Certification of Substances Division

CBW/CB

PUBLIC DOCUMENT
(LEVEL 1)

English only/Anglais seulement

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Certification of suitability to the Monographs of the European Pharmacopoeia

Use of CESP to submit electronic documents to EDQM

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Before submitting electronic documents via the CESP, you must first create a user account. You can register from the Home page of the CESP.

Connect to the CESP: **https://cespportal.hma.eu/**

Step A – Preparation of Delivery file

To submit documents to the EDQM, you should login from the home page using your account details, and create a delivery file for the submission.

The "delivery file" is the file which the CESP system uses to route the submission to the required agencies.

You are required to provide information about the submission:

New Delivery File

Step 1	Step 2

Company *

_CESP TEST Company

Area *

EDQM

Regulatory Activity *

Request for new CEP

Sub Activity *

H001 Not Applicable

Zip File Type *

-- Select --

Comment

Place comments here concerning your dossier.

Next >

For the choice **"Area"**, ensure to select **"EDQM"**.

Below this, choose the most appropriate **"Regulatory Activity"** which corresponds to the type of information you are sending to the EDQM. The list of regulatory activities is as follows:

- Request for new CEP
- Notification/revision/renewal
- Response to request for additional information
- EDQM inspection
- Other (e.g. submission of information not requested by EDQM)

Any comments or information relating to your submission should be mentioned in the **"comments"** box, which is a free text box.

In particular, the following information must be given at a minimum:

- CEP Dossier Number (if you have one)
- Substance Name
- Supporting comments relating to the submission

Select one of the Zip File Types "Microsoft compressed folders", "Winzip", "WinRaR", "7-Zip", "Zipped with other software"

Note: It is recommended to submit your files as zipped files. This will reduce the possibility of complications during the delivery of your file. It is also important to note that zipped file names should not contain any special characters, and the file name / path length should not exceed 240 characters.

Please consult the HMA guide to zipping submissions correctly, which is available on the HMA website under "General Information".

Clicking **"Next"** will present the following screen:

Please ensure that **"EDQM"** is selected. Once you have selected "EDQM", click **"Submit"** which will present the "Delivery Note Download" page.

Click the download button to download the delivery file (xml file):

Delivery File Download

IMPORTANT NOTICE: Please check for any national requirements for electronic submissions, refer to the contacts page for agency specific information.

When uploading your submission with either the sFTP client or the web based file transfer system :

1. Download the delivery file to your local PC, by selecting the "Download XML file" button.
2. Do not rename or modify the delivery file.
3. Ensure that there are no other files or folders in the root of the remote server
4. Upload you submission zip file to the remote server, ensuring that is its fully uploaded before going to the next step.
5. Upload your delivery file to the remote server.
6. The submission will then be delivered and you will receive confirmation emails of delivery.
7. Ensure that the emails from cesp@hma.eu are not blocked or sent to your junk mail.

Download Delivery File

Note: This delivery file is unique for the submission and should not be reused. You should save it to an appropriate location and must not change the file name.

Step B –Transfer the submission documents to CESP

Once the delivery file has been created and saved in the appropriate location, the next step is to transfer the documentation using an sFTP client or via a Web Based File Transfer System.

The following section is relative to the Web based file transfer system only, as it is not possible to provide details of all available sFTP client software.

Note: More detailed information on creating delivery files and transferring submissions to CESP are available on the HMA website: https://cespportal.hma.eu/GeneralInfo

Web Based File Transfer System:

The web based file transfer system is accessible on the CESP home page once you have logged in.
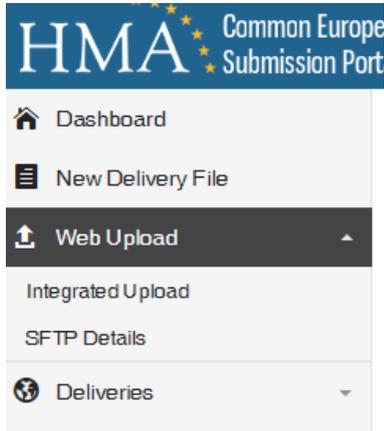
Once logged in, you must create a folder to place your submission. Please ensure you name your folder appropriately**.**
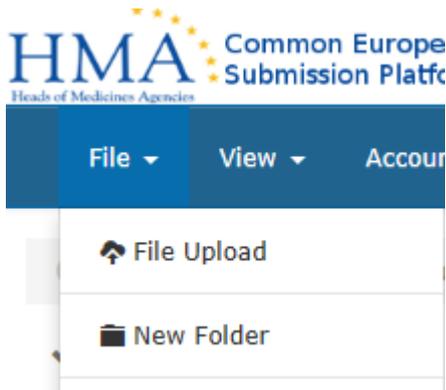
Drag and Drop items into the specified field or upload via the file menu.
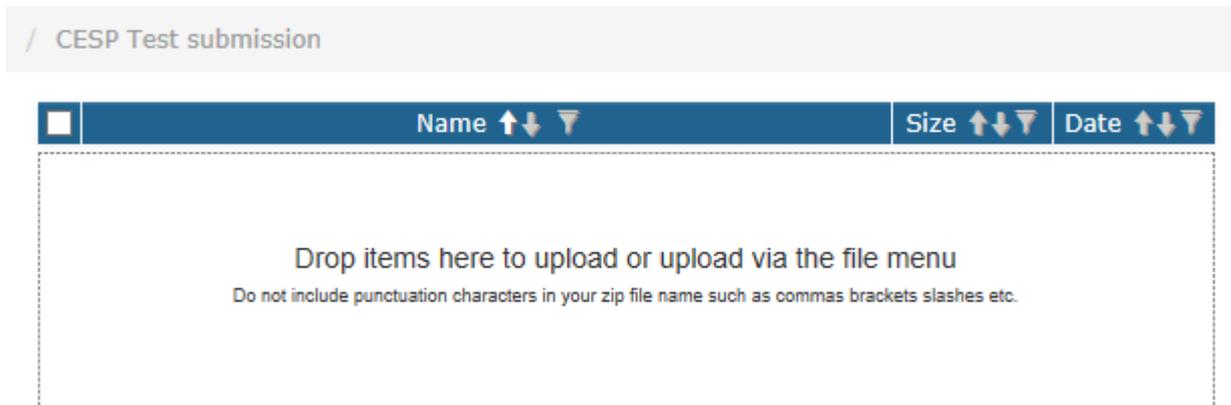
Once all files for submission have been selected and dragged over to the pane on the right, the system will build the transfer queue on the right.

Note: Before progressing to the next step, ensure that ALL files have been completely uploaded, i.e. "completed".

Once all files have been uploaded fully, select the delivery file (this is the .xml file which was created in step A) and drag it into the same folder in the pane on the right. Moving the delivery file to the folder in the transfer pane on the right will trigger the sending of the submission to CESP.

As soon as you drag across the delivery file, the transfer to CESP is initiated and the files which are fully loaded in the transfer queue are transferred.

If the files are not fully loaded in the transfer queue, the transfer will happen and a partial submission will be received by the EDQM (perhaps only the .xml file will be received) as a result.

Attention: You must allow all the files in the transfer queue to reach the status "Completed" before you add the delivery xml file because as soon as you add this file the software will launch the transfer to CESP and only the files present in the transfer queue will be transferred. This will result in a partial transfer and will delay your submission.

Confirmation of submission and confirmation of delivery to the agency

After the submission has been sent, you will receive two emails:

- Firstly, you will receive an email to confirm that the submission has been uploaded to the CESP server.

- Secondly, you will receive an email to confirm that the submission has been delivered to EDQM.

The EDQM will then proceed with the normal reception and validation of the submission before issuing the acknowledgement of receipt as appropriate.

Generally you should receive the first email (confirmation of submission to CESP) within **2 hours**, and the second email (confirmation of delivery to agency) within **24 hours**. If you do not receive either of these emails within the timeframes specified, please do not contact the EDQM. Please contact the CESP team using the support portal on the CESP website.