



CESP Demonstration



CESP is an online delivery system , capable of accepting information from stakeholders through one portal and distributing it to one or more agencies.

Features:

- A simple and secure mechanism for exchange of information between stakeholders and agencies.
- Currently provides a delivery system for:
 - CAP/ MRP / DCP / National submissions for both human and veterinary products.
 - Clinical Trial Information
 - Scientific Establishments
- Accepts all submission types and includes mechanisms to handle resubmitting of updated information.
- Not dependent on submission standards, i.e. will accept eAF, eCTD , NeeS , vNeeS.
- One-way, from Industry to Regulator, with simple notification systems
- Can manage files and folders of varying sizes
- Eliminates the effort for handling CD/DVD submissions

- ✓ Reduces manual processing of submissions for agencies and stakeholders.
- ✓ Low cost solution for industry.
- ✓ Multi purpose delivery system, can be used for any type of digital information transfer.
- ✓ Simple , fast , efficient delivery system for information.
- ✓ Single submission platform to multiple agencies.
- ✓ Allows faster submission updates/ responses to agency information requests.

- Austria (AGES)
- Belgium (FAGG)
- Croatia (HALMED)
- Cyprus (MOH)
- Czech Republic (UKZBL)
- Denmark (DKMA)
- EDQM
- Estonia (Ravimiamet)
- Finland (Fimea)
- France (ANSM)
- France (ANSES)
- Germany (BfArM)
- Germany (PEI)
- Iceland (IMA)
- Ireland (IMB)
- Italy (AIFA)
- Latvia (State Agency for Medicines)
- Lithuania (VVKT)
- Luxembourg (Ministere de la Sante)
- Malta (MITTS)
- Netherlands (MEB)
- Norway (NOMA)
- Portugal (Infarmed)
- Slovenia (JAZMP)
- Spain (AEMPS)
- Sweden (MPA)
- United Kingdom (MHRA)
- United Kingdom (VMD)

➤ Testing Agencies

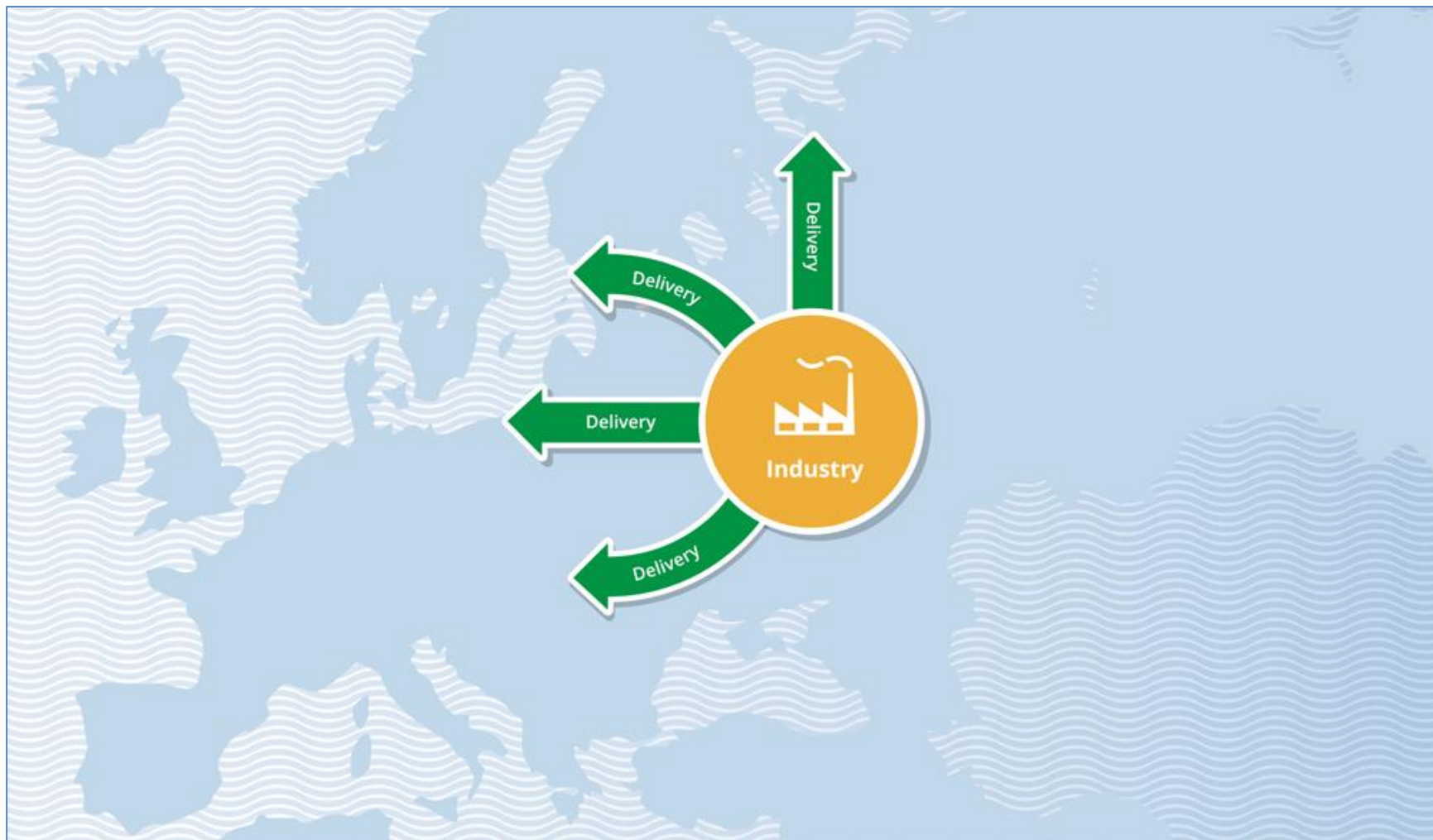
- Germany (BVL)
- CZ SUKL

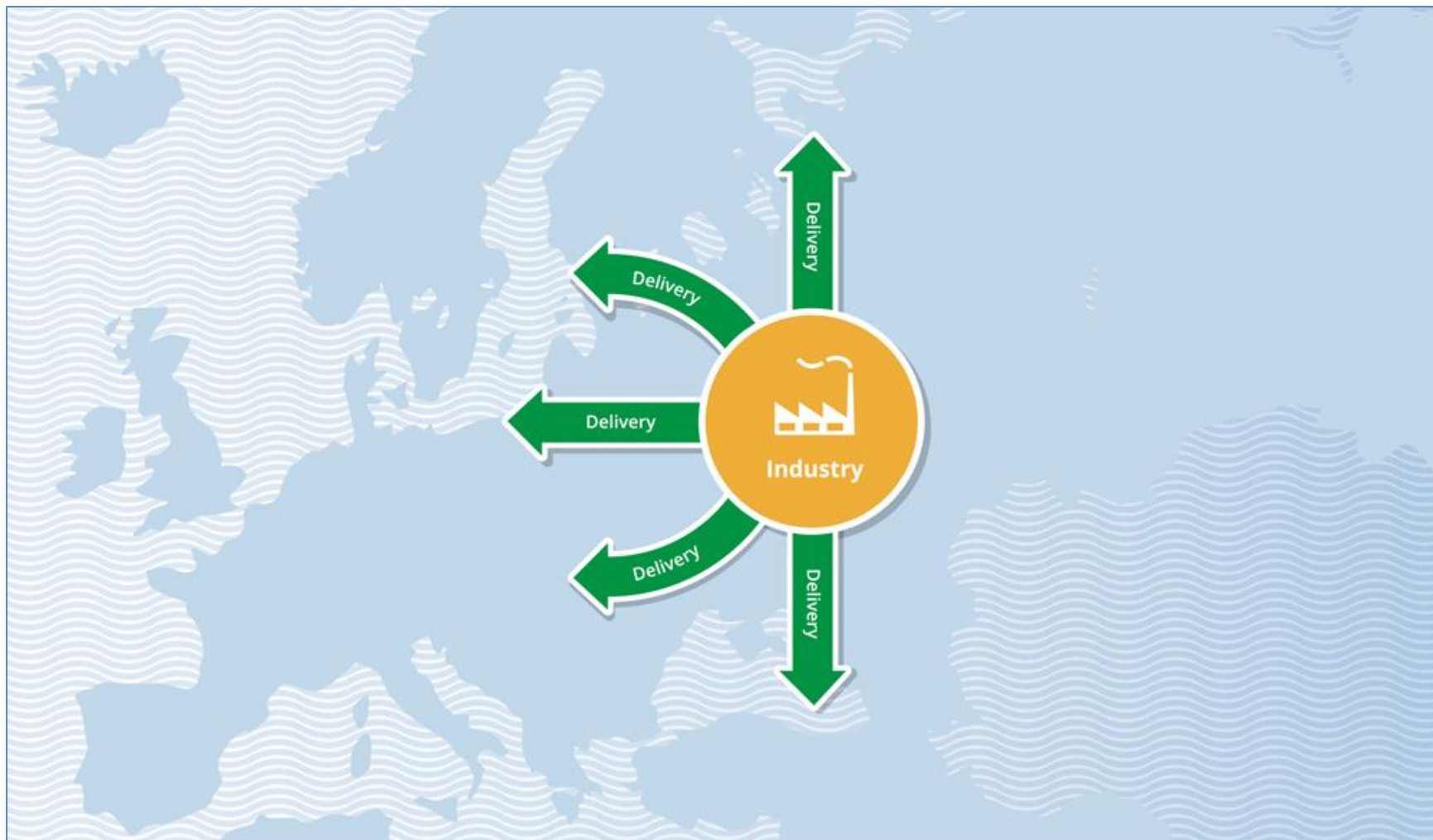






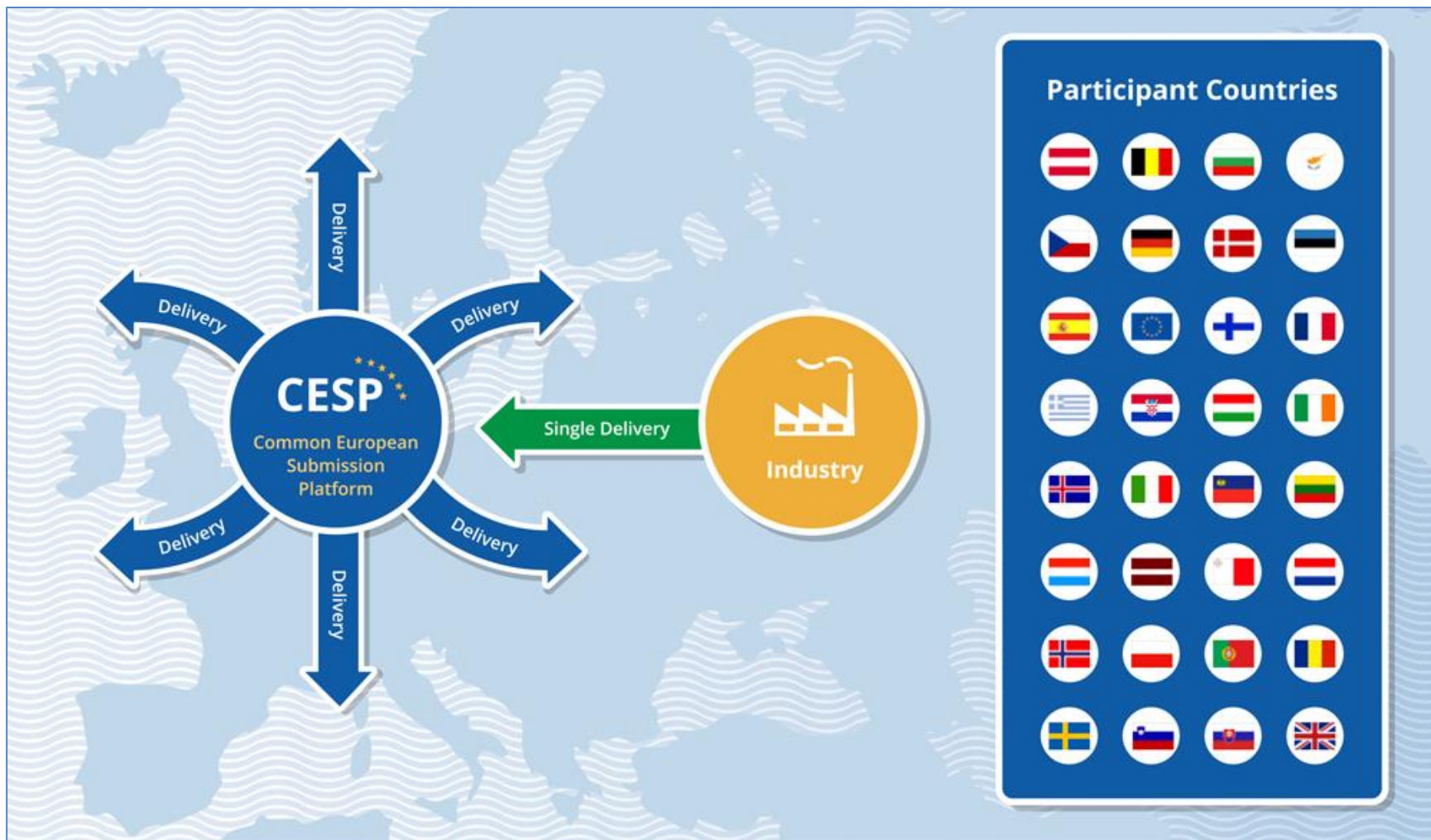












1

User logs on to
registration server &
creates delivery file



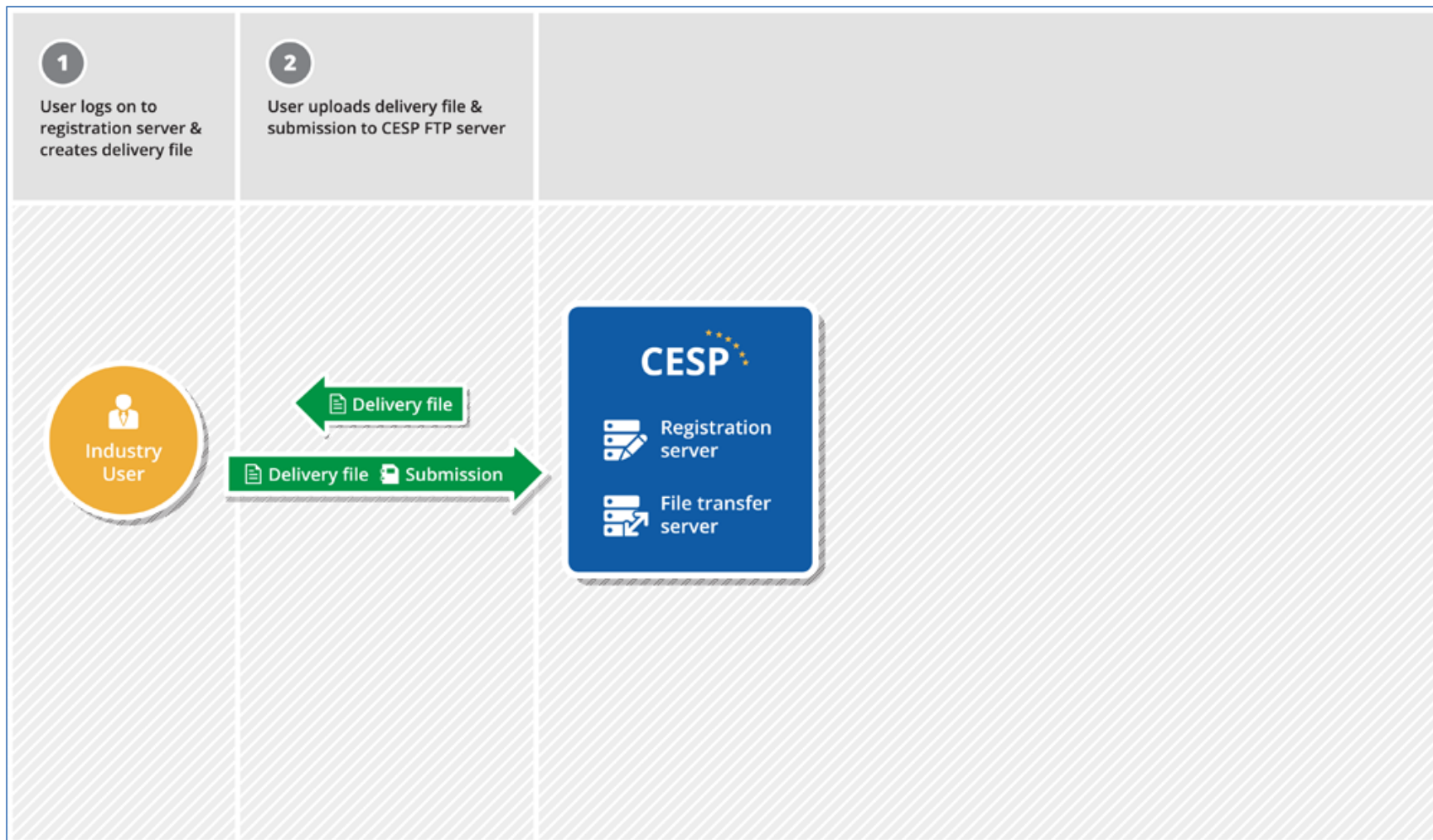
CESP

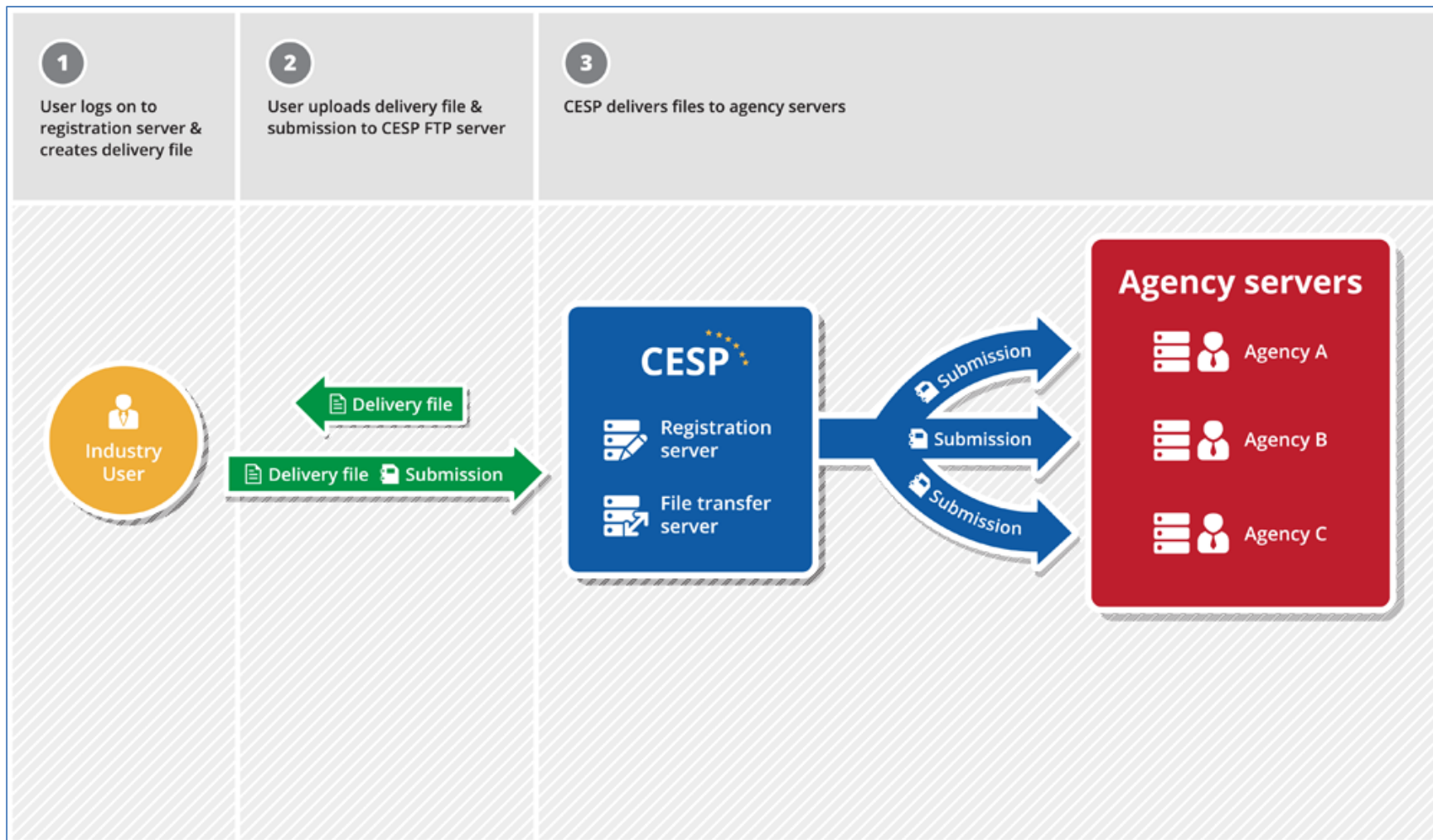


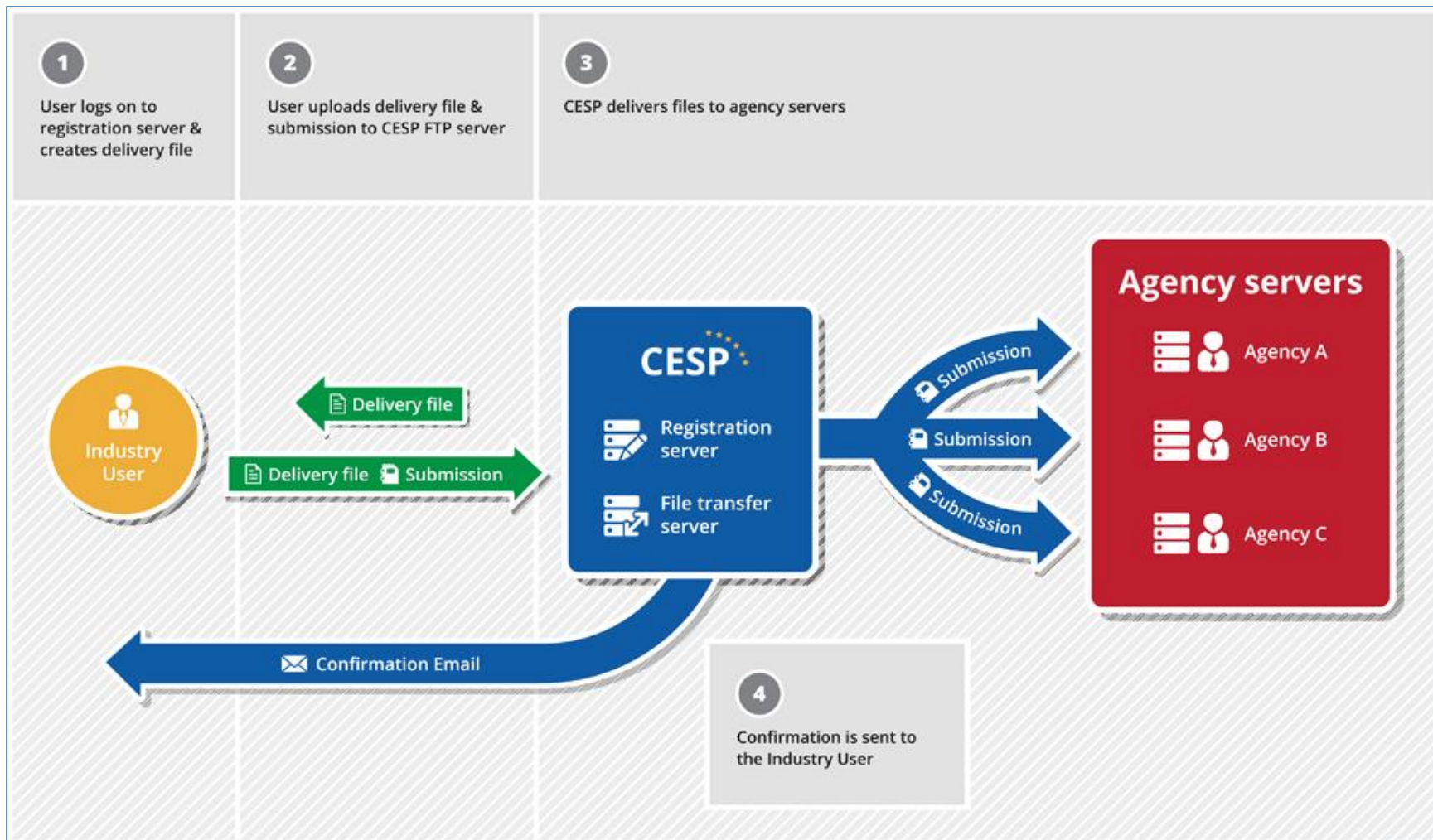
Registration
server



File transfer
server

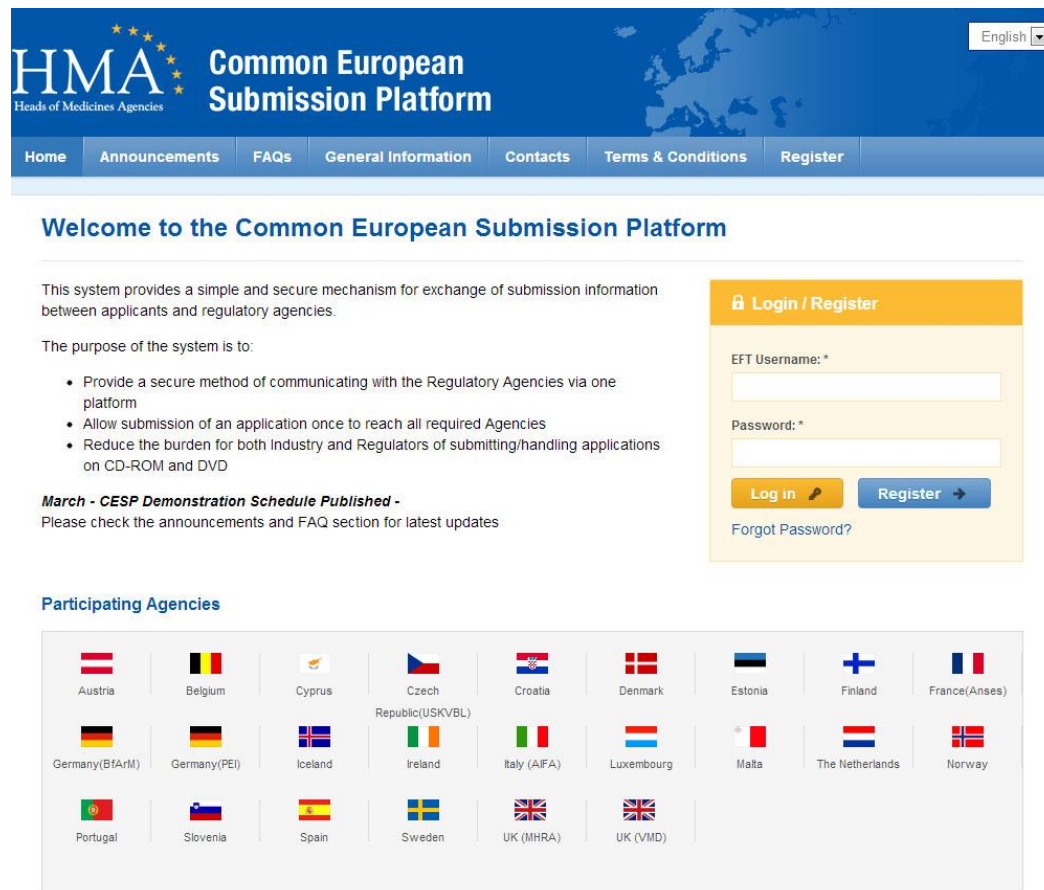






Main Website

- Login panel
- Forgotten password
- Announcement Section
- FAQ with search
- General Information
- Contacts
- Terms & Conditions
- Register



The screenshot shows the homepage of the Common European Submission Platform. The header features the HMA logo and the text 'Common European Submission Platform'. A navigation bar includes links for Home, Announcements, FAQs, General Information, Contacts, Terms & Conditions, and Register. The main content area welcomes users and provides a brief overview of the system's purpose. A 'Login / Register' section on the right contains input fields for EFT Username and Password, along with 'Log in' and 'Register' buttons. Below this, a 'Participating Agencies' section displays a grid of flags and names for various European countries and agencies.

Welcome to the Common European Submission Platform

This system provides a simple and secure mechanism for exchange of submission 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

March - CESP Demonstration Schedule Published -
Please check the announcements and FAQ section for latest updates

Login / Register

EFT Username: *

Password: *

Log in **Register**

[Forgot Password?](#)

Participating Agencies

Austria	Belgium	Cyprus	Czech Republic (USKVBL)	Croatia	Denmark	Estonia	Finland	France (Anses)
Germany (BfArM)	Germany (PEI)	Iceland	Ireland	Italy (AIFA)	Luxembourg	Malta	The Netherlands	Norway
Portugal	Slovenia	Spain	Sweden	UK (MHRA)	UK (VMD)			

- Fill in the mandatory fields indicated by an asterix.
- You can ignore the CESP registration code which is used for additional registrations.
- Agree to the terms & conditions
- Press submit
- You will be displayed the registration confirmation page and an email will be sent to the address indicated in the form.

Register

Complete the form to register for access to the CESP system. Once you submit your registration, you will be contacted to verify the account setup after which time you will receive connection details for the portal.

Registration Process

1 Submit registration application / 2 Verify and Review request / 3 If approved, you will receive an email with access details

Your Details

First Name: *

Last Name: *

Email: *

Confirm Email: *

Contact Number: *

Please include the international dialing code with your phone number.

For example: 44123456789 for United Kingdom or 49123456789 for Germany.

Job Title:

To assist us in any troubleshooting of your access to the system please indicate the following:

Browser:

FTP Client:

Bandwidth:

Company Information

If you do have the CESP registration code for your company then please enter it here and click the 'Find Company' button. Please contact your company administrator to get the CESP registration code.

CESP Registration Code:

If you do not have the CESP registration code for your company then please fill in the Company Information fields below.

Please note that you can request to add more companies to your account once your account has been setup.

Areas: *

☐ Human Medicines

☐ Cosmetics

☐ GxP

☐ Scientific Establishments

☐ Medical Devices

☐ EDQM

☐ Veterinary Medicines

Parent Company:

Company: *

Address 1:

Address 2:

Creating a Delivery file and Uploading Submissions

- The first step in uploading a submission is to create a “delivery file” for you submission.
- Select the “New Delivery File” option in step 1.

Welcome to the Common European Submission Platform

You have successfully logged in

The portal can be accessed using two methods either through an sFTP client (preferred option) or through the web based file transfer system. In order to connect to the portal you will need:

- A PC with broadband access
- FTP client that has sFTP capability currently tested clients are Filezilla V3.4+ (free ftp client) or CuteFTP V6.3+ professional
- Standard web browser with java enabled

IMPORTANT NOTICE: Please note that BfArM (Germany) have special requirements for electronic submissions please refer to [BfArM's website](#)



STEP

1

For both sFTP client and Web Based File Transfer System

Create a new delivery file

1. Select the New Delivery File option
2. Complete the form as required
3. Download the XML version of the form to your submission folder on your local PC

New Delivery File +

STEP

2

sFTP client

Upload your Submission and Delivery file

1. Launch your sFTP client and enter the following information
 - a. Host: cesp.hma.eu
 - b. Username
 - c. Password
 - d. Port 22
2. Once connected please follow these steps:
 - a. **Ensure that there are no other files in the root of the remote server**
 - c. Drop you submission documents / folder to the remote server
 - a. Drop the delivery XML file to the remote server
 - b. Once delivered all files will be removed from this remote server
4. On successful upload of your submission you will receive an automated email confirming delivery to each of the agencies indicated in your delivery file, please do not reply to this email as it is not monitored.

Web Based File Transfer System

Upload your Submission and Delivery file

1. Launch web interface and enter the following information
 - a. Username
 - b. Password
2. Once connected please follow these steps:
 - a. **Ensure that there are no other files in the root of the remote server**
 - c. Drop you submission documents / folder to the remote server
 - a. Drop the delivery XML file to the remote server
 - b. Once delivered all files will be removed from this remote server
4. On successful upload of your submission you will receive an automated email confirming delivery to each of the agencies indicated in your delivery file, please do not reply to this email as it is not monitored.

Access Web Based

Step 1

Step 2

Step 3

Step 4

EFT User:
c1190-ca (cesptest@hotmail.com)

Company: *
Agence Nationale du Medicament Veterinaire

Comments:
test

Area: *
☒ Veterinary Medicines

Regulatory Activity: *
Initial Marketing Authorisation Application

Zip File: *
☒ Yes ☐ No

Zip File Type:
Microsoft Compressed Folders

Next →

Cancel ✕

Fields marked with * are mandatory

Step

1

Step

2

Step

3

Step

4

Procedure Type: *

☐ CP ☐ DCP ☐ MRP ☒ National

Procedure Number:

1234

Submission Type: *

☐ eCTD ☐ Nees ☒ Other eSubmission Type ☐ vNees

Technically Validated: *

☐ Yes ☒ No

← Previous

Next →

Cancel ✕

Fields marked with * are mandatory

Step 1

Step 2

Step 3

Step 4

Reference Member State: *

<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
AT	BE	CZ (USKVBL)	DE (PEI)	DK	EE	ES	FI	FR (Anses)	HU (NEBIH)	IE	IS	LU	NL	NO
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>											
SE	SI	UK (VMD)	ZZ											

National Agencies

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AT	BE	CZ (USKVBL)	DE (PEI)	DK	EE	ES	FI	FR (Anses)	HU (NEBIH)	IE	IS	LU	NL	NO
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
SE	SI	UK (VMD)	ZZ											

Additional Email Addresses:

Email Address

Please enter any email addresses (a maximum of 5), that you wish to receive a delivery receipt for this submission. Note: cesptest@hotmail.com will automatically receive a delivery receipt.

Fields marked with * are mandatory

Step
1

Step
2

Step
3

Step
4

Product(s):

Agency

MAA No

Product Name

Test Country - ZZ ▼

Add

Product Details Filename:

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

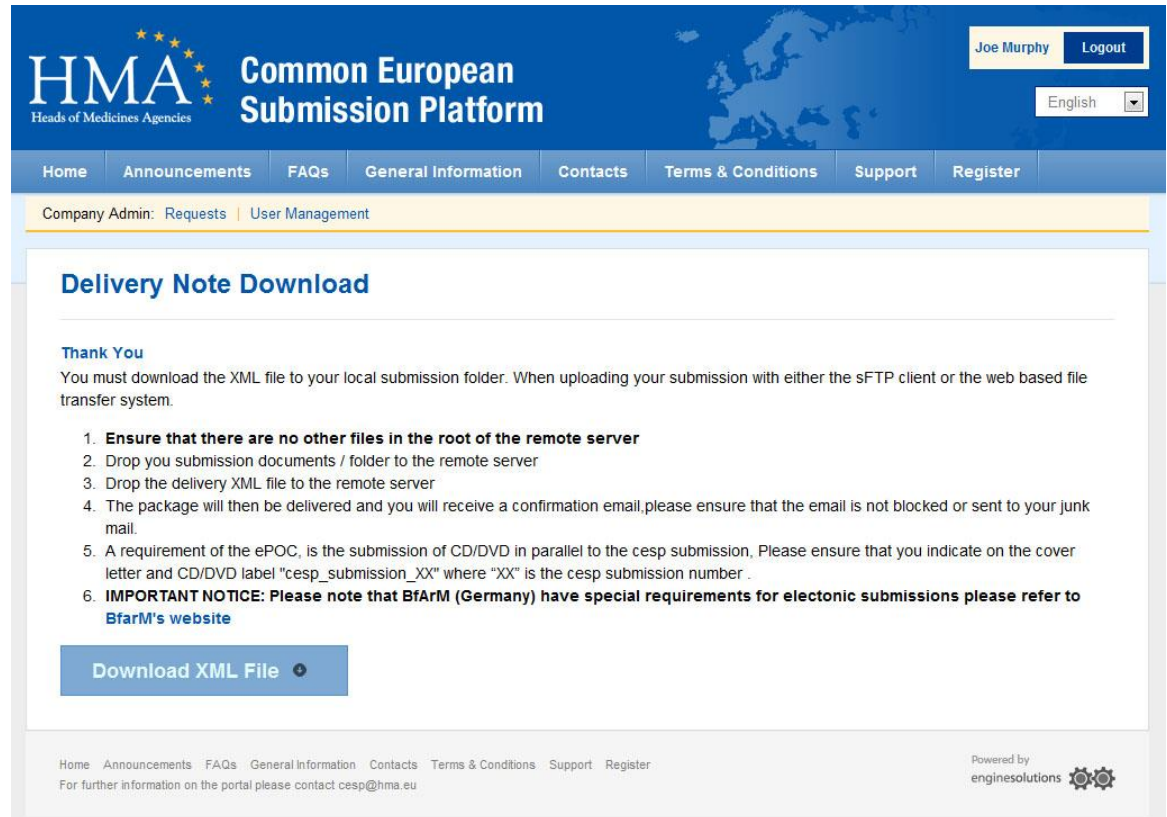
← Previous

Submit →

Cancel ✕

Fields marked with * are mandatory

- Select the “Download XML File”
- Save the delivery file to your local pc/laptop/ network drive
- Do not rename the delivery file
- Do not edit the delivery file



The screenshot shows the HMA Common European Submission Platform interface. The header includes the HMA logo, the platform name, a user profile for 'Joe Murphy' with a 'Logout' button, and a language dropdown set to 'English'. A navigation menu contains links for Home, Announcements, FAQs, General Information, Contacts, Terms & Conditions, Support, and Register. Below this is a 'Company Admin' section with links for Requests and User Management.

The main content area is titled 'Delivery Note Download'. It includes a 'Thank You' section with the text: 'You must download the XML file to your local submission folder. When uploading your submission with either the sFTP client or the web based file transfer system.'

A numbered list of instructions follows:

1. **Ensure that there are no other files in the root of the remote server**
2. Drop you submission documents / folder to the remote server
3. Drop the delivery XML file to the remote server
4. The package will then be delivered and you will receive a confirmation email, please ensure that the email is not blocked or sent to your junk mail.
5. A requirement of the ePOC, is the submission of CD/DVD in parallel to the cesp submission, Please ensure that you indicate on the cover letter and CD/DVD label "cesp_submission_XX" where "XX" is the cesp submission number .
6. **IMPORTANT NOTICE: Please note that BfArM (Germany) have special requirements for electronic submissions please refer to [BfarM's website](#)**

At the bottom of the instructions is a blue button labeled 'Download XML File' with a download icon.

The footer contains a secondary navigation menu with links for Home, Announcements, FAQs, General Information, Contacts, Terms & Conditions, Support, and Register. It also includes the text 'For further information on the portal please contact cesp@hma.eu' and a 'Powered by enginesolutions' logo.

Two Methods for Uploading

1. sFTP client

Upload your Submission and Delivery file

Launch your sFTP client and enter the following information

Host: cesp.hma.eu
Username
Password
Port 22

Once connected please follow these steps:

- **Ensure that there are no other files in the root of the remote server**
- Create a folder on the remote server e.g. submission1
- Drop you submission into the folder on the remote server
- **Ensure that all files and folders are uploaded fully; check that each file has been uploaded by viewing the file transfer status before going to the next step**
- Drop the delivery file into the folder on the remote server
- Your submission is now being processed for delivery

OR

2. Web Based File Transfer System

Upload your Submission and Delivery file

Launch web interface and enter the following information

Username
Password

Once connected please follow these steps:

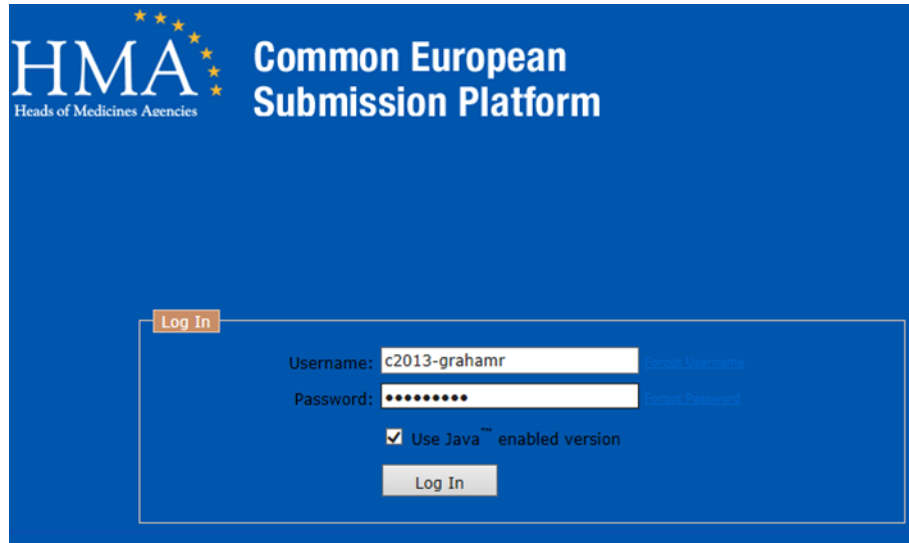
- **Ensure that there are no other files or folders in the root of the remote server**
- Create a folder on the remote server e.g. submission1
- Drop you submission into the folder on the remote server
- **Ensure that all files and folders are uploaded fully; check that each file has been uploaded by viewing the file transfer status before going to the next step**
- Drop the delivery file into the folder on the remote server
- Your submission is now being processed for delivery.

- For all methods you must :
 1. Create your delivery file
 2. Upload your submission first and fully
 3. Then upload your delivery file
 4. Await email acknowledgements

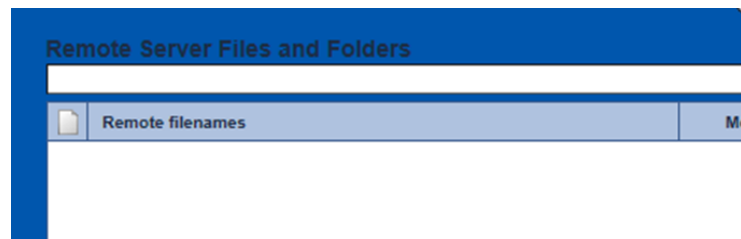
- **Do not**
 - **Do Not Reuse** your delivery file
 - **Do Not Rename** your delivery file
 - **Do Not Place** more than one delivery file with the same submission (one submission - one delivery file).
 - **Do Not Delete** your submission until you have received all email acknowledgements for that submission.

Web based File Transfer

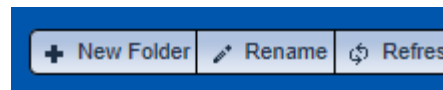
- Open the website: <https://cesp.hma.eu/EFTClient/Account/Login.htm>
- Enter in username and password
- Tick 'Use Java enabled version'

The image shows a login form for the Common European Submission Platform. The form is set against a blue background with the HMA logo and text at the top. The form itself is a white box with a thin border. It contains a 'Log In' button in the top left corner. Below this, there are two input fields: 'Username:' with the value 'c2013-grahamr' and 'Password:' with a masked password '*****'. To the right of each input field is a small blue link: 'Forgot Username?' and 'Forgot Password?'. Below the password field is a checkbox labeled 'Use Java™ enabled version', which is checked. At the bottom of the form is a 'Log In' button.

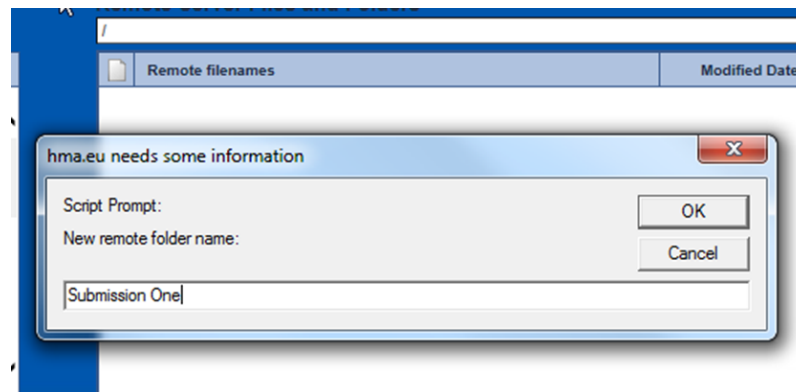
- Click the white area in the section Remote filenames



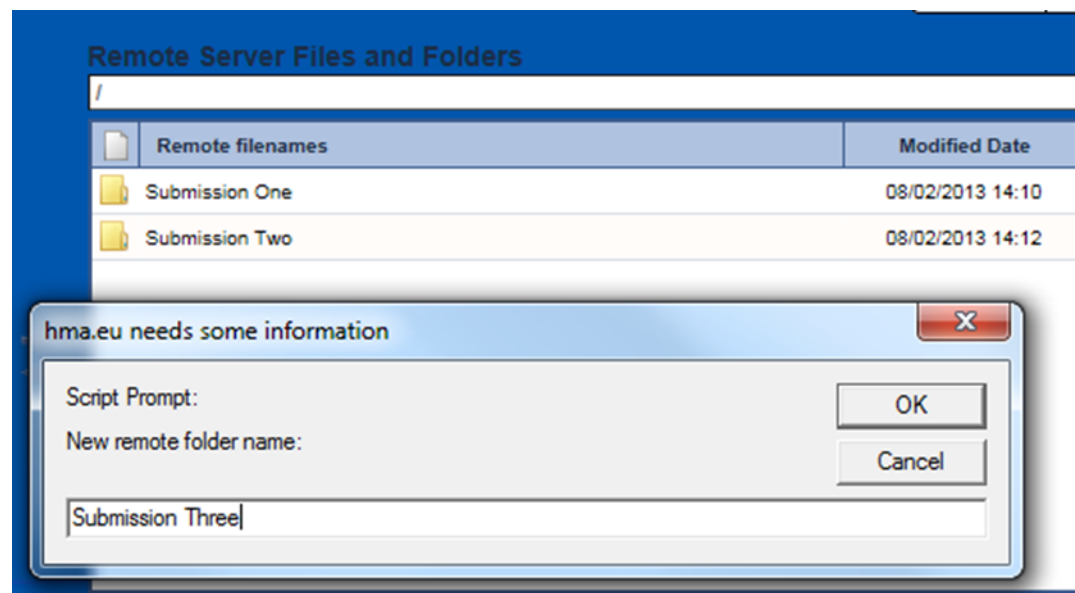
- Click New Folder



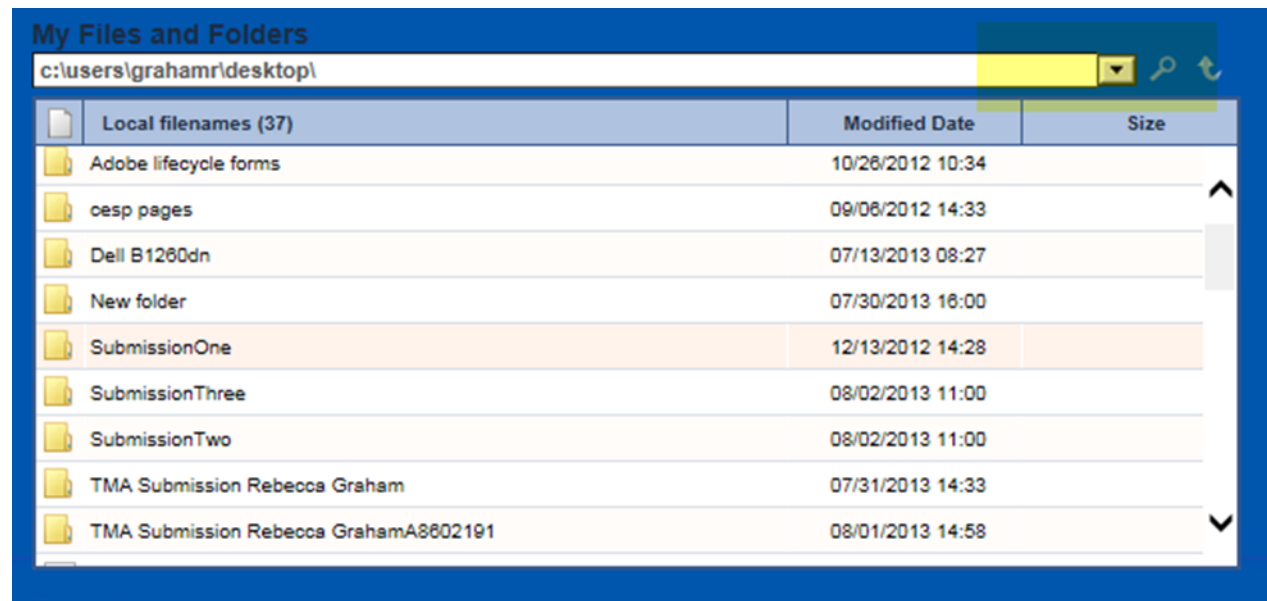
- Enter in name of folder



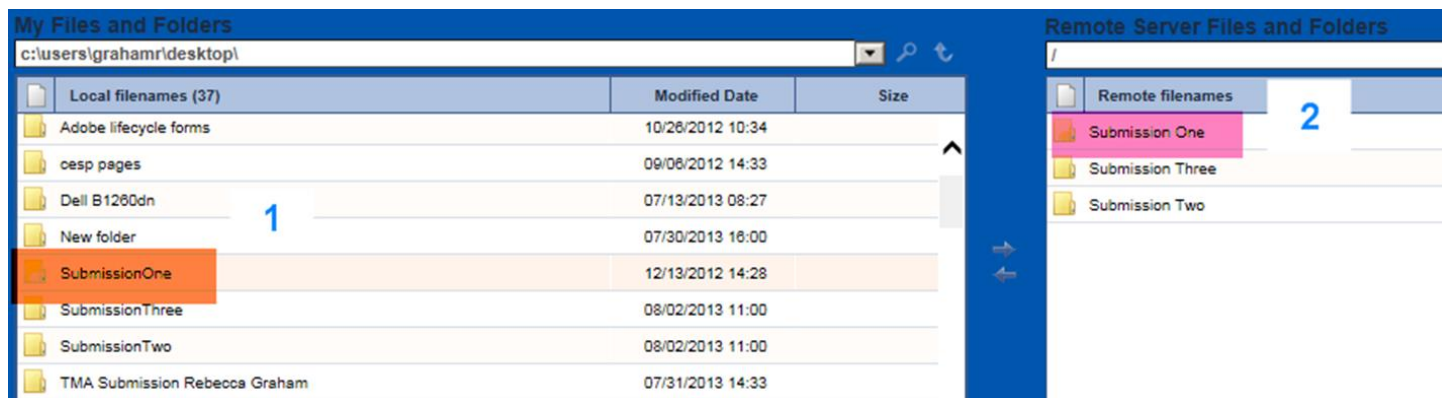
- For each submission you wish to upload repeat the process



- Navigate on your local pc / network to your submission folders and delivery files



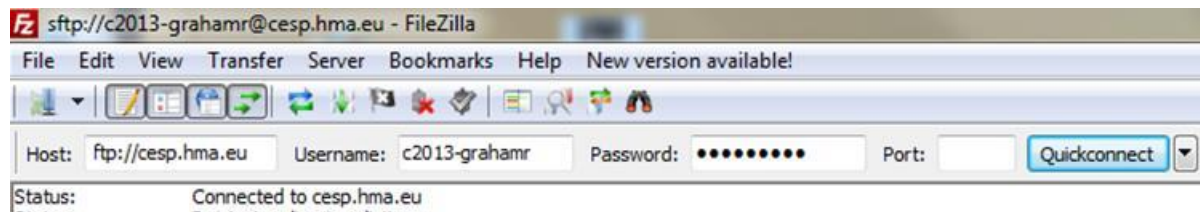
- Drag the submission 1 from My files and folders **into** Submission 1 on the Remote Server and folders



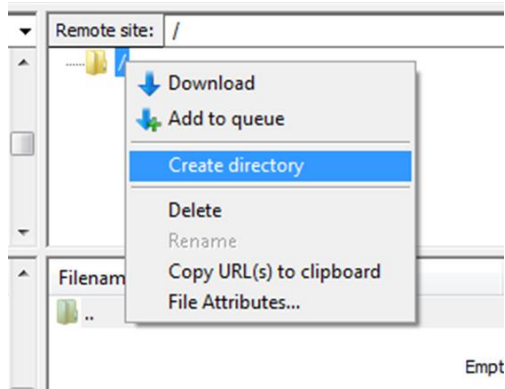
- Drag the Delivery file for submission 1 from My files and folders **into** Submission 1 folder on the Remote Server and folders
- Repeat the process for each submission
- NOTE IF USING THIS METHOD EACH SUBMISSION SHOULD BE IN ITS OWN FOLDER WITH THE DELIVERY FILE FOR THAT SUBMISSION, UPLOAD THE SUBMISSION FIRST AND FULLY BEFORE UPLOADING THE DELIVERY FILE.**

Sample sFTP Client File Transfer

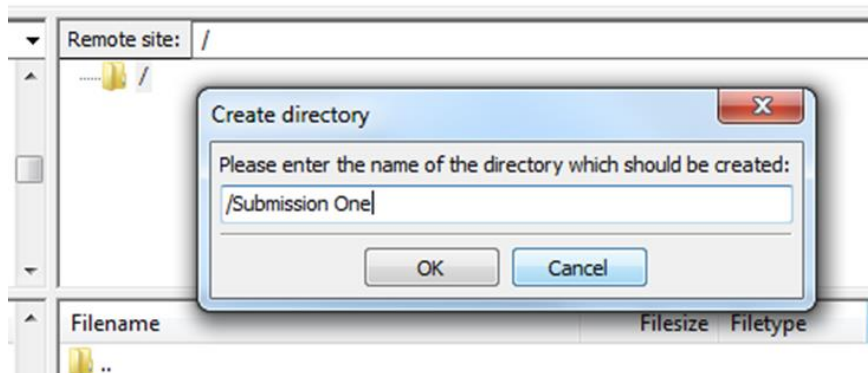
- Log onto the sftp client, using the details below:
- Host: <ftp://cesp.hma.eu>
- Username: Enter users username
- Password: Enter users password
- Port: 22



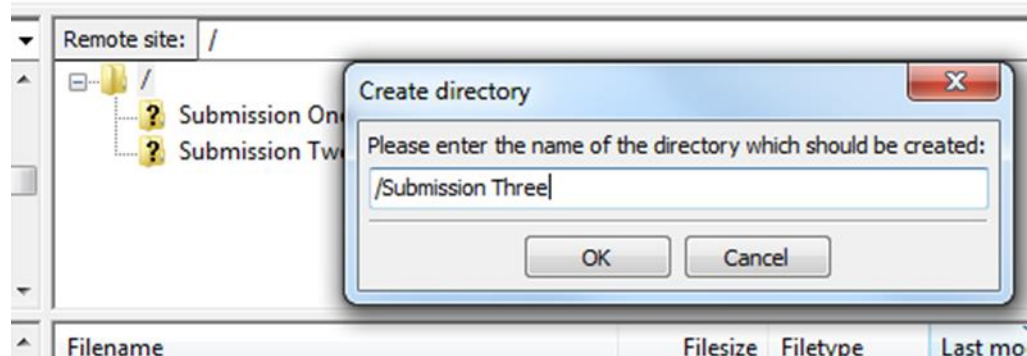
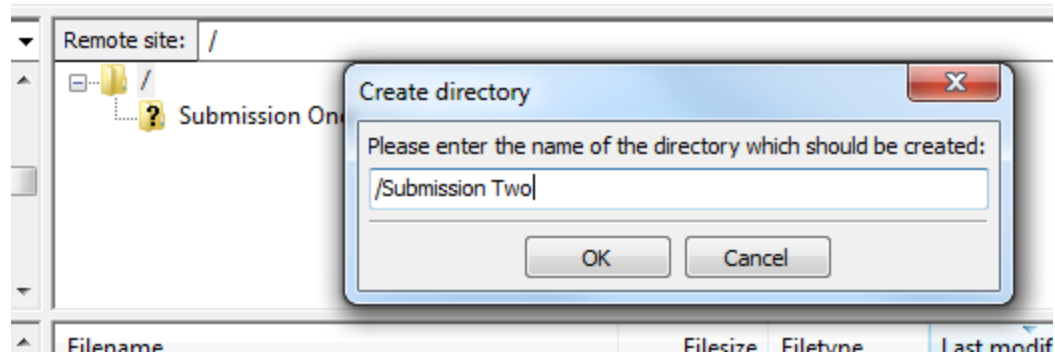
- Click the white area in the section Remote site
- Right mouse key and select Create Directory



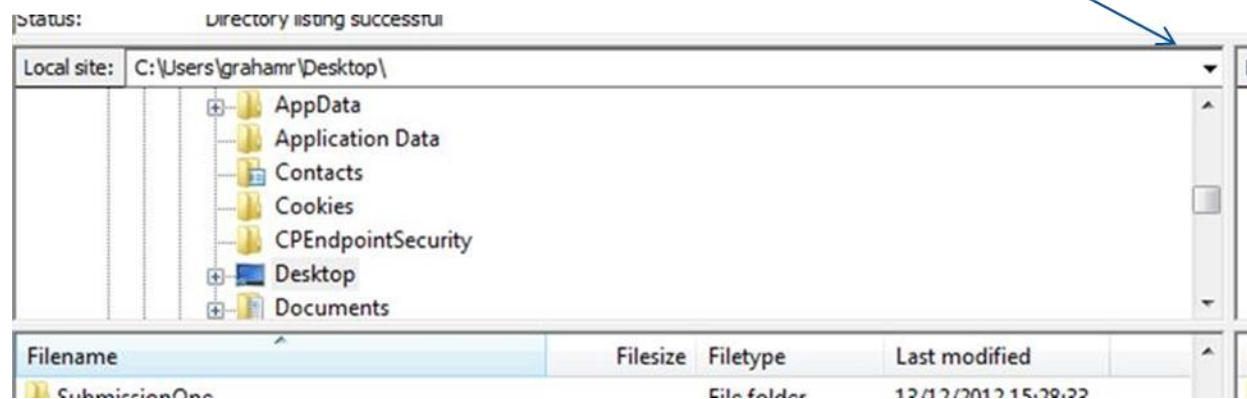
- Enter a folder name e.g. "submission one"



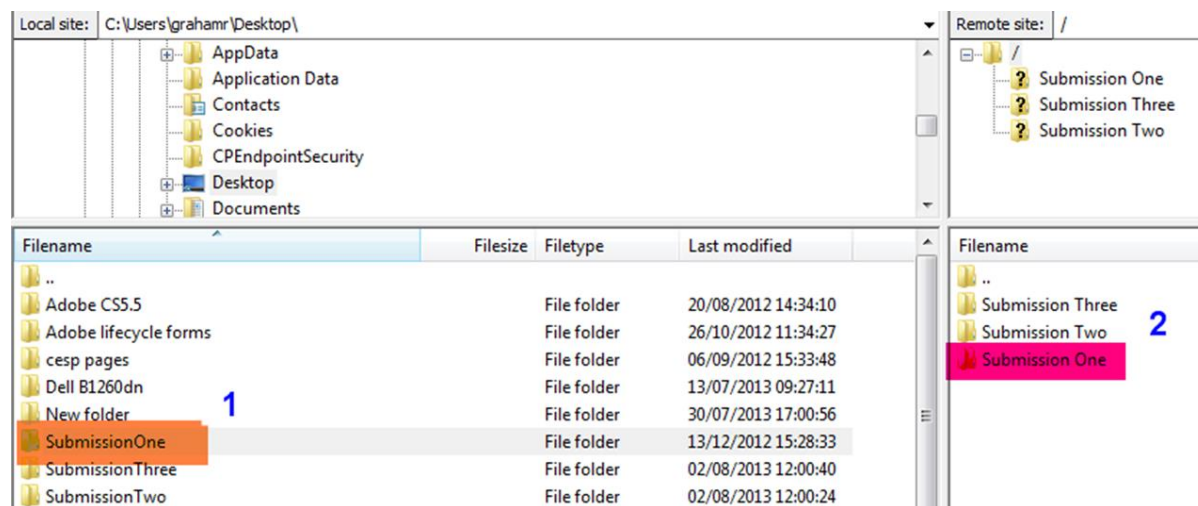
- For each submission you wish to upload repeat the process



- Navigate on your local pc / network to your submission folders and delivery files



- Drag the submission 1 from My files and folders **into** Submission 1 on the Remote Server and folders



- Drag the Delivery file for submission 1 from My files and folders **into** Submission 1 folder on the Remote Server and folders
- Repeat the process for each submission
- NOTE IF USING THIS METHOD EACH SUBMISSION SHOULD BE IN ITS OWN FOLDER WITH THE DELIVERY FILE FOR THAT SUBMISSION, UPLOAD THE SUBMISSION FIRST AND FULLY BEFORE UPLOADING THE DELIVERY FILE.**

All submissions take time, before removing a directory from your user account please ensure that there are no files in any part of the directory.

Email Notifications

- Two emails are sent to acknowledge the receipt.
 - CESP Submission Upload Notification.
 - CESP Agency Delivery Notification.

- CESP Submission Upload Notification
- Only one per submission
- Indicates that's the submission has been received by CESP and the submission is in the processing queue for agency delivery.

Submission Upload Notification for CESP_Submission_17137.xml



CESP@HMA.EU 02:07 |
To: cesptest@hotmail.com ✓

[Actions](#) ▾

This is to confirm that your submission with delivery file CESP_Submission_17137.xml has been received by the CESP submission system.

The Submission is now being processed and distributed to the Agencies as selected in your delivery file.

Further e-mails will follow when the submission is delivered fully to each agency.

CESP Support Team

- Agency receipt of acknowledgement.
- One per agency.
- Depending on size and number of agencies emails may take time to be delivered.
- Emails only triggered by system when submission delivered to an agency.

CESP Agency Delivery Notification - A New Submission File Name
CESP_Submission_17597.xml has been uploaded to ZZ



CESP@HMA.EU 19:36
To: cesptest@hotmail.com

Actions

This message was sent to you automatically by CESP.HMA.EU

Your Submission CESP_Submission_17597.xml has been uploaded to ZZ TEST SITE.

Details of your Submission:

First Name : Company
Surname : Admin
Email : cesptest@hotmail.com
Contact Number :
Company Name : Test Company
Procedure Number : test
Comments : thsi si a test please ignore
Department Type: Human Medicines
Regulatory Activity Type : var-type1a
Procedure Type : MRP
Submission Type : Other eSubmission Type
Checksum :
Agency Reference Numbers :
Products :
Technically Validated : false
Validation Tool :
Other Validation Tool :
ZIP File Format: false
Other Zip File Format:

Common Errors

- Incomplete Upload
 - This occurs when the user uploads the delivery file before the submission is fully uploaded.
- Non supported Zip software
 - We have noticed that a number of zip files uploaded are created using non support zip software, please note that zip files created using the **WinZip or standard Microsoft compression software** available on windows operating systems are the only supported zip files. Use of non standard software can create issues with deliveries. If you cannot create a zip file with either of these formats please upload your submission uncompressed.
- Naming of zip files with special characters
 - A number of zip files have been created and uploaded using non ascii characters, when naming your zip file please do not use any special characters in the file name for example ä , Ä , é, ö, Ö, ü, Ü, ß, &, æ, ç, û, etc.
- File names and Path length
 - Please note that file names and paths should **not exceed 240 characters** , I a few submissions users have prefixed the product / substance name to the file and path name , maximum length of file / path name in windows is 256 characters.
- Training on System
 - User are now attempting to use the system with **no formal training** either by the CESP team or through their own company administrators , whish has caused a number of issues on the system. The CESP team provide training every week on the system via webx and its free of charge , these can be accessed by registering online for a session.

Company Administrators & User Management

- Each company must register on the system for access to be provided.
- For each company a “Company administrator” must be registered. This CA is a super user for the company and grant access and manage user accounts on the system.
- Once registered you will receive an email with instructions on the requirements to register your company on the system.
- On receipt of the required documentation you will be set up on the system and receive a second email with login instructions.

- Companies can have more than one CA per company.
- CA's once confirmed can manage users and companies and are responsible for:
 - New user setup
 - Locking, unlocking users
 - Resetting user passwords
 - Requesting new companies
 - Granting access to users to companies

- Select the text indicated in the email.
- Complete the information requested.
- Print on letter head paper.
- Sign , Scan and email to cesp@hma.eu

New Registration



Actions ▾



CESP@HMA.EU (cesp@hma.eu) 11:43
To: cesptest@hotmail.com

Dear test user,

Thank you for registering for access to the Common European Submission Platform (CESP). Please review the terms and conditions of use of this system located at <http://cesp.hma.eu/TermsConditions>.

If you are registering as a "Standard User", your company administrator is responsible for authorising you on the system. Your company administrator will receive an automated alert, that you have requested access and will process your request.

If you are registering as a "Company Administrator" you are required to provide the following information on letter headed paper from your company and signed by a company director. This document can then be scanned and emailed back to CESP support team at cesp@hma.eu. Once this document is received your organisation will then be contacted by the CESP Support Team, verified and set up on the system.

--- This text should be copied into your request ---

We formally request that the person indicted below as "Company administrator " be set up on the system as our company administrator. We have read and agreed to the terms and conditions relating to the usage of the system as published as of the date of this request.

Company Director Name:

Contact Email:

Contact Telephone Number:

Company Registration number or VAT No:

Company Administrator First Name: test

Company Administrator Last Name: user

Company Administrator Email: cesptest@hotmail.com

Organisation Name: Test Company March

Registration Date: 02/03/2013 11:43:10

Registration Number: 1140

--- end copy---

All support calls should be logged through the online support system available to registered users of the system or by emailing cesp@hma.eu.

Business hours:

Monday to Friday, 09:00hrs to 17:00hrs (GMT)

Main contact details Telephone: +35316343817

- Once approved and set up by the support desk you will receive an email.
- Login details are provided to use the system.

CESP New account setup



CESP@HMA.EU (cesp@hma.eu) 11:45

To: cespctest@hotmail.com

Actions

Dear test user,

You have been registered for use of the CESP portal. By using the web site/portal or ftp site you agree to the terms and conditions of use for both the portal and the secure FTP system. Below are your connection details for the portal and the sFTP site:

CESP Portal URL: <http://cesp.hma.eu/>

Username: c1549-ca

Password: 1234test

Please remember to change your password by using the "Forgot Password" option on the home page and following the instructions you will receive via email.

sFTP Server

HOST: cesp.hma.eu

PORT: 22

Username: c1549-ca

Password: 1234test

All support calls should be logged through the online support system available to registered users of the system or by emailing cesp@hma.eu.

Business hours:

Monday to Friday, 09:00hrs to 17:00hrs (GMT)

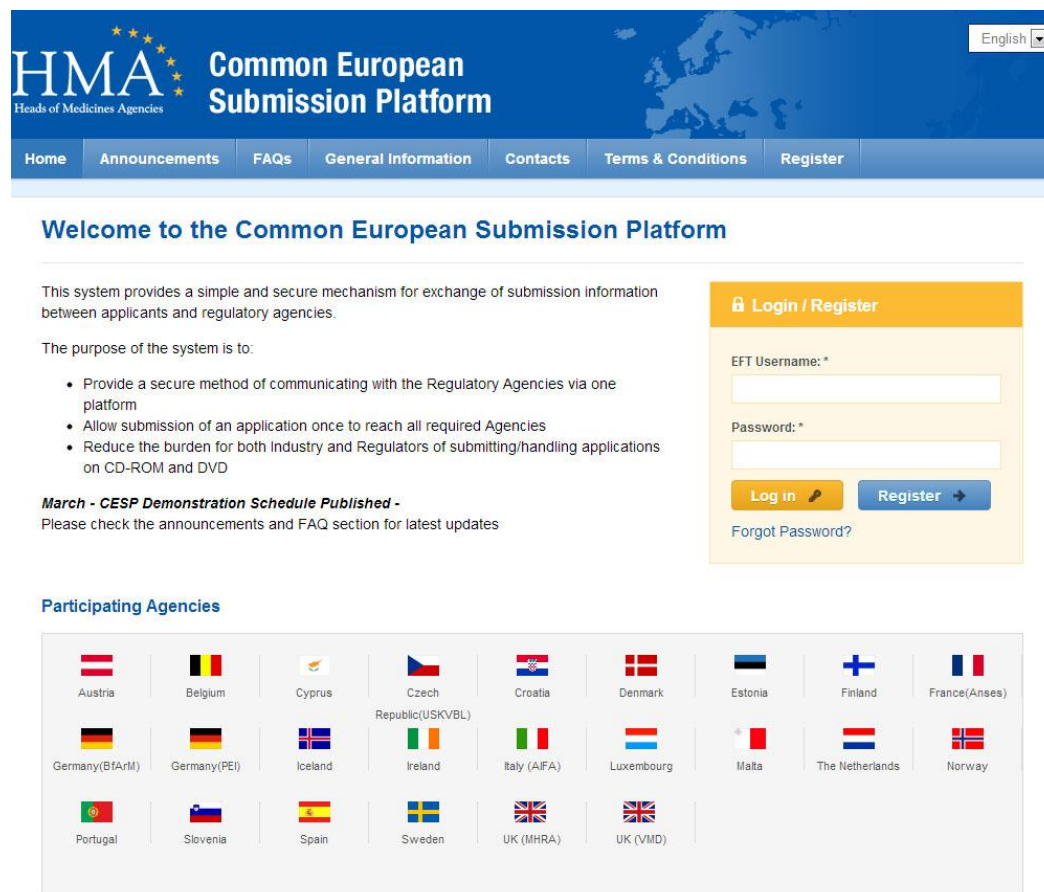
Main contact details Telephone: +35316343817

Email Address: cesp@hma.eu

Regards,

CESP Support Team.

- Change your password using the “forgot password” link and follow the instructions.
- Once changed log in to the system using your username and new password.



The screenshot shows the homepage of the Common European Submission Platform. The header includes the HMA logo and the text 'Common European Submission Platform'. A navigation bar contains links: Home, Announcements, FAQs, General Information, Contacts, Terms & Conditions, and Register. A language dropdown menu is set to 'English'.

The main content area features a welcome message: 'Welcome to the Common European Submission Platform'. Below this, a paragraph states: 'This system provides a simple and secure mechanism for exchange of submission information between applicants and regulatory agencies.' The purpose of the system is listed as follows:

- 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

A notice reads: 'March - CESP Demonstration Schedule Published - Please check the announcements and FAQ section for latest updates'.

On the right side, there is a 'Login / Register' section with the following fields and buttons:

- EFT Username: *
- Password: *
- Log in button (with a key icon)
- Register button (with a right arrow icon)
- Forgot Password? link

Below the login section, there is a 'Participating Agencies' section displaying a grid of flags and agency names:

Austria	Belgium	Cyprus	Czech Republic (USKVBL)	Croatia	Denmark	Estonia	Finland	France (Anses)
Germany (BfArM)	Germany (PEI)	Iceland	Ireland	Italy (AIFA)	Luxembourg	Malta	The Netherlands	Norway
Portugal	Slovenia	Spain	Sweden	UK (MHRA)	UK (VMD)			

- Once logged in as a company administrator you will have access to requests and the user management screen.

Requests and
user
management

HMA
Heads of Medicines Agencies

**Common European
Submission Platform**

test user Logout English

Home Announcements FAQs General Information Contacts Terms & Conditions Support Register

Company Admin: Requests User Management

Welcome to the Common European Submission Platform

You have successfully logged in

The portal can be accessed using two methods either through an sFTP client (preferred option) or through the web based file transfer system. In order to connect to the portal you will need:

- A PC with broadband access
- FTP client that has sFTP capability currently tested clients are Filezilla V3.4+ (free ftp client) or CuteFTP V8.3+ professional
- Standard web browser with java enabled

STEP 1 For both sFTP client and Web Based File Transfer System

Create a new delivery file

- Select the New Delivery File option
- Complete the form as required
- Download the XML version of the form to your submission folder on your local PC

New Delivery File +

STEP 2

sFTP client

Upload your Submission and Delivery file

- Launch your sFTP client and enter the following information
 - Host: cesp.hma.eu
 - Username
 - Password
 - Port 22
- Once connected please follow these steps:
 - Ensure that there are no other files in the

Web Based File Transfer System

Upload your Submission and Delivery file

- Launch web interface and enter the following information
 - Username
 - Password
- Once connected please follow these steps:
 - Ensure that there are no other files in the root of the remote server
 - Drop you submission documents / folder to the

1. You can manage each user in the system by selecting the 'edit' beside there name.

2. You can manually add a new user by selecting the 'Create New User' button

Or

a better option is to use the company registration code.

3. By providing this to your users they can register on the system and you can approve their access.

The screenshot shows the 'User Management' page of the HMA Common European Submission Platform. The page includes a navigation bar with links like Home, Announcements, FAQs, General Information, Contacts, Terms & Conditions, Support, and Register. Below the navigation bar, there's a section for 'Company Admin' with links for Requests and User Management. The main content area is titled 'User Management' and contains instructions for users registering for CESP. A table lists users with columns for Username, Firstname, Lastname, Email, Enabled, LockedOut, and Action. The 'Action' column for the user 'c1549-ca' has an 'Edit' link. A 'Create New User' button is also visible. Callouts highlight the 'Edit' link (1), the 'Create New User' button (2), and the 'CESP Registration Code' (3).

1. "Edit"

2. "create"

3. registration code

Process for your users registering for CESP

1. Supply the appropriate CESP Registration Code to your users (see below for codes)
2. Direct your users to <http://cesp.hma.eu/Register> where they will enter the CESP Registration Code, fill out their details and submit a registration request
3. You will receive a notification email of the registration request which you can review and process into a user account for CESP

The CESP Registration Codes for the companies you manage are:

- Company: Test Company March (1549) - Registration Code: **750fci**

View
☒ Users
☐ Companies

Filter List

User Role: -- Select -- Company: -- Select --

Username	Firstname	Lastname	Email	Enabled	LockedOut	Action
c1549-ca	test	user	cesptest@hotmail.com	True	False	Edit

« First Previous Page 1 Next » Last »

- User completes the registration available on the website
- Enter your CESP registration code provided by your company administrator .
- Select 'Find Company'.
- You will be displayed the company name associated with the code.
- Complete the form as required and select submit.
- Your request will be notified to the company administrator.


Common European
Submission Platform

English

Home
Announcements
FAQs
General Information
Contacts
Terms & Conditions
Register

Register

Complete the form to register for access to the CESP system. Once you submit your registration, you will be contacted to verify the account setup after which time you will receive connection details for the portal.

Registration Process

1 Submit registration application / 2 Verify and Review request / 3 If approved, you will receive an email with access details

Your Details

First Name: *

Last Name: *

Email: *

Confirm Email: *

Contact Number: *

Please include the international dialling code with your phone number.
For example: 44123456789 for United Kingdom or 49123456789 for Germany.

Job Title:

Company Information

If you do have the CESP registration code for your company then please enter it here and click the 'Find Company' button. Please contact your company administrator to get the CESP registration code.

CESP Registration Code:

Company Found: Test Company March

- CA logs back into the system and opens the request section
- Review the request and either delete or process the request

Company Admin: Requests | User Management

Displaying Registration Request

Registration Request Details
Request ID: 1141
Request Type: User Registration
Received: 02/03/2013 11:52:22
Received From: CESP Website
Processed Yet: No

firstname: **Second**
lastname: **User**
email: **cesptest@hotmail.com**
emailconfirm: **cesptest@hotmail.com**
contactnumber: **1234**
jobtitle:
browser:
ftpclient:
bandwidth:
os:
terms: **on**
registrationcode: **750fci**
orgprofileid: **1549**

This was created on 02 March 2013 at 11:52:22 (1 minute ago)

- Selecting to process the request displays the 'create a new user screen'.
- Complete the username field using the 'last name' & 'first initial' of firstname all lowercase e.g bloggsj.
- Assign a role , Company administrator or Standard User.
- Press save.

Company Admin: Requests | User Management

Create a new User

User Details

Username: *

c1549-

sa

Email: *

cesptest@hotmail.com

First Name: *

Second

Last Name: *

User

Password: *

1234test

Generate New Password

User Role: *

CESPCOMPANYUSER

Enabled:

☒

Company

Primary

Test Company March (1549)

Delete

Locked Out: [UnLock Account](#)

-- Select --

Add

Contact Number:

1234

Mobile Number:

Company Admin: [Requests](#) | [User Management](#)

User Management

Process for your users registering for CESP

1. Supply the appropriate CESP Registration Code to your users (see below for codes)
2. Direct your users to <http://cesp.hma.eu/Register> where they will enter the CESP Registration Code, fill out their details and submit a registration request
3. You will receive a notification email of the registration request which you can review and process into a user account for CESP

The CESP Registration Codes for the companies you manage are:

- Company: Test Company March (1549) - Registration Code: **750fci**

View
☒ Users
☐ Companies

User Role:
Company:

Username	Firstname	Lastname	Email	Enabled	LockedOut	Action
c1549-sa	Second	User	cesptest@hotmail.com	True	False	Edit
c1549-ca	test	user	cesptest@hotmail.com	True	False	Edit

[|« First](#)
[« Previous](#)

Page 1

[Next »](#)
[Last »|](#)

- User is displayed for that company

Company Admin: [Requests](#) | [User Management](#)

User Management

Process for your users registering for CESP

1. Supply the appropriate CESP Registration Code to your users (see below for codes)
2. Direct your users to <http://cesp.hma.eu/Register> where they will enter the CESP Registration Code, fill out their details and submit a registration request
3. You will receive a notification email of the registration request which you can review and process into a user account for CESP

The CESP Registration Codes for the companies you manage are:

- Company: Test Company March (1549) - Registration Code: **750fci**

View
☒ Users
☐ Companies

Filter List

Create New User +

User Role: -- Select --
Company: -- Select --

Username	Firstname	Lastname	Email	Enabled	LockedOut	Action
c1549-sa	Second	User	cesptest@hotmail.com	True	False	Edit
c1549-ca	test	user	cesptest@hotmail.com	True	False	Edit

|« First
« Previous
Page 1
Next »
Last »|

Companies

- Logged in as a company administrator
- Select the “Companies” Radio Button

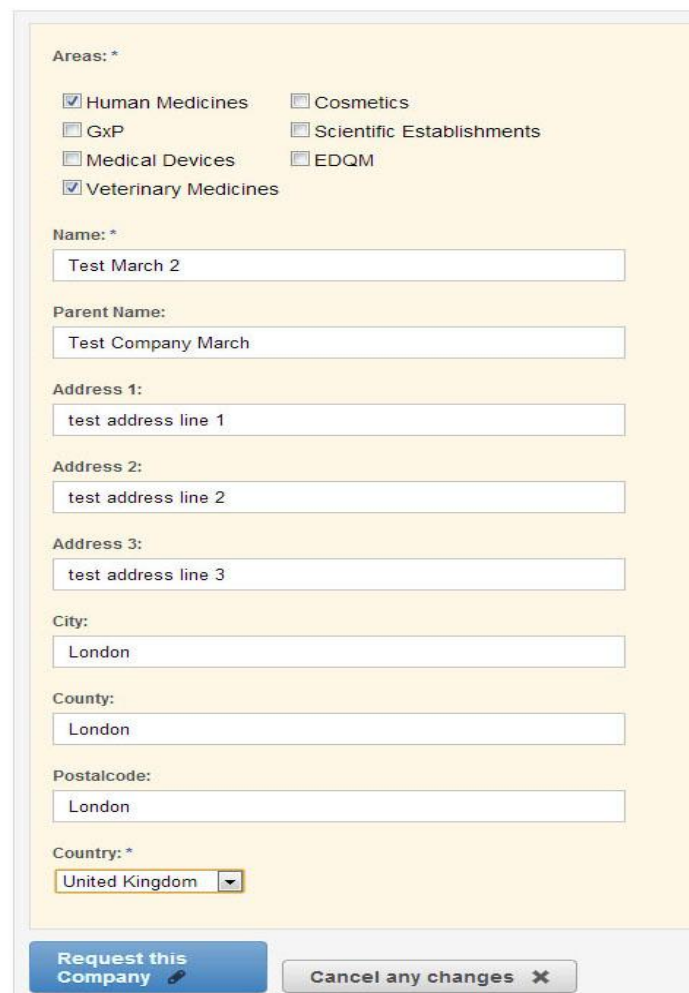
User Management

View			
<input type="radio"/> Users			
<input checked="" type="radio"/> Companies		Request New Company +	
Name	Areas	Country	Action
Test Company March (1549)	Human Medicines, GxP, Medical Devices, Veterinary Medicines, Cosmetics, Scientific Establishments, EDQM	Ireland	Edit
 « First « Previous Page 1 Next » Last » 			

- Current listing of companies is displayed
- Select the “Request New Company” Button

- Enter the new company information
- Select “Request New Company” Button
- When this is processed an Email will be sent to the CA requesting confirmation of company details
- Complete the information in the email and return to system administrator

Create a new Company



The form is titled "Create a new Company" and contains the following fields and options:

- Areas: ***
 - ☒ Human Medicines
 - ☐ GxP
 - ☐ Medical Devices
 - ☒ Veterinary Medicines
 - ☐ Cosmetics
 - ☐ Scientific Establishments
 - ☐ EDQM
- Name: ***
- Parent Name:**
- Address 1:**
- Address 2:**
- Address 3:**
- City:**
- County:**
- Postalcode:**
- Country: ***

At the bottom of the form, there are two buttons: "Request this Company" (blue) and "Cancel any changes" (grey).

Company Admin: Requests | User Management

User Management

Your Company Request has been Submitted

We have sent you an email with instructions for the documentation we require.

View

☐ Users

☒ Companies

[Request New Company](#) +

Name	Areas	Country	Action
Test Company March (1549)	Human Medicines, GxP, Medical Devices, Veterinary Medicines, Cosmetics, Scientific Establishments, EDQM	Ireland	Edit

[« First](#)

[« Previous](#)

Page 1

[Next »](#)

[Last »](#)

[Go to the First page in the list](#)

- Email will be sent to the CA requesting confirmation of company details
- Complete the information in the email and return to system administrator

Company Admin: [Requests](#) | [User Management](#)

User Management

Process for your users registering for CESP

1. Supply the appropriate CESP Registration Code to your users (see below for codes)
2. Direct your users to <http://cesp.hma.eu/Register> where they will enter the CESP Registration Code, fill out their details and submit a registration request
3. You will receive a notification email of the registration request which you can review and process into a user account for CESP

The CESP Registration Codes for the companies you manage are:

- Company: Test Company March (1549) - Registration Code: **750fci**
- Company: Test March 2 (1550) - Registration Code: **lj0wup**

View
☒ Users
☐ Companies

Filter List

Create New User +

User Role: -- Select --
Company: -- Select --

Username	Firstname	Lastname	Email	Enabled	LockedOut	Action
c1549-sa	Second	User	cesptest@hotmail.com	True	False	Edit
c1549-ca	test	user	cesptest@hotmail.com	True	False	Edit

|< First
« Previous
Page 1
Next »
Last >|

- Once confirmed your additional company will be displayed with a new registration code.


Company Admin: [Requests](#) | [User Management](#)

User Management

View <input type="radio"/> Users <input checked="" type="radio"/> Companies		Request New Company +	
Name	Areas	Country	Action
Test March 2 (1550)	Human Medicines, Veterinary Medicines	United Kingdom	Edit
Test Company March (1549)	Human Medicines, GxP, Medical Devices, Veterinary Medicines, Cosmetics, Scientific Establishments, EDQM	Ireland	Edit
 « First « Previous Page 1 » Next Last » 			

- The additional company will be displayed on the companies screen.

- You can grant existing users access to this company by providing them with the registration code.
- Each user can then enter this registration code in the cesp registration code section of the “My Account” screen and press find company



HMA Common European Submission Platform
Heads of Medicines Agencies

Second User Logout English

Home Announcements FAQs General Information Contacts Terms & Conditions Support Register

My Account

Your Account Details

Name:
Second User

Username:
c1549-sa

Email:
cesptest@hotmail.com

Company:
Test Company March

You can request access to additional companies by entering their CESP registration code below and clicking the 'Find Company' button. Please contact your company administrator to get the CESP registration code.

CESP Registration Code:

Subscriptions

Your Subscriptions:

☒ Announcement
☐ FAQ

Formats to Receive:

☒ Email
☐ SMS

Phone Number to Receive SMS:

Please include the international dialing code with your phone number.
 For example: 44123456789 for United Kingdom or 49123456789 for Germany.
 Please only include numbers, do not include any spaces or other characters.

Save Cancel

- When a valid company is found the user can select the “request this company” button
- This sends the request to the company administrator

My Account

Your Account Details

Name:
Second User

Username:
c1549-sa

Email:
cesptest@hotmail.com

Company:
Test Company March

You can request access to additional companies by entering their CESP registration code below and clicking the 'Find Company' button. Please contact your company administrator to get the CESP registration code.

CESP Registration Code:

Company Found: Test March 2

Subscriptions

Your Subscriptions:

☒ Announcement
☐ FAQ

Formats to Receive:

☒ Email
☐ SMS

Phone Number to Receive SMS:

Please include the international dialling code with your phone number.
For example: 44123456789 for United Kingdom or 49123456789 for Germany.
Please only include numbers, do not include any spaces or other characters.

Granting users access to a Company

Company Admin: Requests | User Management

Manage Requests

Company: <input type="text" value="-- Select --"/>		Processed: <input type="radio"/> Yes <input checked="" type="radio"/> No		
Request ID	Request Type	Company	Created	Action
1143	User Company Access	Test March 2 (1550)	2/3/2013 12:08:31	View
 < First « Previous Page 1 Next » Last » 				

- CA can view and process the request

Company Admin: Requests | User Management

Displaying Registration Request

Registration Request Details

Request ID: 1143
Request Type: User Company Access
Received: 02/03/2013 12:08:31
Received From: CESP Website
Processed Yet: No

registrationcode: lJ0wup
orgprofileid: 1550
requestedcompanyname: Test March 2
username: c1549-sa
firstname: Second
lastname: User
email: cesptest@hotmail.com

[Process this Request](#) ✓

[Delete this Request](#) ✕

[Cancel](#) ✕

This was created by Second User on 02 March 2013 at 12:08:31 (1 minute ago)

[Home](#)
[Announcements](#)
[FAQs](#)
[General Information](#)
[Contacts](#)
[Terms & Conditions](#)
[Support](#)
[Register](#)

Company Admin: Requests | User Management

User Company Access Request

Please confirm that you wish to grant access to the company **Test March 2** to the user **Second User (c1549-sa)**.

[Confirm](#) ✓

[Cancel any changes](#) ✕

Fields marked with * are mandatory

- You can add new areas to your company profile as a company administrator by opening the my account page by selecting the hyperlink of your name beside the logout button.
- Select the area hyperlink “area” on the page beside your company name and either select or de-select areas.

My Account

Your Account Details

Name:
Company Admin

Username:
c1190-ca

Email:
cesptest@hotmail.com

Company:
Test Company [Areas](#)
to be deleted 10 [Areas](#)
to be deleted 5 [Areas](#)

☐ Human Medicines
 ☐ Cosmetics

☐ GxP
 ☐ Scientific Establishments

☐ Medical Devices
 ☒ EDQM

☐ Veterinary Medicines

Subscriptions

Your Subscriptions:

☒ Announcement
 ☐ FAQ

Formats to Receive:

☒ Email
 ☐ SMS

Phone Number to Receive SMS:

Please include the international dialing code with your phone number.
For example: 44123456789 for United Kingdom or 49123456789 for Germany.
Please only include numbers, do not include any spaces or other characters.

Areas

- Register the parent company and set up a company administrator for that parent
- This CA can then request the setup of each of the affiliates through the system which would then be linked back to the parent.
- Once the affiliates are set up you can then provide each affiliate with the registration code and each user can request access to that affiliate.
- You can then assign a user from that affiliate as the CA for the affiliate and they can then manage their own users.

- Consultancy registers under its own name and assign a company administrator
- Consultancy Company administrator (CCA) sets up their own users under the consultancy company
- MAH registers on cesp and assigns a company administrator
- MAH company administrator (MCA) sends the CCA the MAH company registration code and the CCA requests access to the MAH
- MCA grants access to the CCA and assigns them the role of company administrator.
- CCA can then sent the MAH registration code to the staff to register for access in the normal manner.

- Business hours are:
Monday to Friday, 09:30hrs to 17:00hrs (GMT)
- Main contact details Telephone: 35316343801
- Email Address: cesp@hma.eu
- Registered user should use the online support desk to raise calls.
- Comments or Queries to kevin.horan@imb.ie