EDQM

EDQM Newsletter: **https://go.edqm.eu/Newsletter**
LinkedIn: **https://www.linkedin.com/company/edqm/**
Twitter: **@edqm_news**
Facebook: **@EDQMCouncilofEurope**