

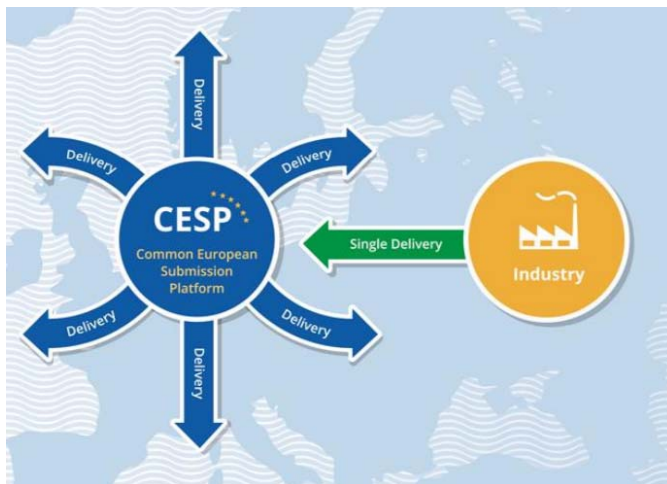
Annex IX: E-SUBMISSION THROUGH THE COMMON EUROPEAN PORTAL (CESP)

The Common European Submission Portal is a simple and secure mechanism for the exchange of information on submissions between applicants and competent authorities in Europe.

CESP is a secure web platform developed by HPRA (Ireland) under the supervision of the Heads of Medicines Agencies.

The main advantages of this portal include:

- A multipurpose delivery system that can be used for any type of digital information transfer
- Tracking system
- Automatic notification by the application
- Simple, fast and efficient delivery system for information
- Allow easier and faster submission of updates / responses to information requests from the Agencies
- Provide a secure method of communication with the Regulatory Agencies via one platform
- Reduce the burden for both Industry and Regulators of submitting/handling applications on CD-ROM and DVD



1.1. For which application CESP must be used ?

Clinical trials (medicines)	Initial application for a clinical trial
	Substantial amendment for a clinical trial
	ASR/DSUR submission
	Urgent safety measure
	Temporary halt notification
	End of trial declaration
	CTR Pilot – initial application for a clinical trial
	CTR Pilot – Substantial modification for a clinical trial
Clinical investigations (medical devices)	Initial application for a clinical investigation
	Serious Adverse Events Notification
	Notification of end of clinical investigation / performance study
Unmet Medical Needs	Initial application for a CUP/MNP
	Periodic Reevaluation for a CUP/MNP
	Substantial Amendment for a CUP/MNP
Clinical trials, clinical investigations and Unmet Medical Needs	Approval of the ethics committee

When using CESP, please do not send the same dossier via other ways to the Agency.

1.2. How to submit an application through CESP?

1.2.1. [Account and connection](#)

Link to the website : <https://cesportal.hma.eu/Account/Login>

If you don't already have an account, please select "register" or follow this link <https://cesportal.hma.eu/delivery/create>

HMA Common European Submission Portal

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Welcome to the Common European Submission Portal

This system provides a simple and secure mechanism for exchange of information between applicants and regulatory agencies.

The purpose of the system is to:

- Provide a secure method of communicating with the Regulatory Agencies via one platform
- Allow submission of an application once to reach all required Agencies
- Reduce the burden for both Industry and Regulators of submitting/handling applications on CD-ROM and DVD

Login

Username

Password [Forgot password?](#)

Log in **Register**

Latest Updates	
Contact DE(FEI)	28-SEP-2017
Contact GR(EOF)	29-JUN-2016
Contact SK(SUKL)	21-JUN-2016
Contact LV(ZVA)	03-JUL-2017
Contact CZ(SUKL)	12-JAN-2018
Contact LT(NMVRVI)	03-JAN-2017
Contact UK(MHRA)	22-FEB-2017
Contact PT	07-FEB-2018
Contact ES	19-DEC-2016
Contact LT(VVKT)	17-SEP-2016

1.2.2. [E-submission](#)

First create a delivery file: A new delivery file has to be made for each submission.

The screenshot shows the 'New Delivery File' form in the HMA Common European Submission Portal. The form is divided into four steps: Step 1 (selected), Step 2, Step 3, and Step 4. The 'New Delivery File' menu item in the left sidebar is circled in red, with an arrow pointing to the form. A red-bordered box contains the following instructions:

1. Select New Delivery File
2. Select Human Medicines or Medical Devices following the subject of your submission

The form fields are as follows:

- Company ***: Text input field containing 'Test Company'.
- Area ***: Dropdown menu with 'Human Medicines' selected.
- Regulatory Activity ***: Dropdown menu with 'Authorisation for temporary use' selected.
- Sub Activity ***: Dropdown menu with 'H001 Not Applicable' selected.
- Zip File Type ***: Dropdown menu with '7-Zip' selected.
- Comment**: Text area for additional information.

A 'Next >' button is located at the bottom right of the form.

- Dashboard
- New Delivery File
- Web Upload
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New Delivery File

Step 1
Step 2
Step 3
Step 4

Company * (0)

Test Company

Area *

Human Medicines

Regulatory Activity * (0)

-- Select --

Sub Activity * (0)

H001 Not Applicable

Zip File Type *

7-Zip

Comment

Next >

3. Select :

Clinical trial for the following related submission :

- Initial application for a clinical trial
- Substantial amendment for a clinical trial
- CTR Pilot – initial application for a clinical trial
- CTR Pilot – Substantial modification for a clinical trial
- Urgent safety measure
- Temporary halt notification
- End of trial declaration

Development Safety Update Report :

- ASR/DSUR submission

Authorization for temporary use for the following related submission :

- Initial application for a CUP/MNP
- Periodic Reevaluation for a CUP/MNP
- Substantial Amendment for a CUP/MNP

Medical device for the following related submission :

- Initial application for a clinical investigation
- Substantial amendment for a clinical investigation / performance study
- Notification of end of clinical investigation / performance study

HMA Common European Submission Portal

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New Delivery File

Step 1 Step 2 Step 3 Step 4

Company *
Test Company

Area *
Human Medicines

Regulatory Activity *
Clinical Trial

Sub Activity *
H001 Not Applicable

Zip File Type *
7-Zip

Comment

Next >

Select the **Sub-Activity** following the procedure step

- Not applicable
- Initial
- Answers to question during validation
- Answers to question during procedure
- Closing Documents

Select the **Zip File Type**

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New Delivery File

Step 1 Step 2 Step 3 Step 4

Company *
Test Company

Area *
Human Medicines

Regulatory Activity *
Clinical Trial

Sub Activity *
H001 Not Applicable

Zip File Type *
7-Zip

Comment

Next >

Indicate here any comment on the process.
e.g. for CTR Pilot: please indicate CTR Pilot

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New Delivery File

Step 1 Step 2 Step 3 Step 4

Choose 'National' as **Procedure Type** and 'Other eSubmission Type' as **Submission Type** for all related processes.

Procedure Type *
National

Submission Type *
Other eSubmission Type

Technically Validated *
 Yes
 No

< Previous Next >

Should always be 'no' for all related processes.

HMA Common European Submission Portal

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New Delivery File

Step 1 Step 2 Step 3 Step 4

National Agency (mouseover flag for National Requirements) *

AT	BE	HR	CY	CZ(SUKL)
DK	EE	FI	FR(ANSM)	DE(BfArM)
DE(PEI)	GR(EOD)	HU(OGYEI)	IS	IE
IT(AIFA)	LV(ZVA)	LT(VKT)	LU	MT
NL	NO	PL(URPL)	PT	RO(ANMCM)
SK(SUKL)	SI(JAZMP)	ES	SE	UK(MHRA)
CESP				

Choose Belgium – famhp to send your submission

HMA Common European Submission Portal

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New Delivery File

Step 1 Step 2 Step 3 Step 4

Additional Email Addresses

Email

[Add Row](#) [Delete Row](#)

Product(s)

Agency	MAA Number	Product Name
Select Country	<input type="text"/>	<input type="text"/>

[Add Product](#) [Delete Product](#)

Product Details Filename

You can enter the file name of the Products Details File you will be submitting instead of listing the products above

[< Previous](#) [Submit](#)

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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

You must download the xml file and upload this with your files to submit the application (see next steps).

1.2.3. [Upload your files \(i.e. the dossier\) on CESP](#)

The screenshot shows the HMA Common European Submission Portal dashboard. At the top, there is a navigation menu with options like Dashboard, New Delivery File, Web Upload, Deliveries, Support, Training, Reports, Announcements, Contacts, General Information, FAQs, and Terms & Conditions. The 'Web Upload' option is highlighted with a red box and an arrow pointing to it from a text box that says "1. Select Web upload".

Below the navigation menu, there are four summary cards: "Deliveries Uploaded (Today)" with a value of 0, "Deliveries Complete (Today)" with a value of 0, "Data Uploaded (Today)" with a value of 0.00 MB, and "Data Delivered (Today)" with a value of 0.00 MB. Below these cards is a chart titled "DELIVERIES COMPLETED BY WEEK" with tabs for WEEK, MONTH, QUARTER, and YEAR. The chart shows data for the years 2014, 2015, 2016, 2017, and 2018, with the x-axis representing months from January to December. The chart area is currently empty.

At the bottom of the dashboard, there is a section titled "CESP REAL-TIME INFORMATION: YEAR TO DATE" with four summary cards: "Deliveries Uploaded Totals for this year" with a value of 0, "Deliveries Complete Totals for this year" with a value of 0, "Data Uploaded Totals for this year" with a value of 0 MB, and "Data Delivered Totals for this year" with a value of 0 MB.

My Folders

Medical dossier

Name	Size	Date
Medical dossier		3/7/2018 14:18:08

Transfers

- Completed - 0
- In Progress - 0
- Pending - 0

No files in this activity zone

Two ways to upload files :

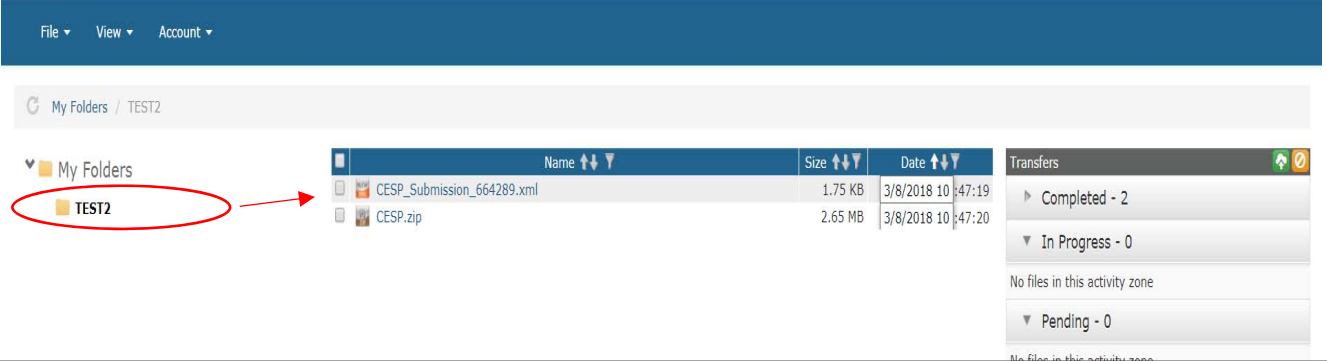
- Select "file" and "upload", select your file that you want to upload.
- You can also directly select your file from your windows explorer, and slip it up to the webpage.

You can create several folders for each application

The details over the transfers :

- Completed upload
- Upload in progress
- Pending upload

Very Important: First upload your dossier – as a zip. When the zip is fully uploaded, then upload your delivery file previously downloaded (i.e. the file ending with xml). Also important – do not include a zip inside the zip as cesp does not allow this.



You will find the uploaded files in your folder:

- “CESP_Submission_XXXXXX.xml” : the delivery information, downloaded previously from CESP. It is different for each applications. It has thus to be systematically done for each application (whatever it is).
- “name of your file.zip” : the content of your application in zip format.

NB :

- Reminder : first upload your dossier in ZIP format on the website. When fully uploaded, then add the XML file.
- No further action is requested, the portal will send it to the selected Agency and will send you an e-mail regarding the notification. You can check it in the “deliveries” section on CESP.

1.3. Training and support

- An On Demand Training module is available for all CESP users. This contains the Latest Video Guides and Training documentation.
- Support : the CESP Group shall provide support in respect of the Portal to authorised users during normal working hours on Monday to Friday (other than public holidays listed below). Contact details for accessing CESP Group support are available on the Portal.
- FAQ is available for your common questions regarding the system :

<https://cespportal.hma.eu/Public/FAQs>