CESP Demonstration

HMA Heads of Medicines Agencies Common European Submission Platform

What is the Common European Submission Platform (CESP) ?

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

HMA Heads of Medicines Agencies Common European Submission Platform

Benefits of CESP

- ✓ 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.

HMA Heads of Medicines Agencies Common European Submission Platform

Participating Agencies

- 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

HMA Heads of Medicines Agencies

Common European Submission Platform

Before CESP | Multiple Deliveries

HMA Heads of Medicines Agencies

Common European Submission Platform

Before CESP | Multiple Deliveries

HMA Heads of Medicines Agencies

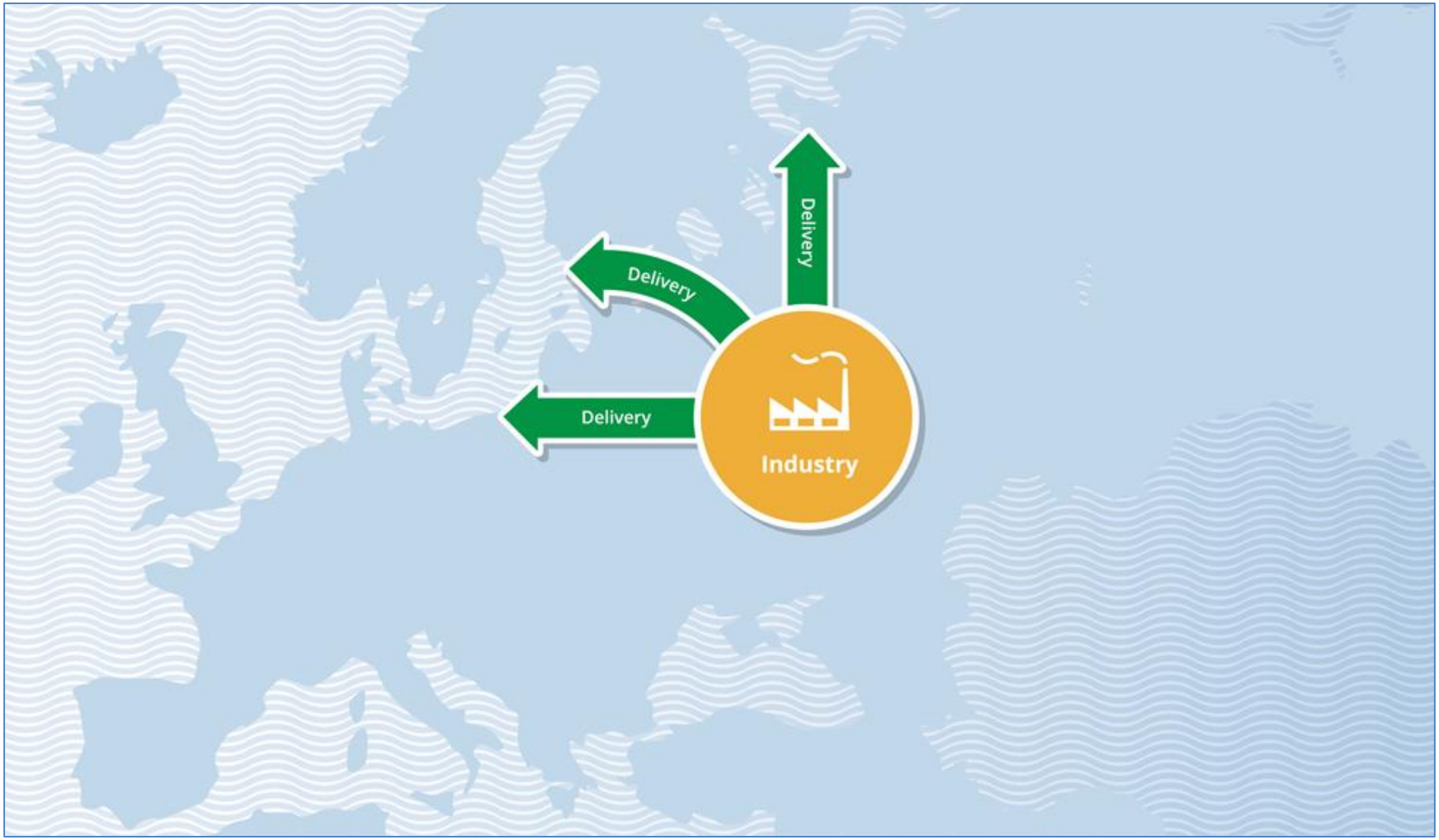
Common European Submission Platform

Before CESP | Multiple Deliveries

HMA Heads of Medicines Agencies

Common European Submission Platform

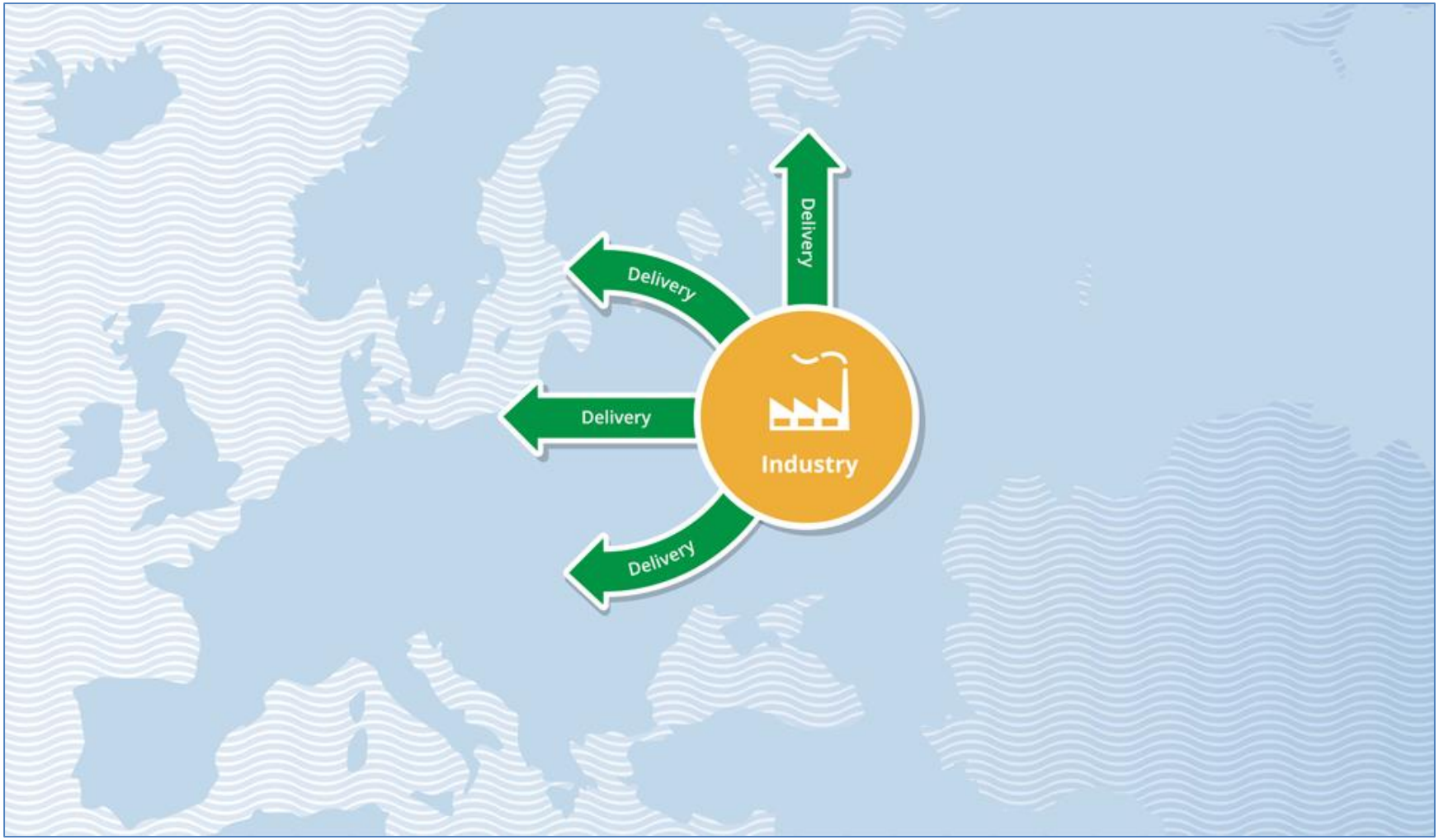
Before CESP | Multiple Deliveries



HMA Heads of Medicines Agencies

Common European Submission Platform

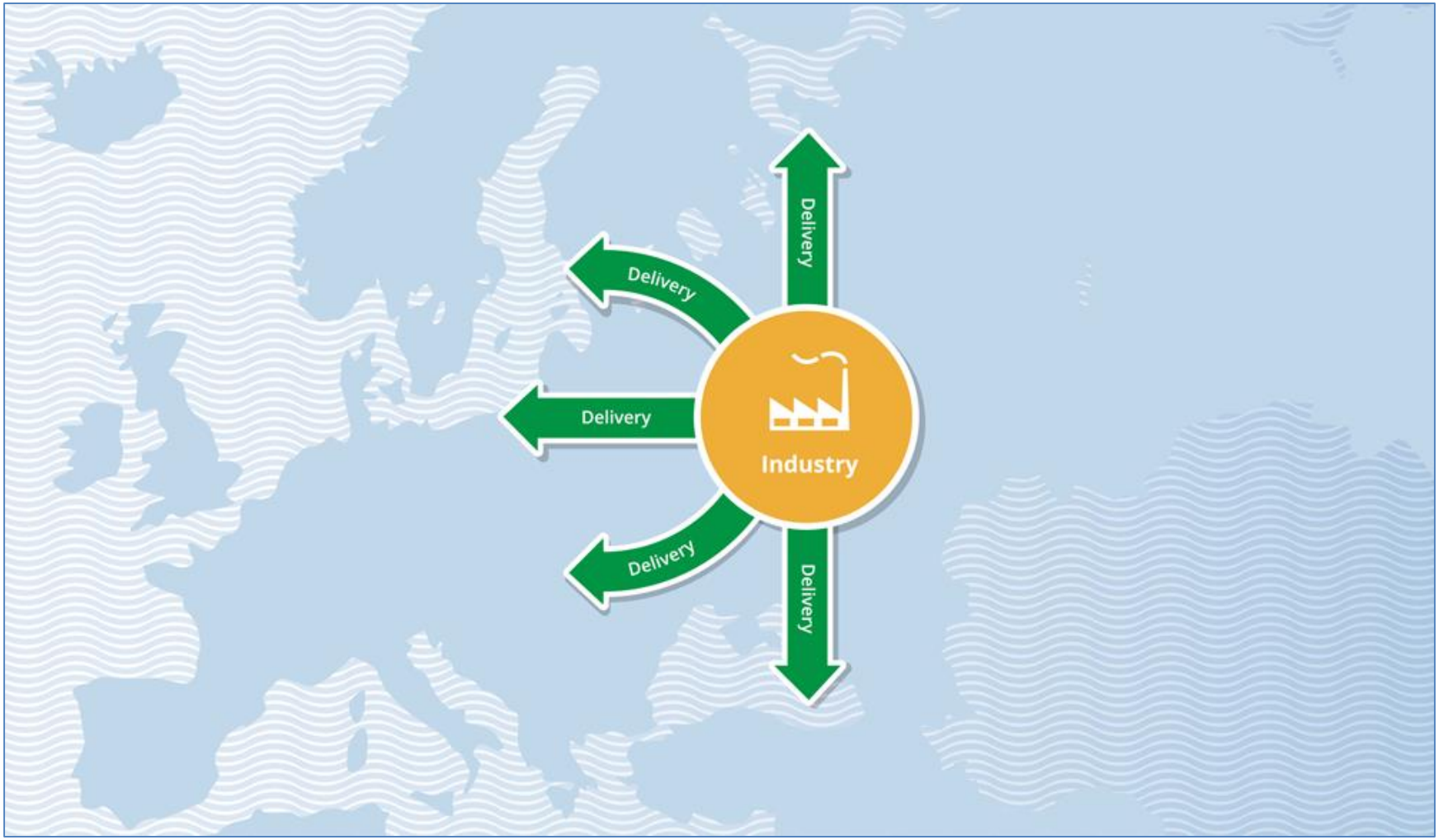
Before CESP | Multiple Deliveries



HMA Heads of Medicines Agencies

Common European Submission Platform

Before CESP | Multiple Deliveries



HMA Heads of Medicines Agencies

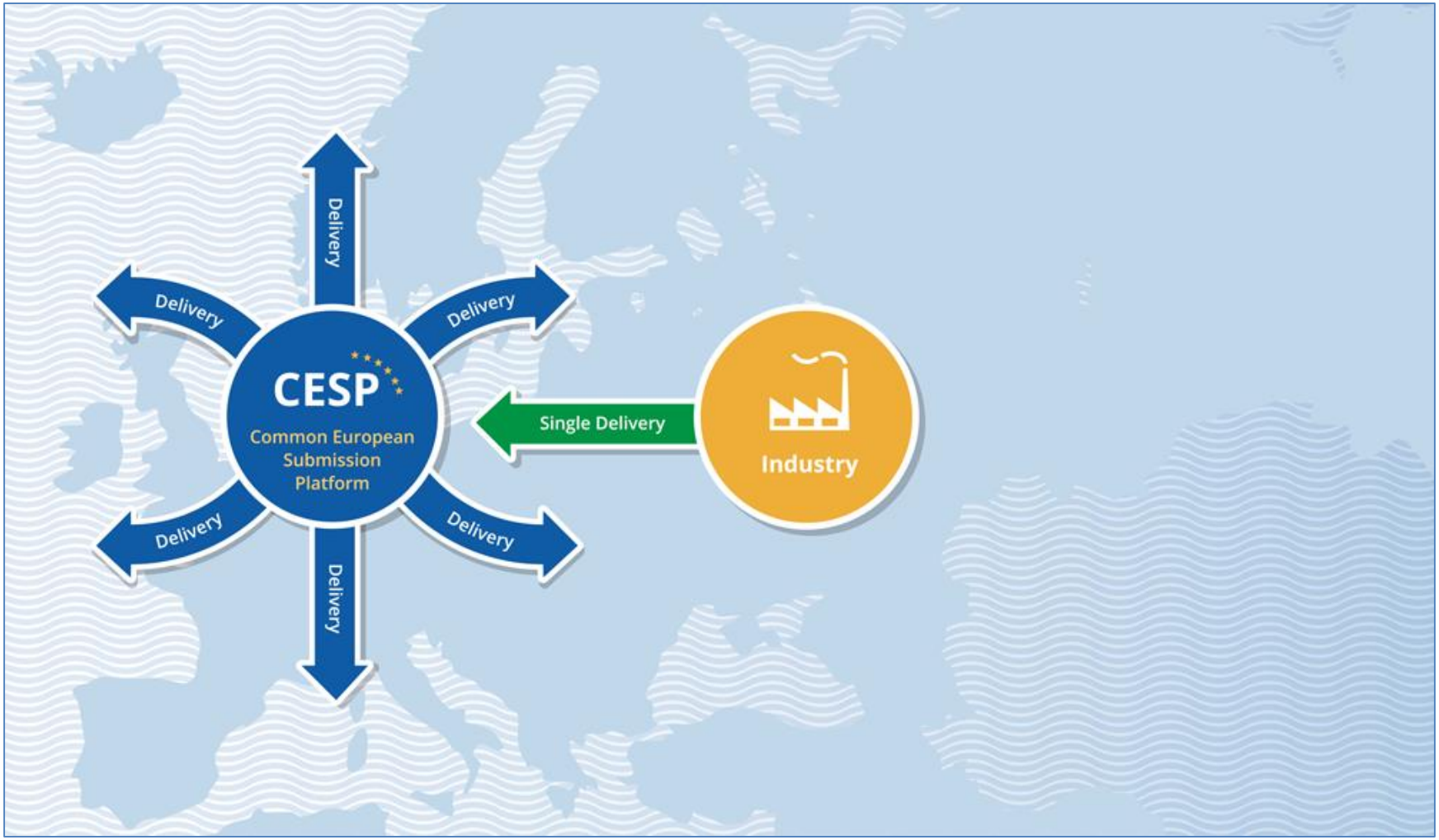
Common European Submission Platform

Using CESP | Single Delivery

HMA Heads of Medicines Agencies

Common European Submission Platform

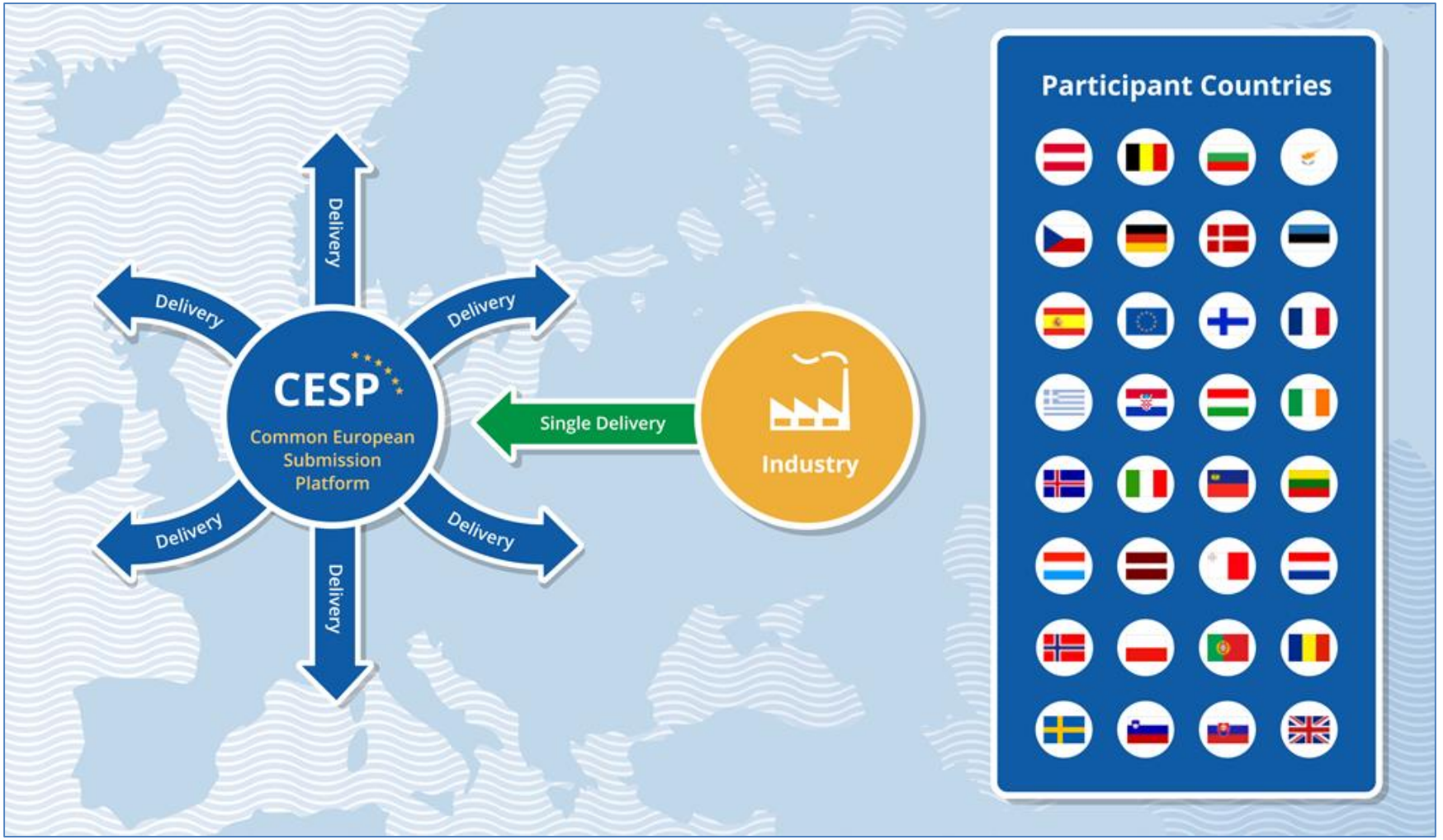
Using CESP | Single Delivery



HMA Heads of Medicines Agencies

Common European Submission Platform

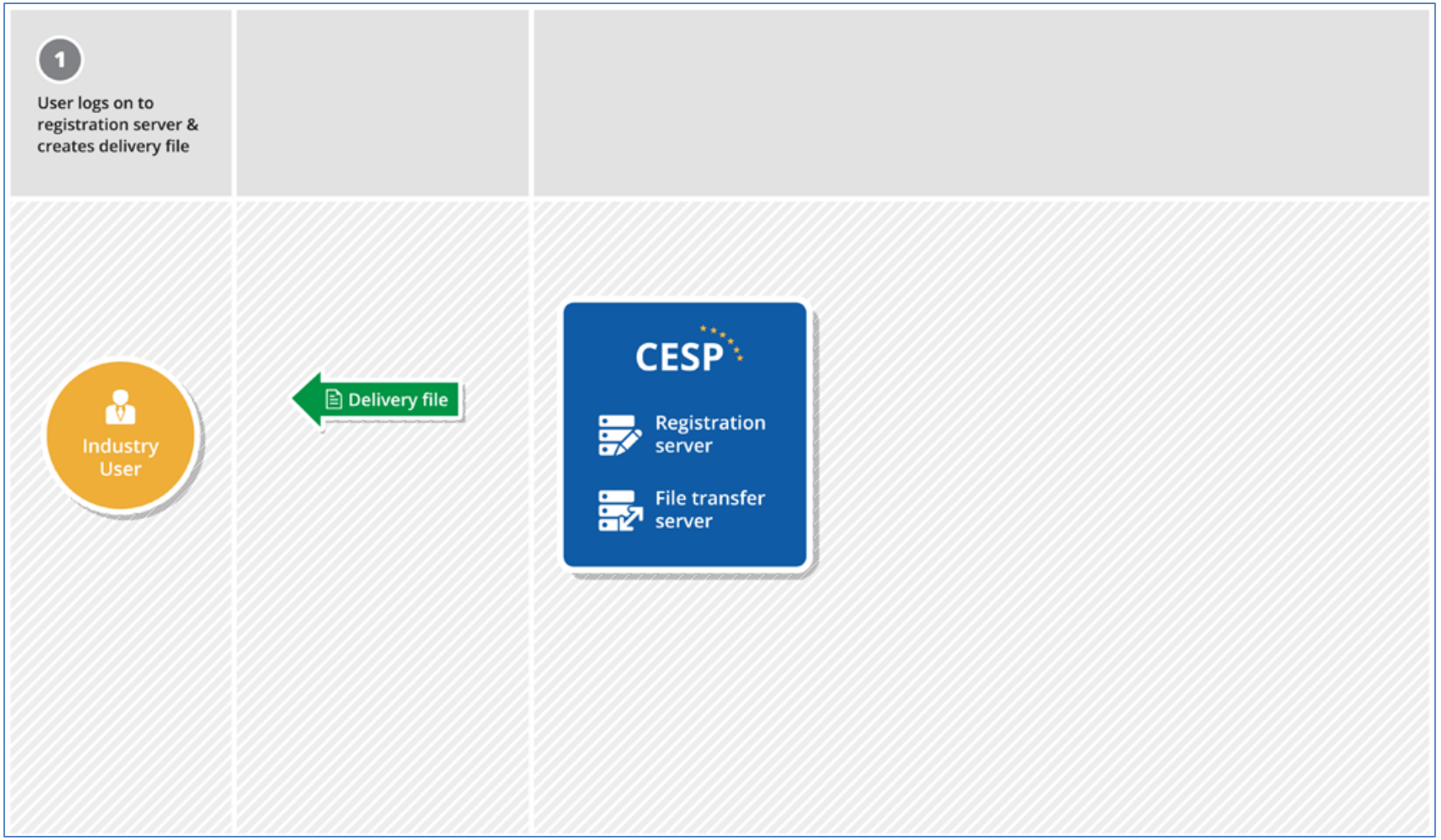
Using CESP | Single Delivery



HMA Heads of Medicines Agencies

Common European Submission Platform

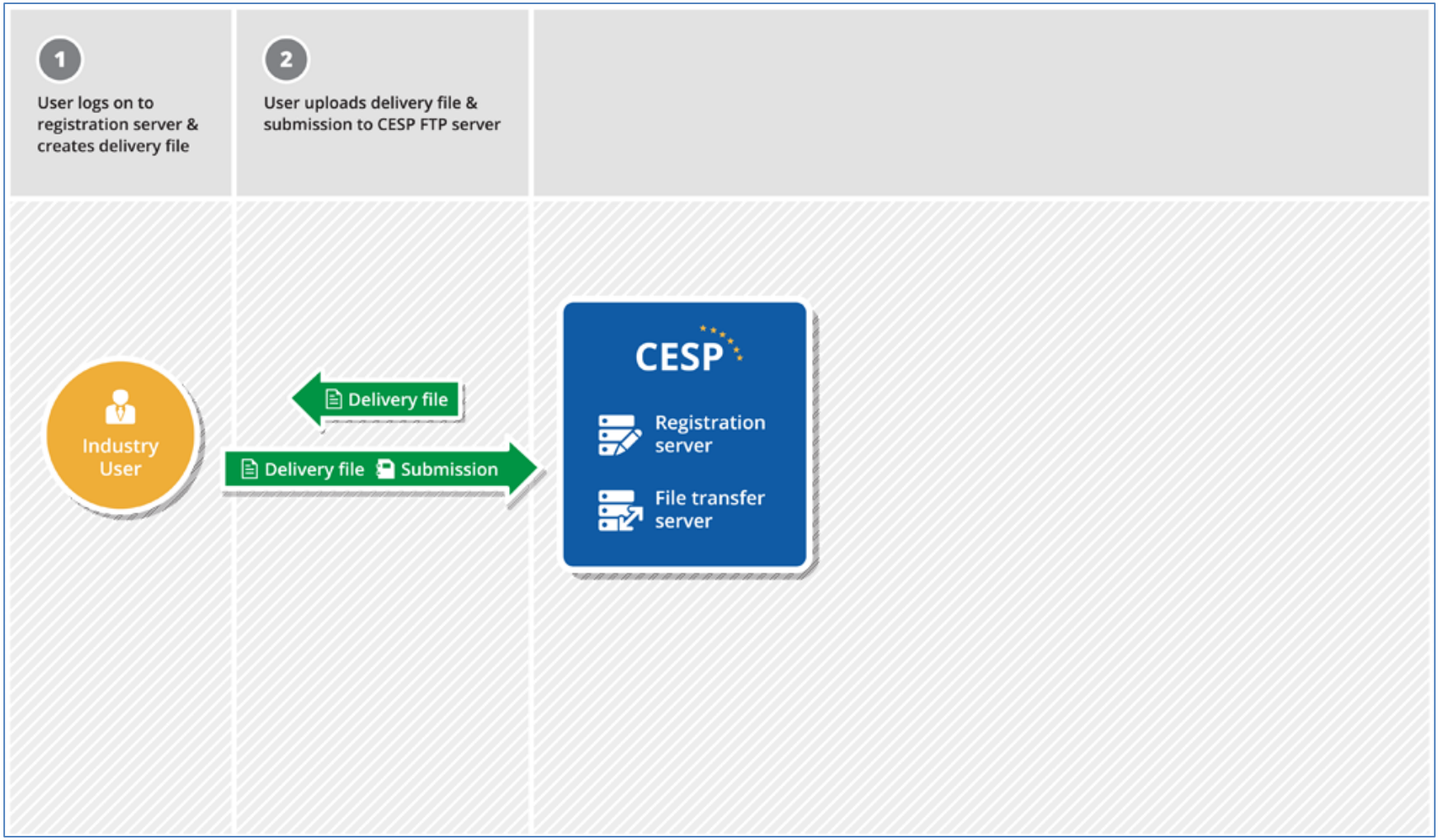
CESP | How it Works



HMA Heads of Medicines Agencies

Common European Submission Platform

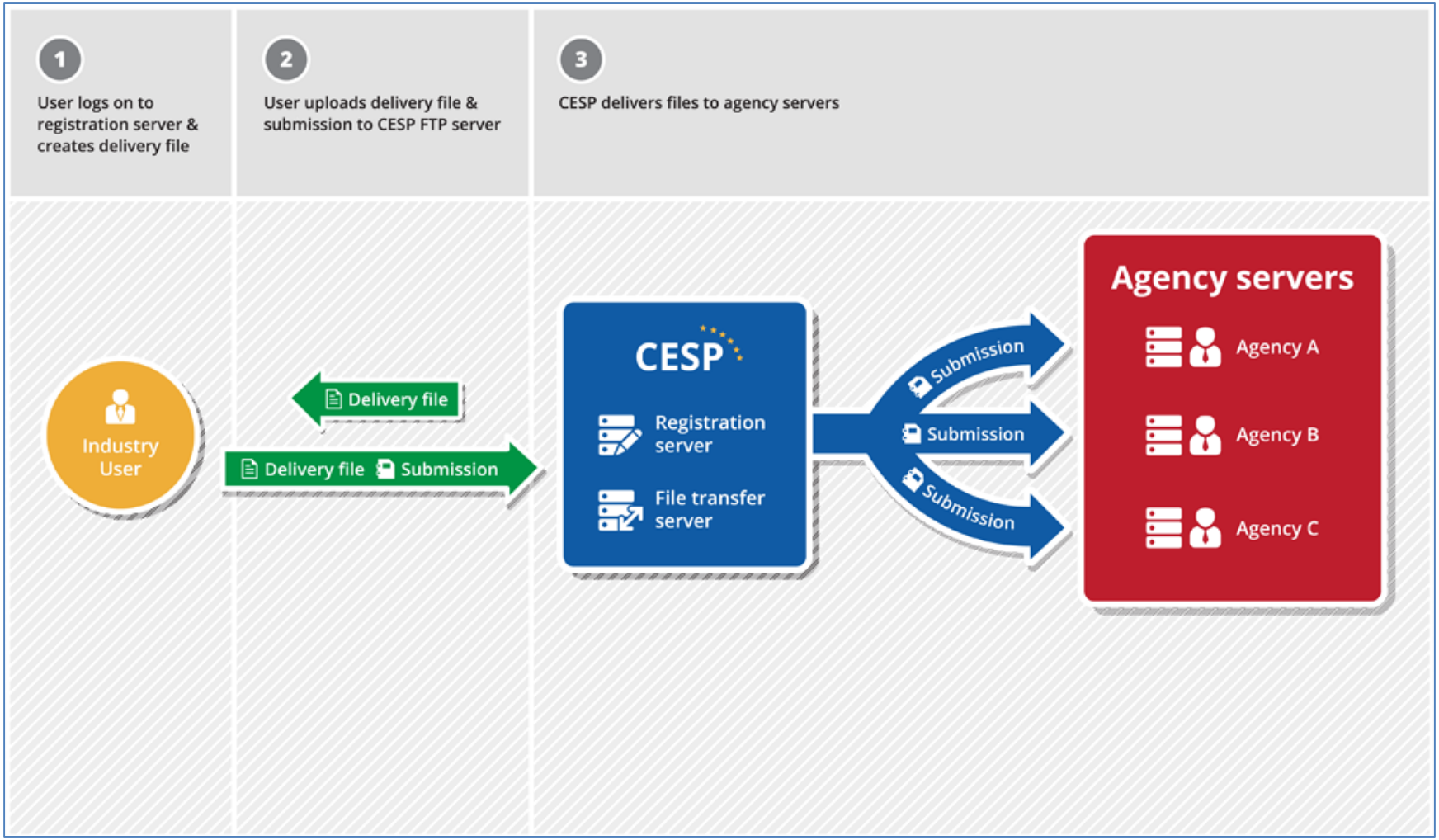
CESP | How it Works



HMA Heads of Medicines Agencies

Common European Submission Platform

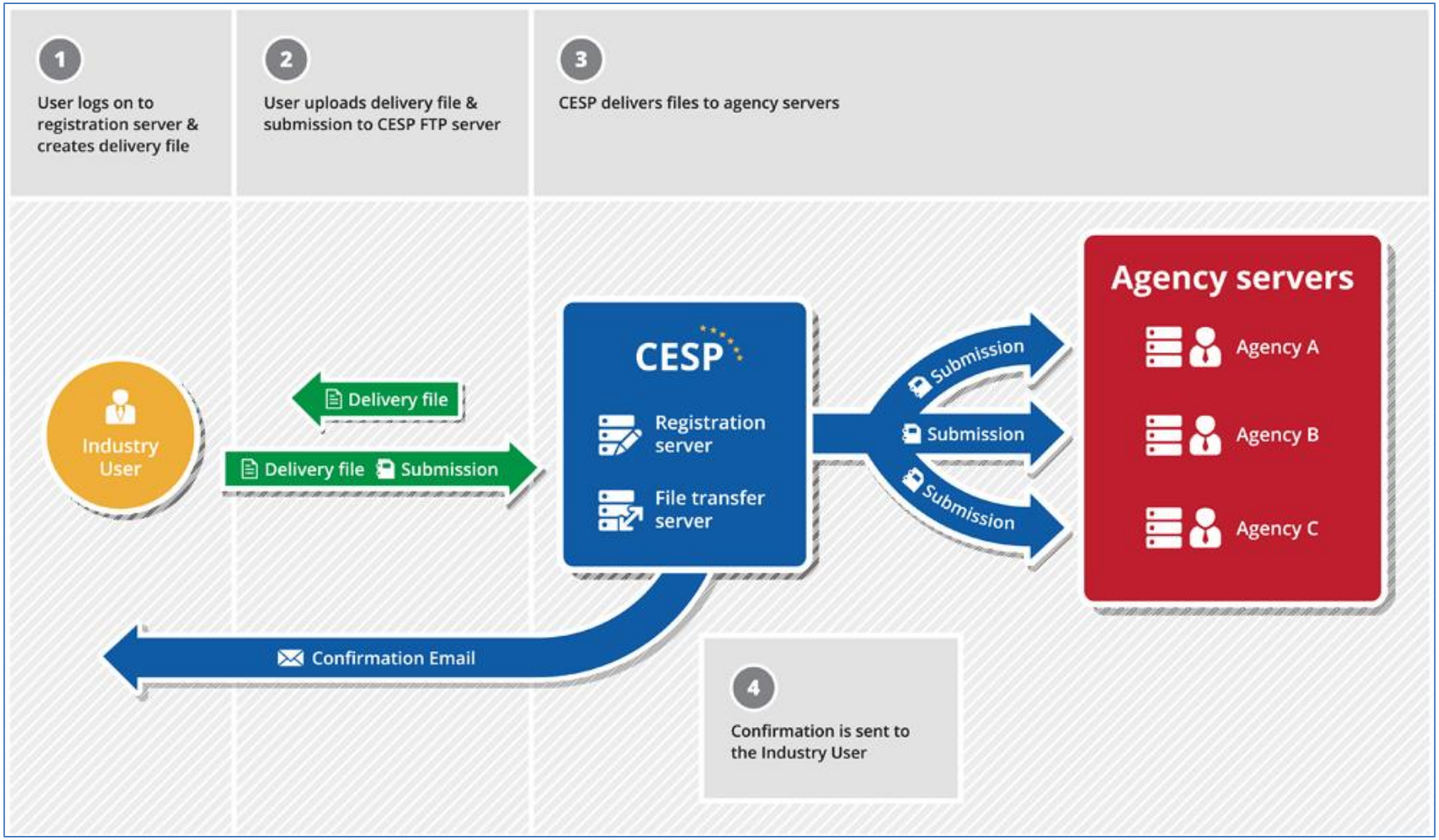
CESP | How it Works



HMA Heads of Medicines Agencies

Common European Submission Platform

CESP | How it Works

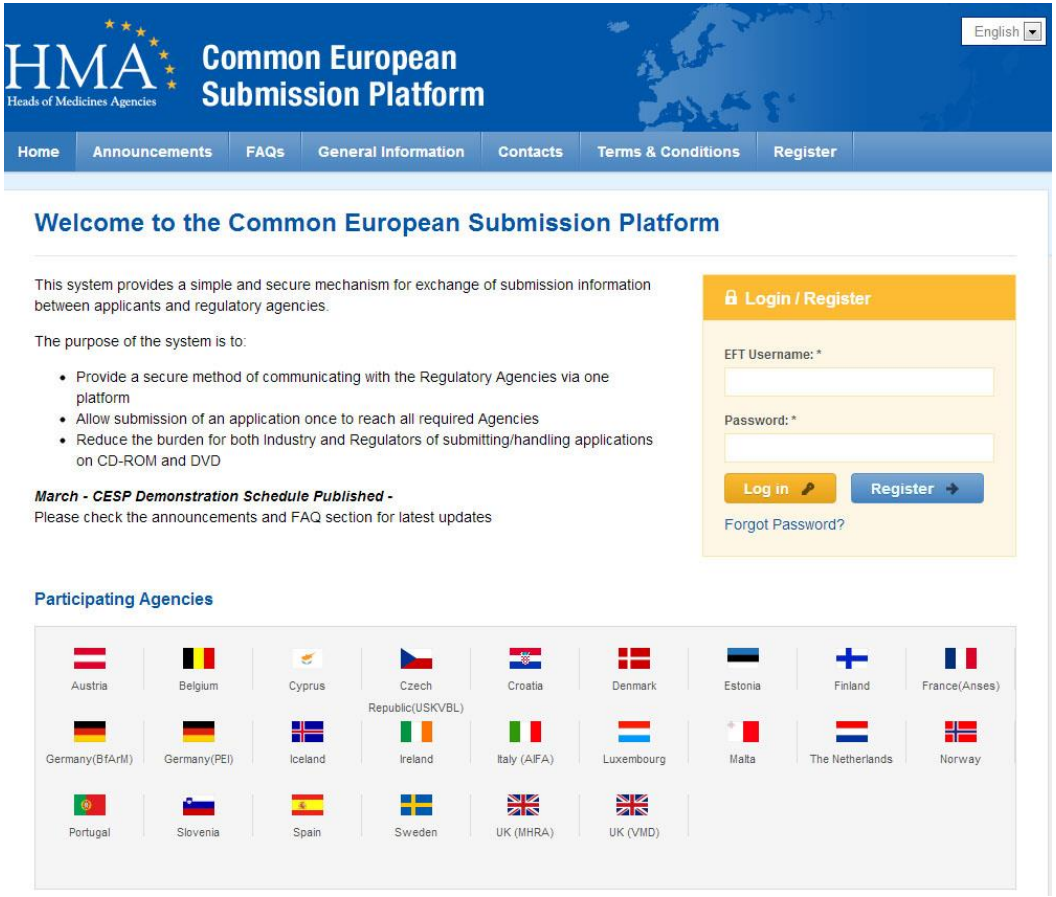


HMA Heads of Medicines Agencies **Common European Submission Platform**

Website

Main Website

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

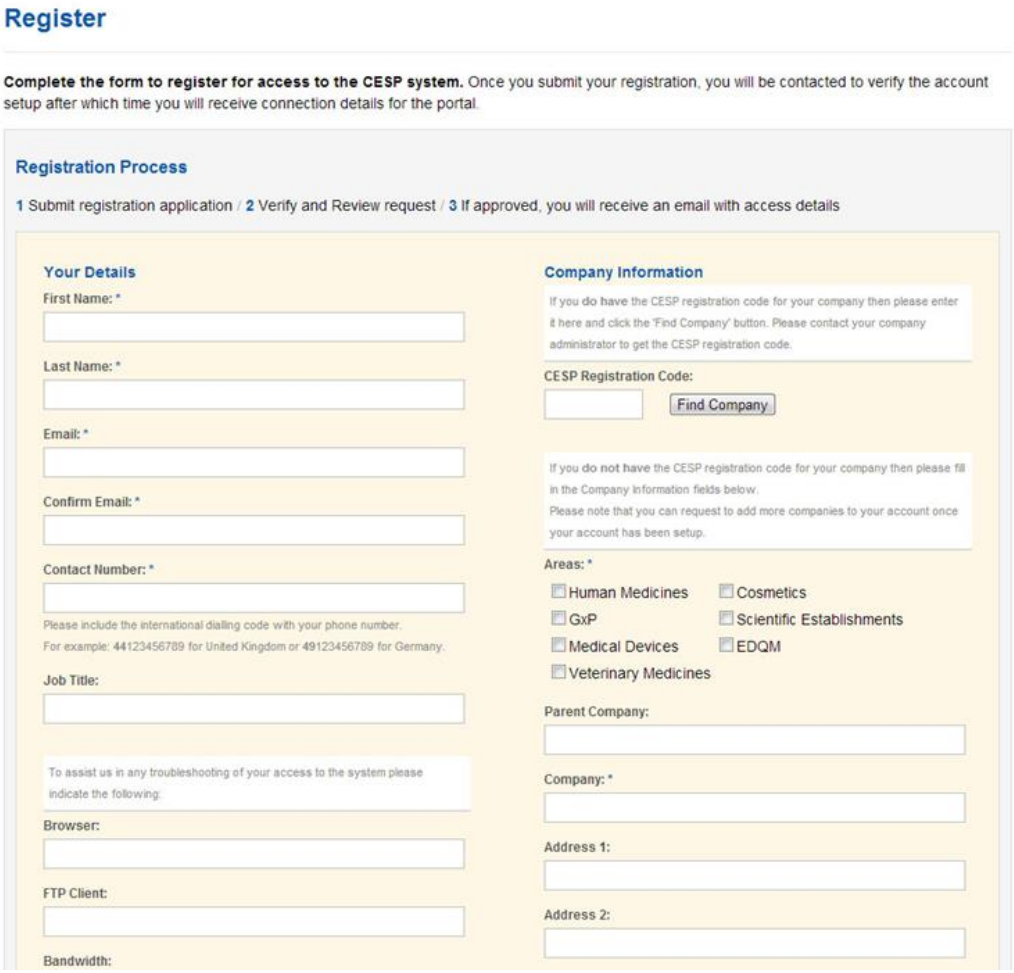


HMA Heads of Medicines Agencies

Common European Submission Platform

Registration screen

- 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 dialling 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:

Find Company

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

HMA Heads of Medicines Agencies Common European Submission Platform

Create a Delivery File

- 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 succesfully logged in

The portal can be accessed using two methods either though 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

IMPORTANT NOTICE: Please note that BfarM (Germany) have special requirements for electonic 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

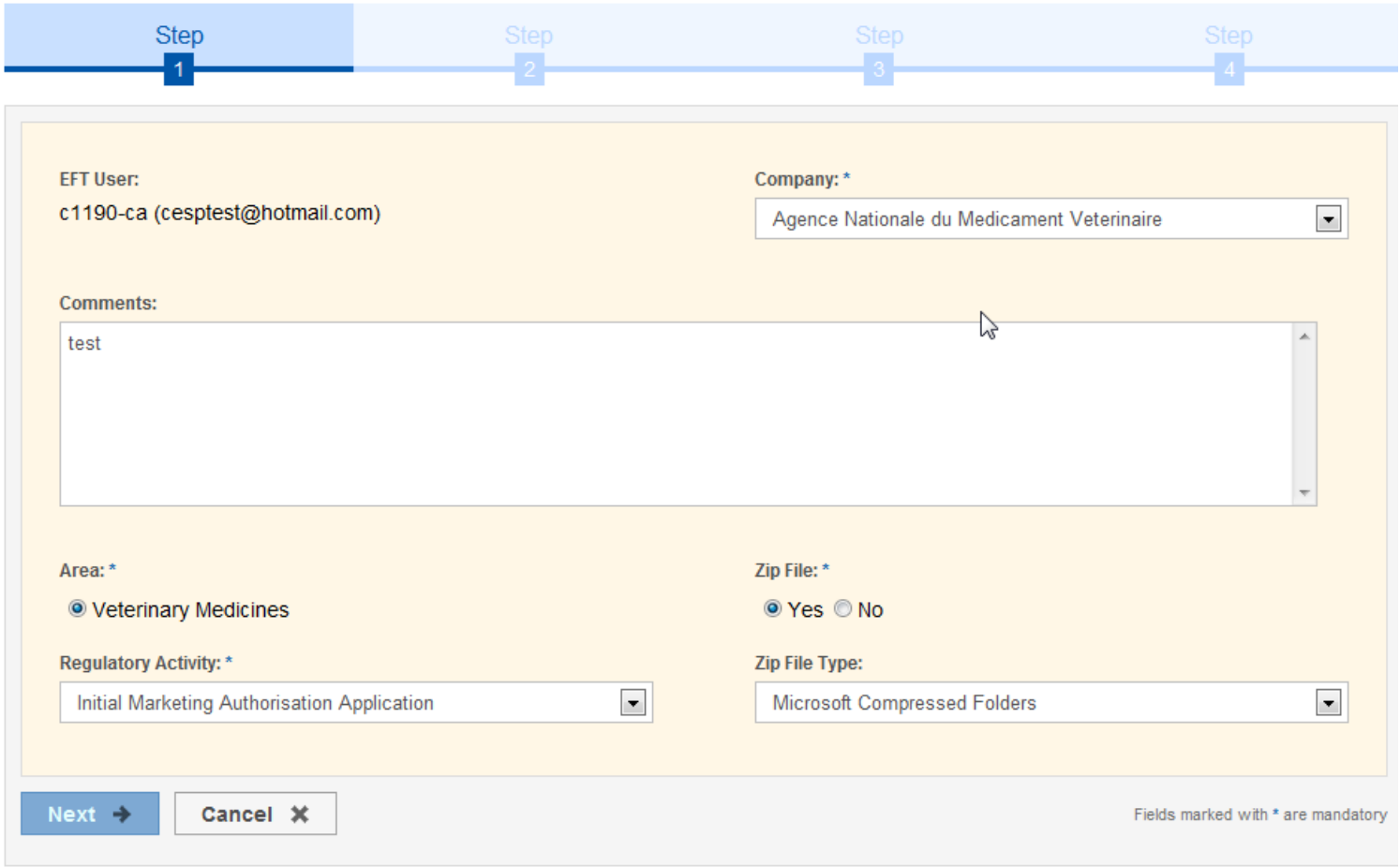
1. Launch web interface and enter the following information
   a. Username
   b. Password
2. Once connected please follow these steps:
   a. Ensure that there are no other files in the root of the remote server
   c. Drop you submission documents / folder to the remote server
   a. Drop the delivery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

HMA Heads of Medicines Agencies

Common European Submission Platform

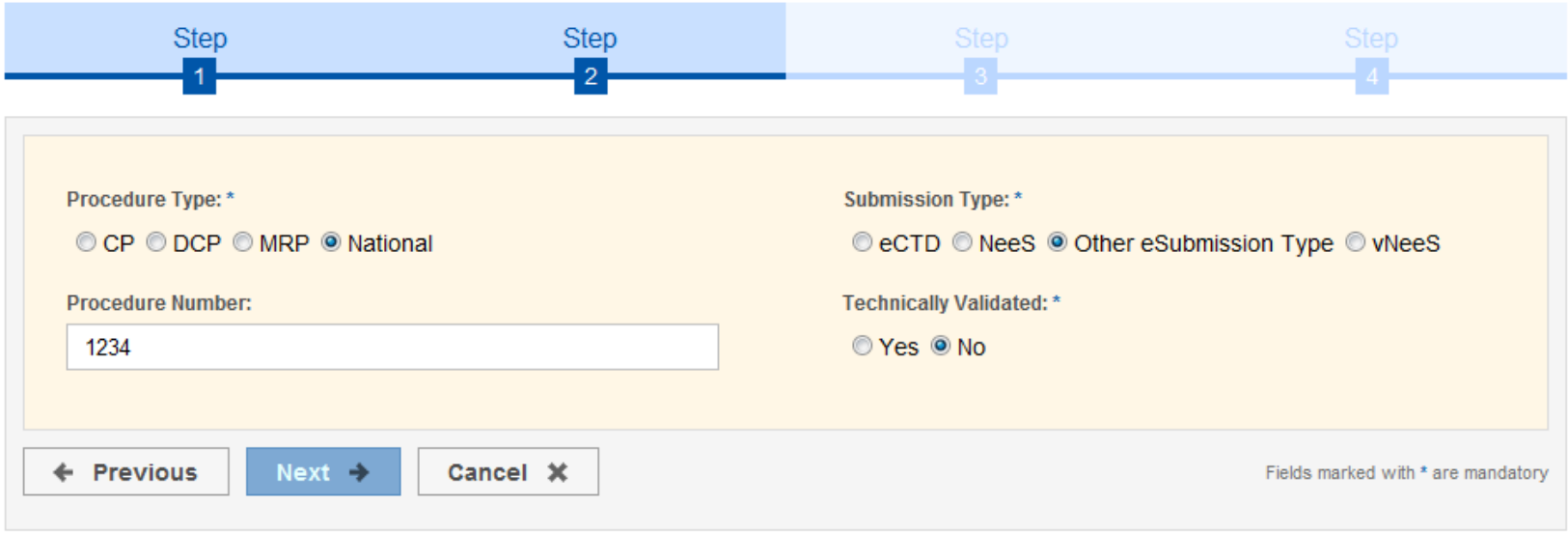
Create a Delivery File



HMA Heads of Medicines Agencies

Common European Submission Platform

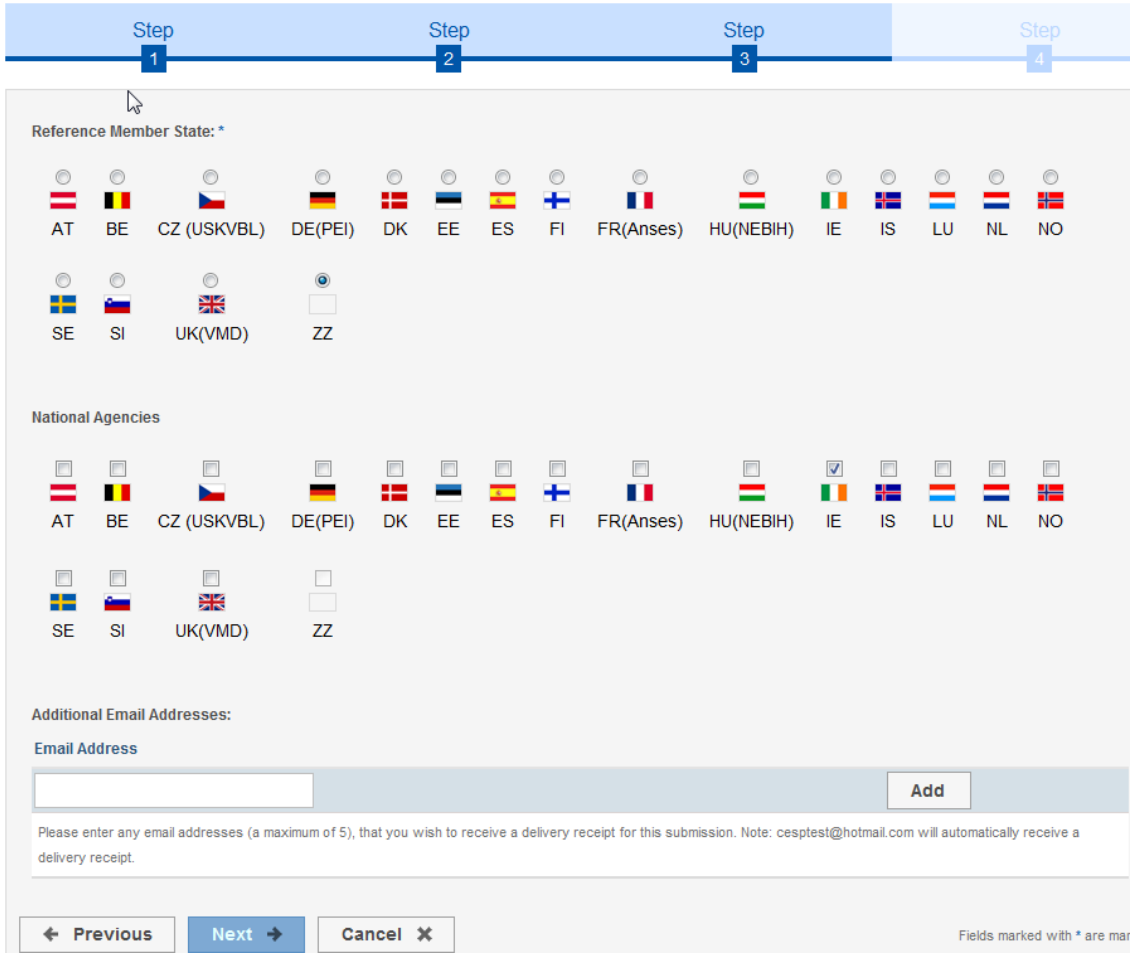
Create a Delivery File



HMA Heads of Medicines Agencies

Common European Submission Platform

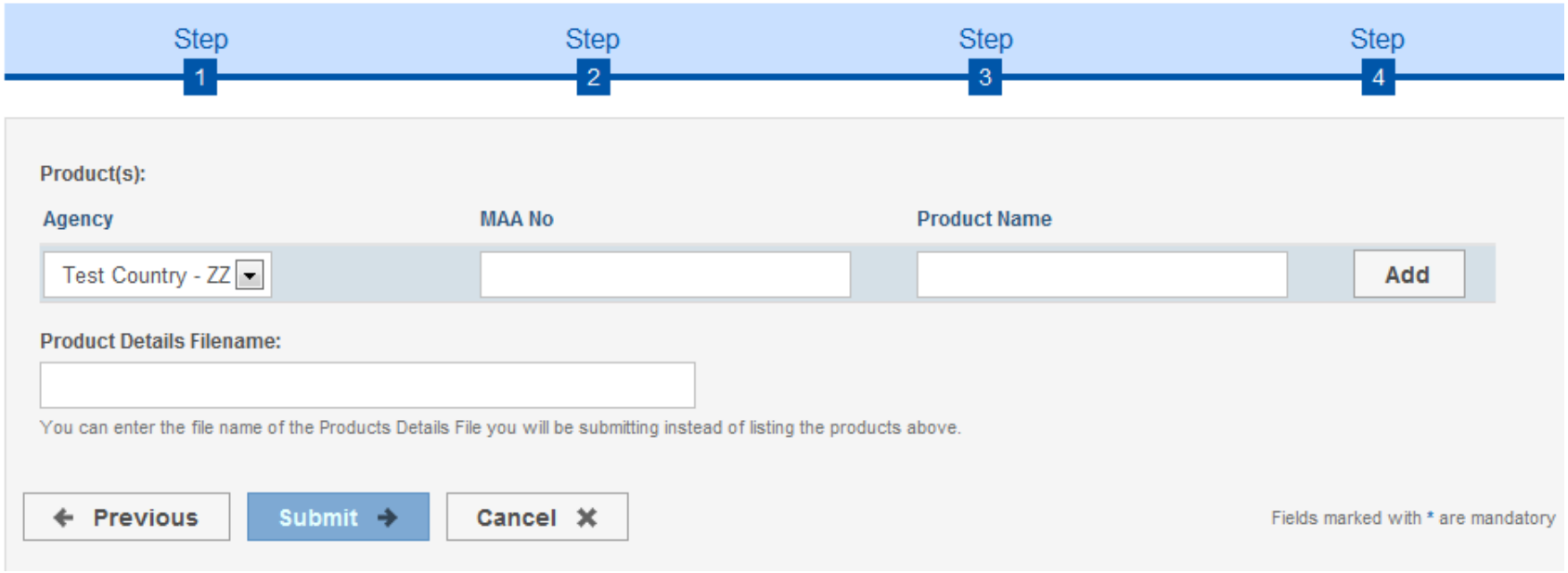
Create a Delivery File



HMA Heads of Medicines Agencies

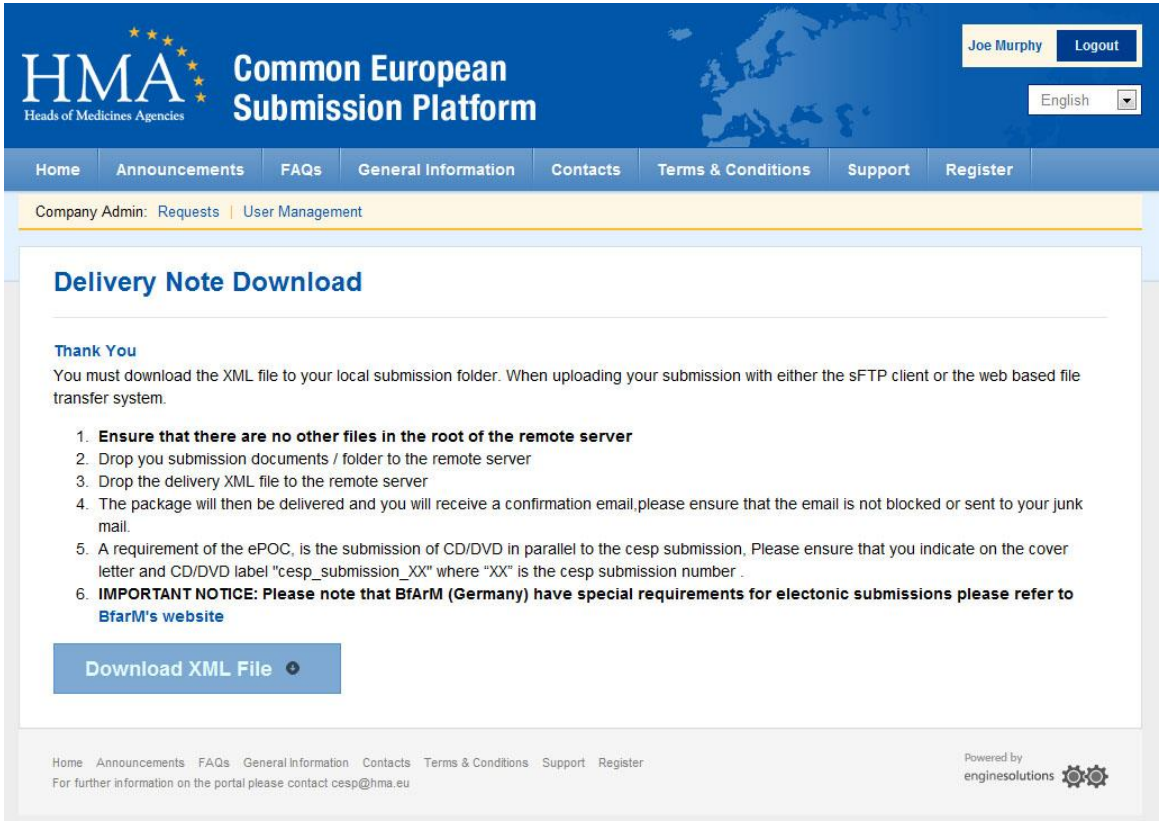
Common European Submission Platform

Create a Delivery File



Create a Delivery File

- 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



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

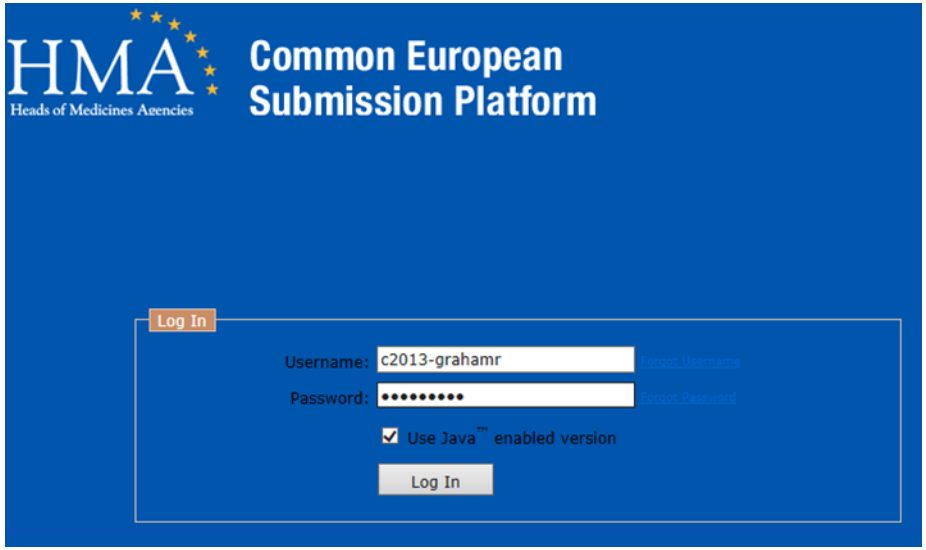
- Do not
  - Do Not Reuse your delivery file
  - Do Not Rename your delivery file
  - Do Not Place more than one delivery file with the same submission (one submission - one delivery file).
  - Do Not Delete your submission until you have received all email acknowledgements for that submission.

Web based File Transfer

HMA Heads of Medicines Agencies Common European Submission Platform

Web Based Transfer

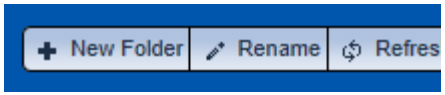
- Open the website: https://cesp.hma.eu/EFTClient/Account/Login.htm
- Enter in username and password
- Tick ‘Use Java enabled version’



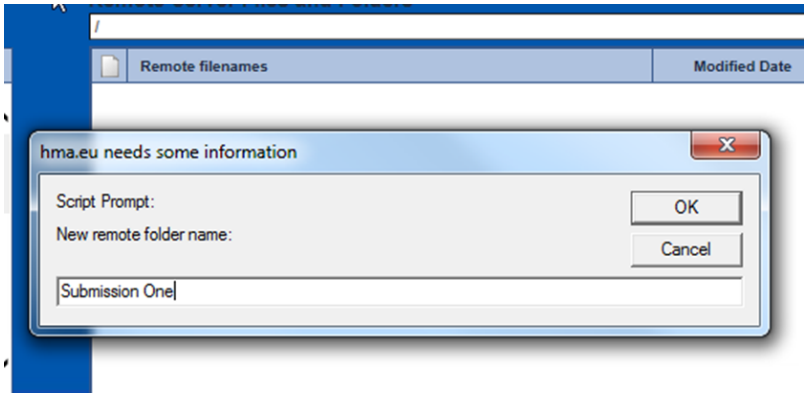
Web Based Transfer

- Click the white area in the section Remote filenames

- Click New Folder

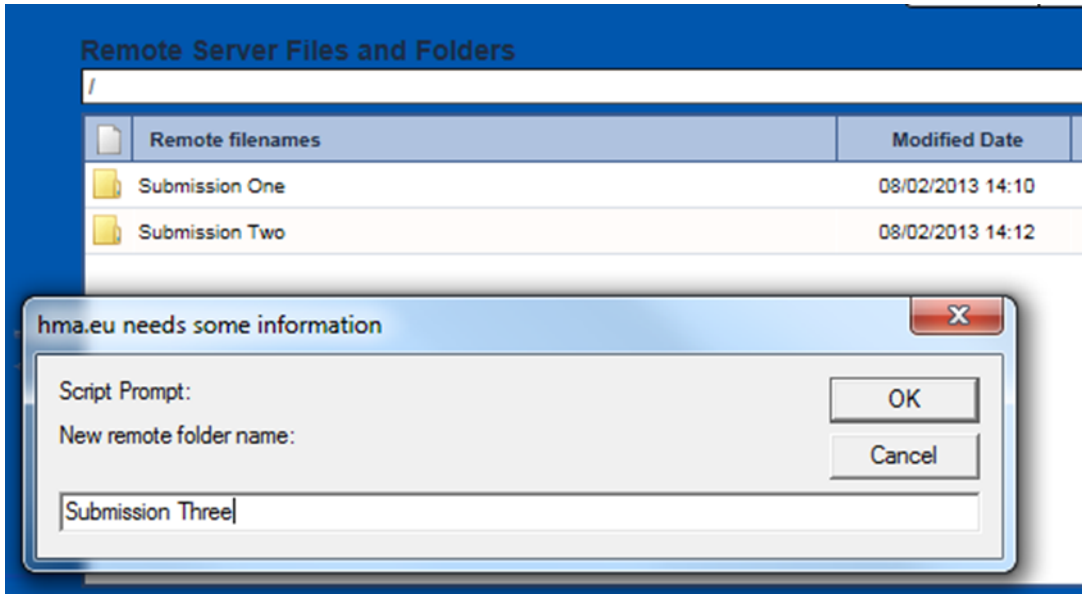


- Enter in name of folder



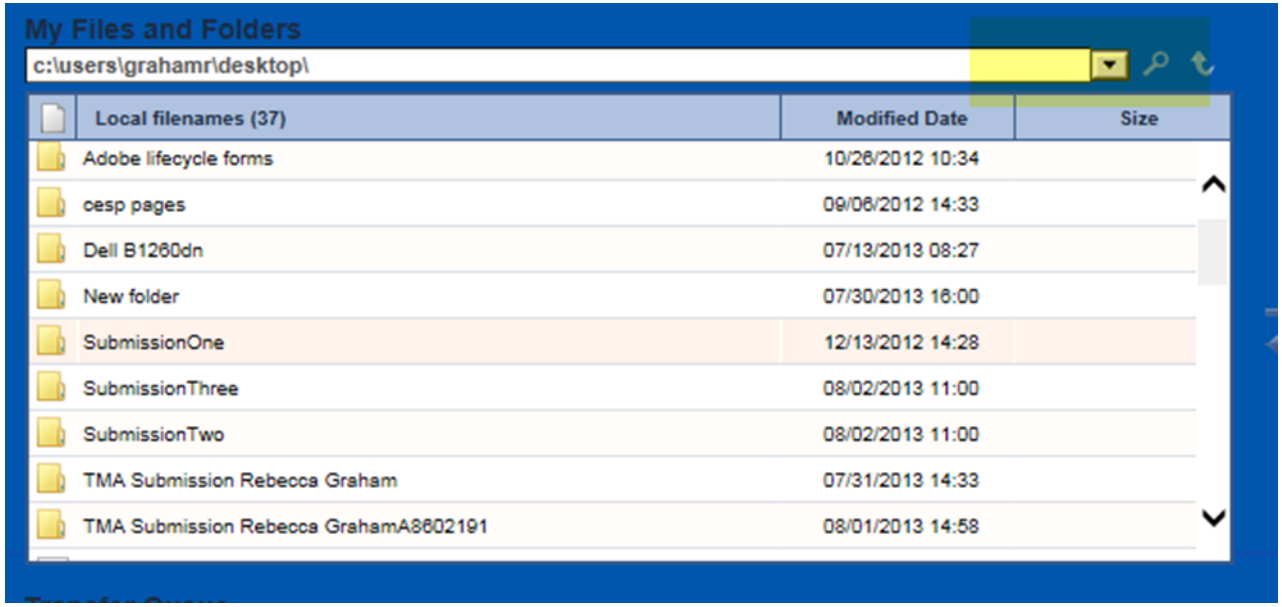
Web Based Transfer

- For each submission you wish to upload repeat the process

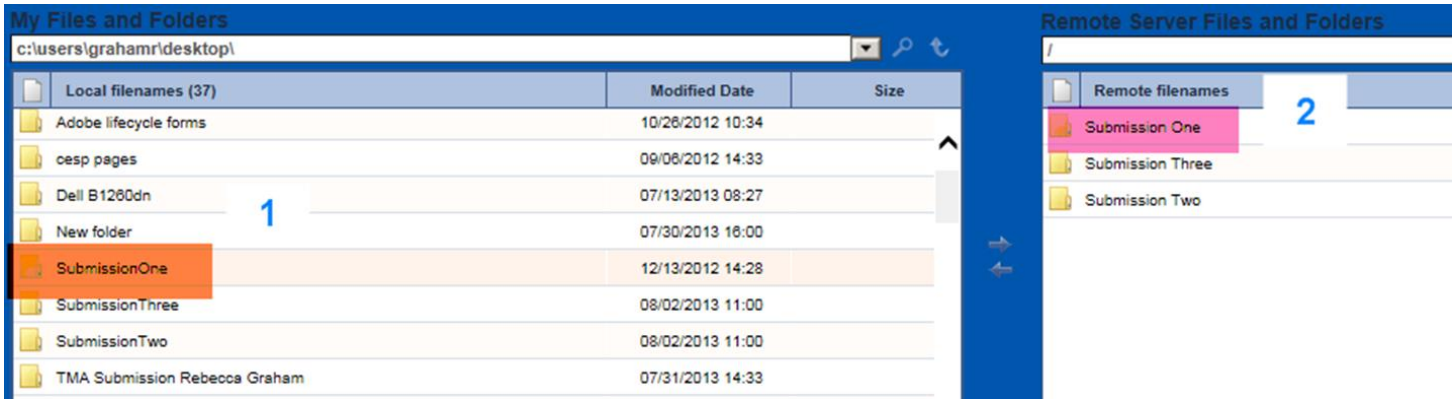


Web Based Transfer

- 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

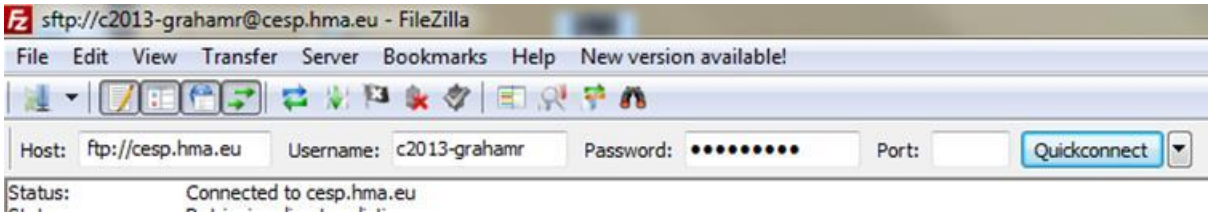


- Drag the Delivery file for submission 1 from My files and folders **into** Submission 1 folder on the Remote Server and folders
- Repeat the process for each submission
- **NOTE IF USING THIS METHOD EACH SUBMISSION SHOULD BE IN ITS OWN FOLDER WITH THE DELIVERY FILE FOR THAT SUBMISSION, UPLOAD THE SUBMISSION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

Sample sFTP Client File Transfer

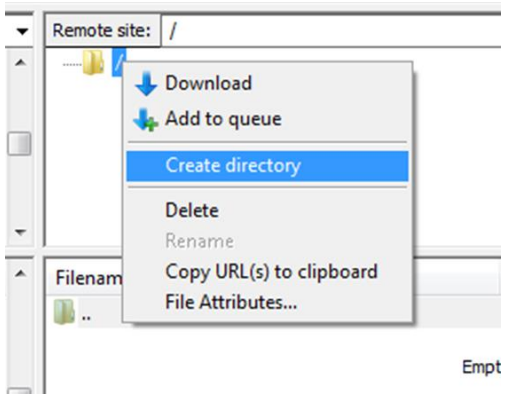
sFTP Based Transfer

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



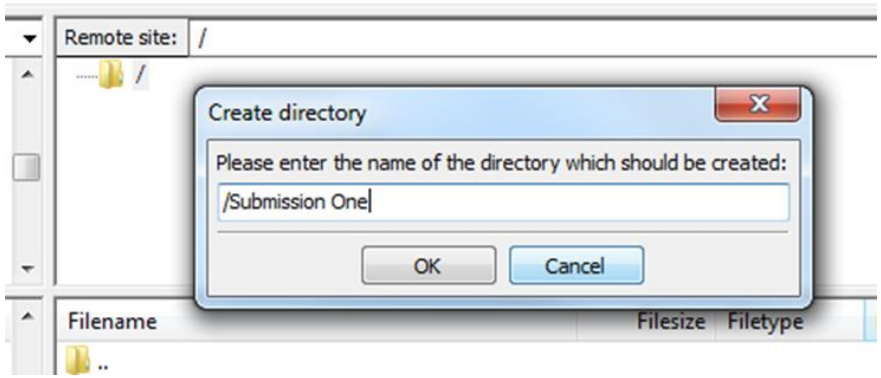
sFTP Based Transfer

- Click the white area in the section Remote site



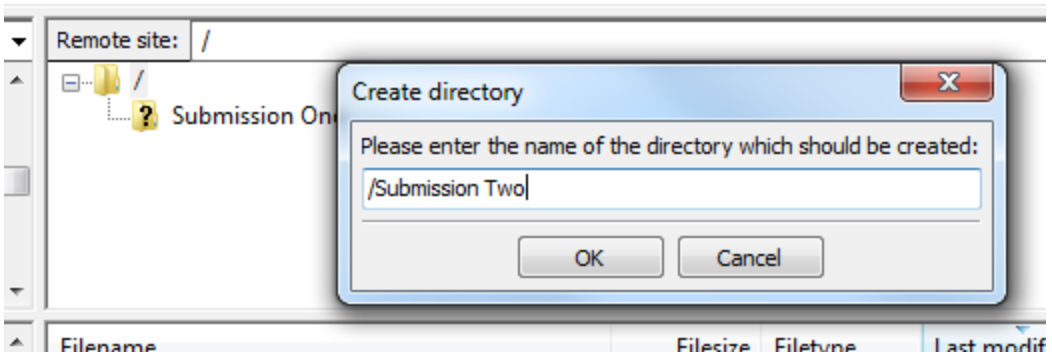
- Right mouse key an select Create Directory

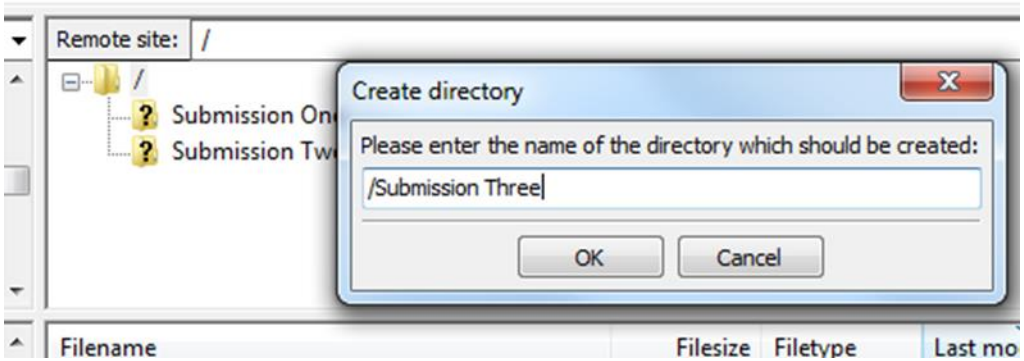
- Enter a folder name e.g. “submission one”



sFTP Based Transfer

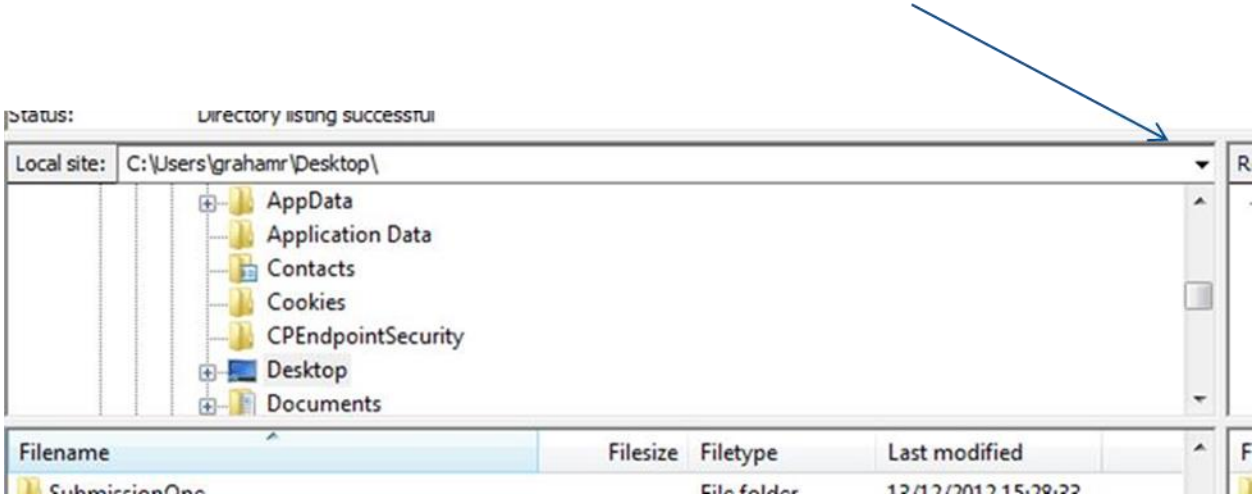
- For each submission you wish to upload repeat the process





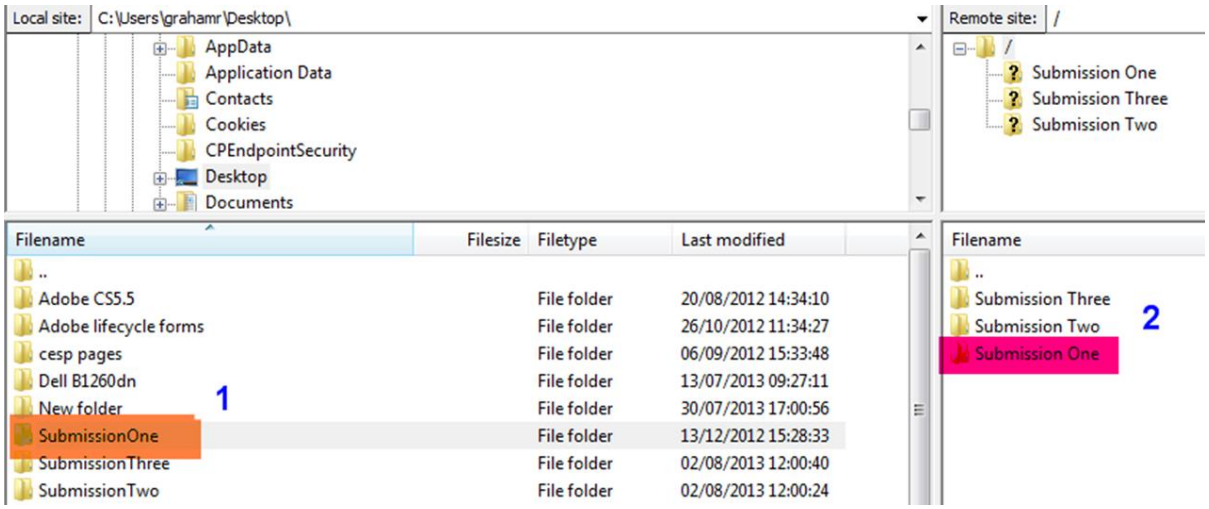
sFTP Based Transfer

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



sFTP Based Transfer

- 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.

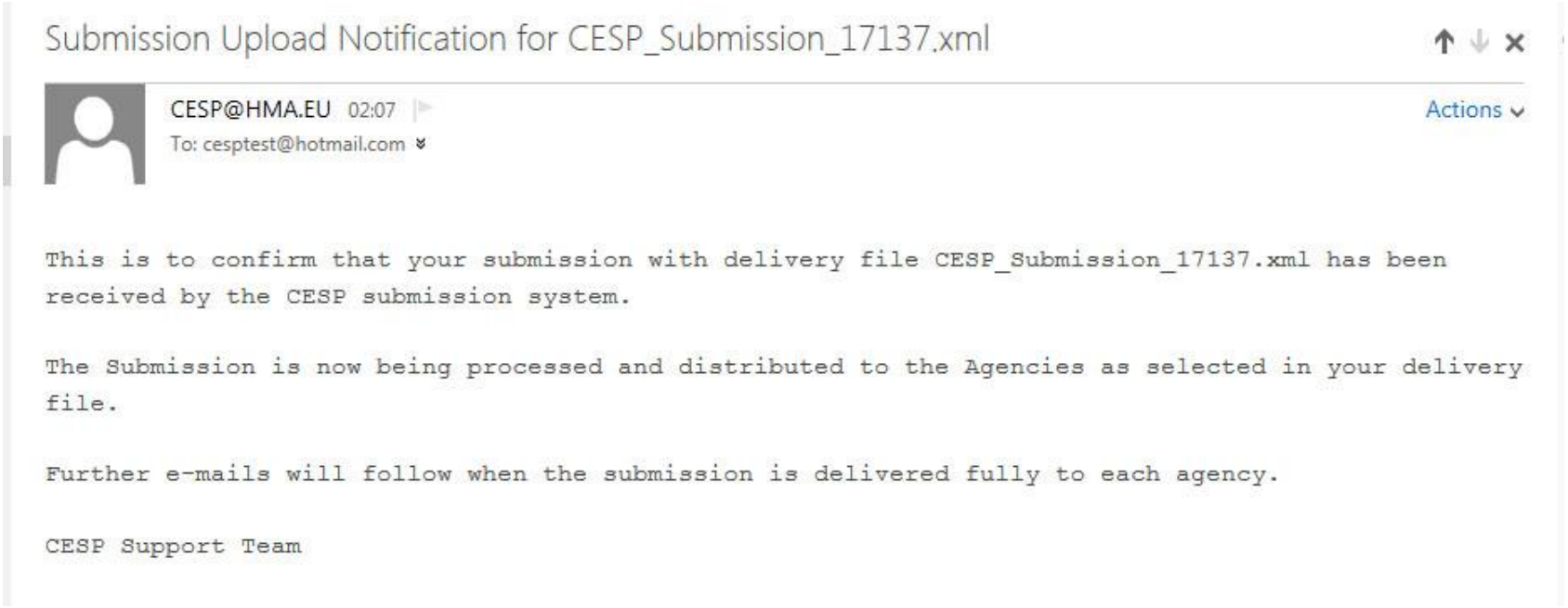
Email Notifications

Email Notifications

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

Email Notifications

- 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.

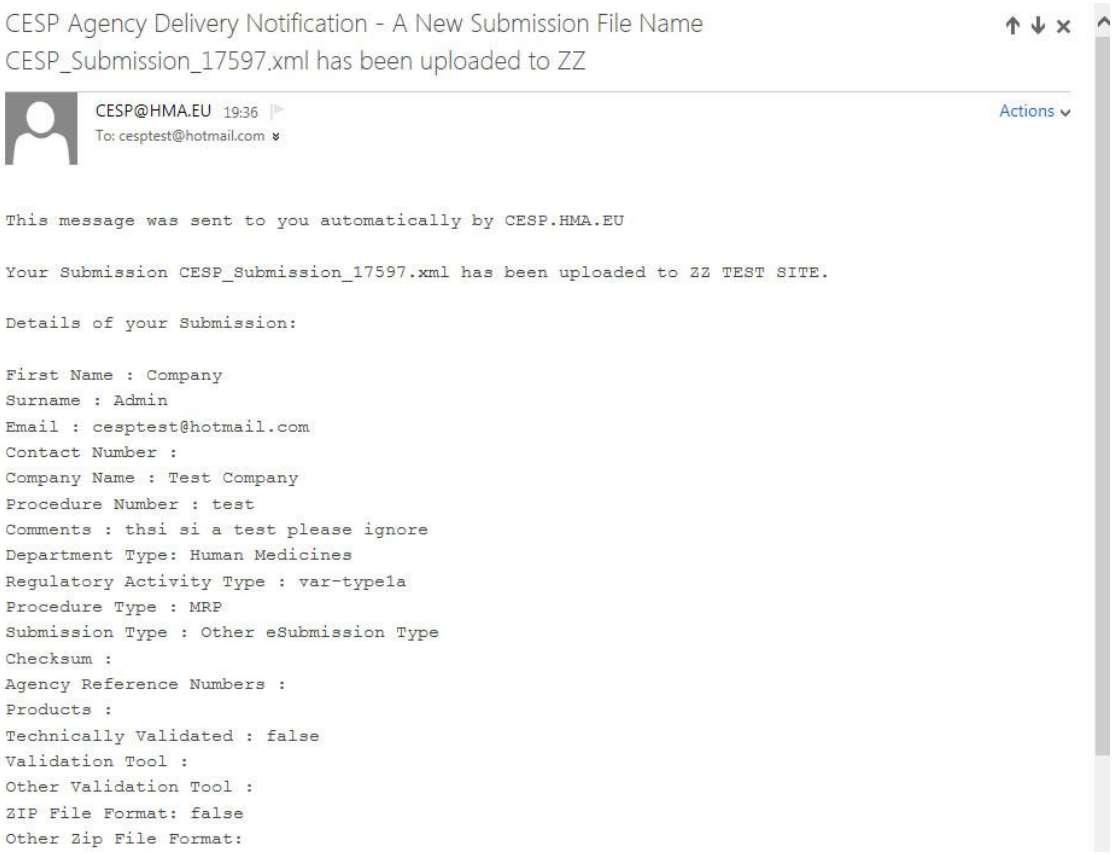
CESP Support Team

HMA Heads of Medicines Agencies

Common European Submission Platform

Email Notifications

- 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

HMA Heads of Medicines Agencies Common European Submission Platform

Uploading Submissions

- 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.

HMA Heads of Medicines Agencies

Common European Submission Platform

Company Administrators & User Management

HMA Heads of Medicines Agencies Common European Submission Platform

Registration process

- 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.

Company administrator (CA) role

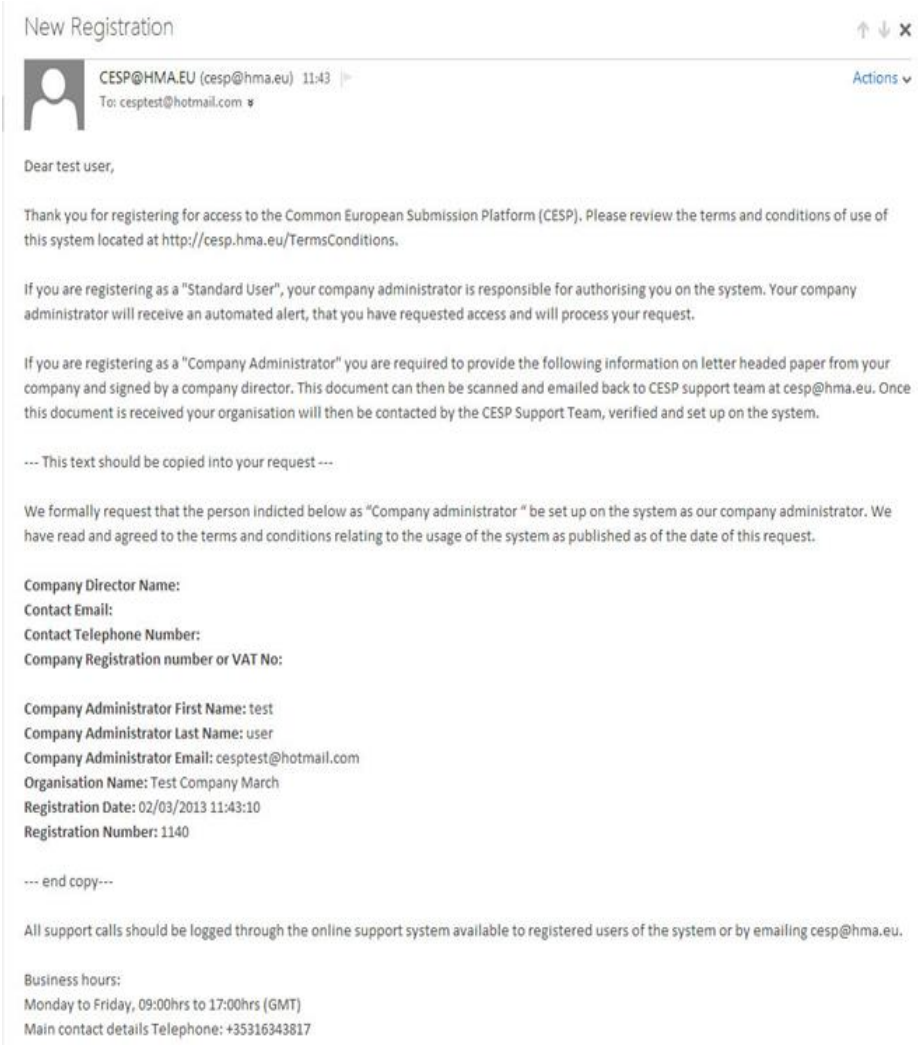
- Companies can have more than one CA per company.
- CA's once confirmed can manage users and companies and are responsible for:
  - New user setup
  - Locking, unlocking users
  - Resetting user passwords
  - Requesting new companies
  - Granting access to users to companies

HMA Heads of Medicines Agencies

Common European Submission Platform

Email registration notification

- 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

CESP@HMA.EU (cesp@hma.eu) 11:43

To: cesptest@hotmail.com

Actions

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---

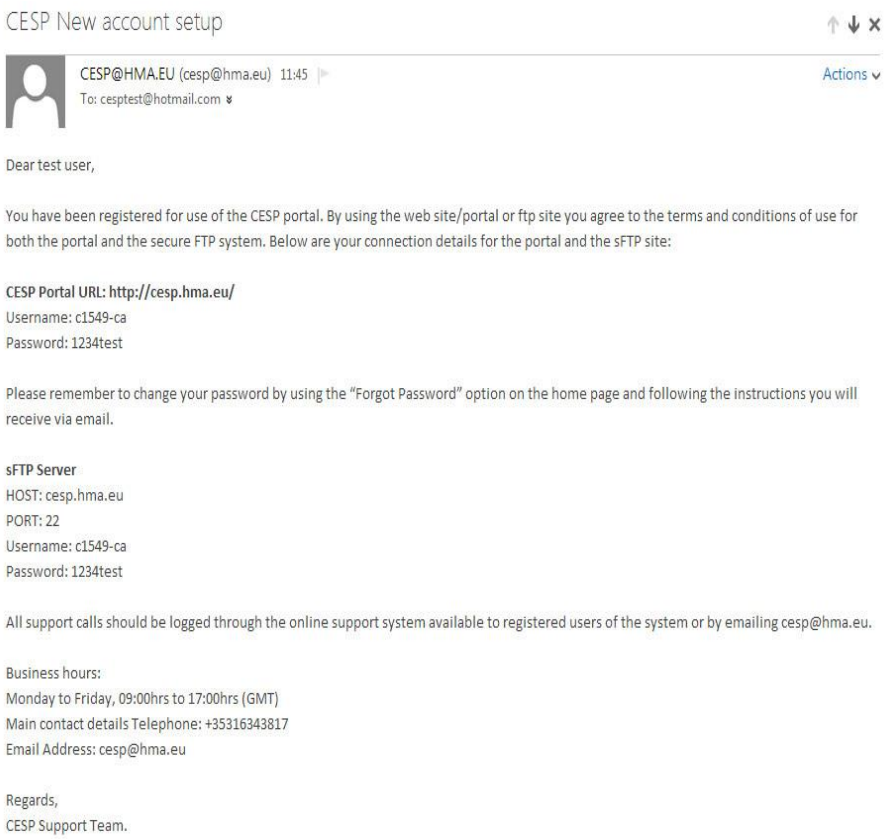
All support calls should be logged through the online support system available to registered users of the system or by emailing cesp@hma.eu.

Business hours:
Monday to Friday, 09:00hrs to 17:00hrs (GMT)
Main contact details Telephone: +35316343817

HMA Heads of Medicines Agencies
Common European Submission Platform

Email confirmation

- 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: cesptest@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

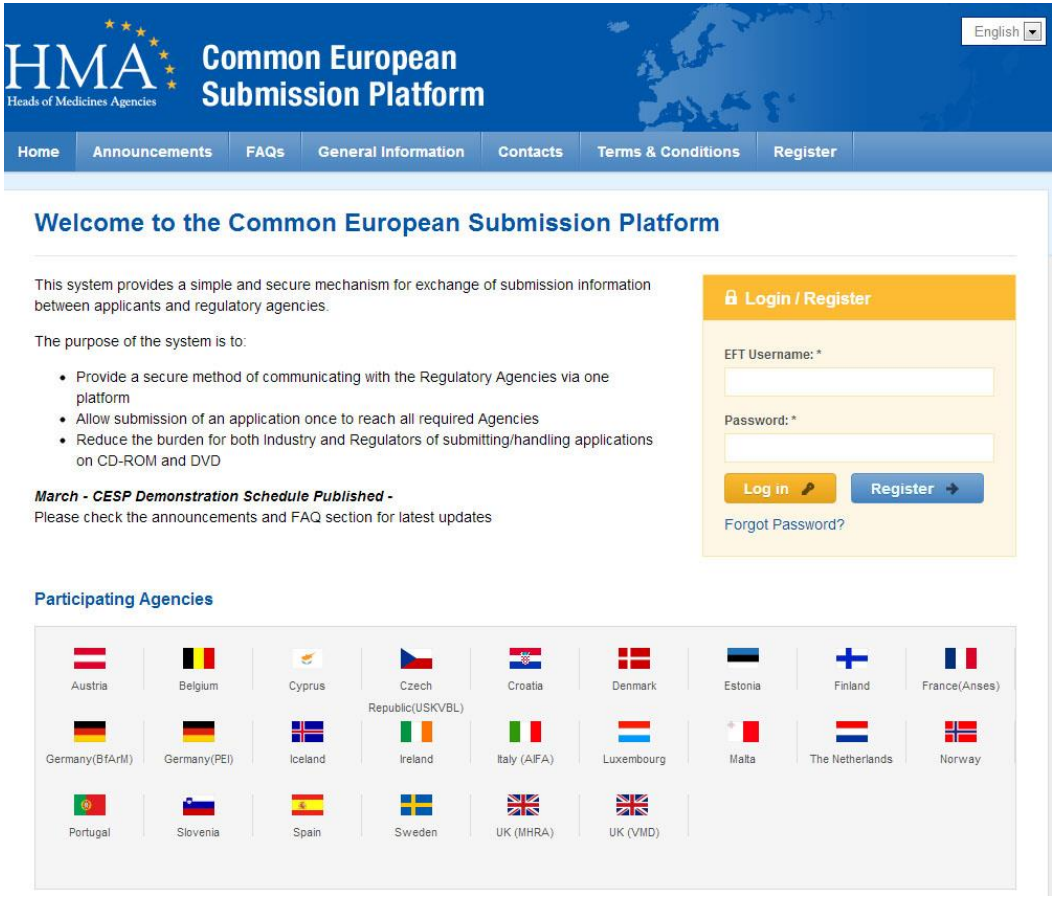
All support calls should be logged through the online support system available to registered users of the system or by emailing cesp@hma.eu.

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.

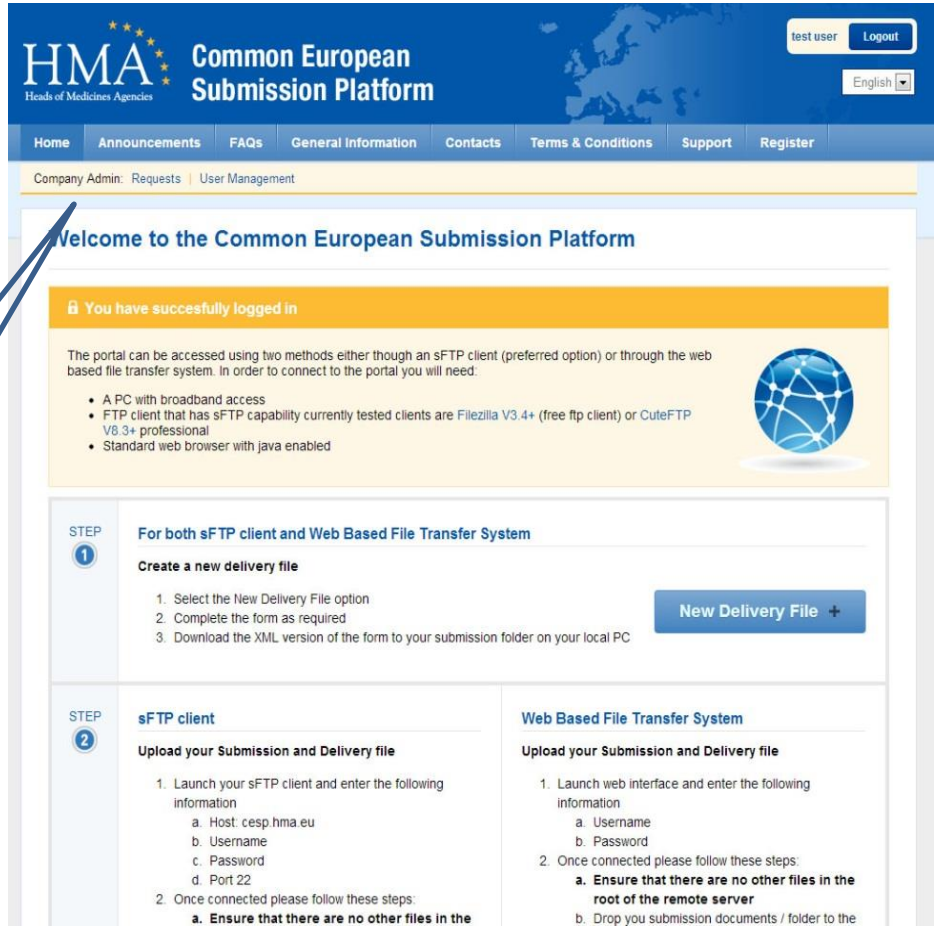
Login in to the Website

- 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.



Company Administrator

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



Requests and user management

User Management

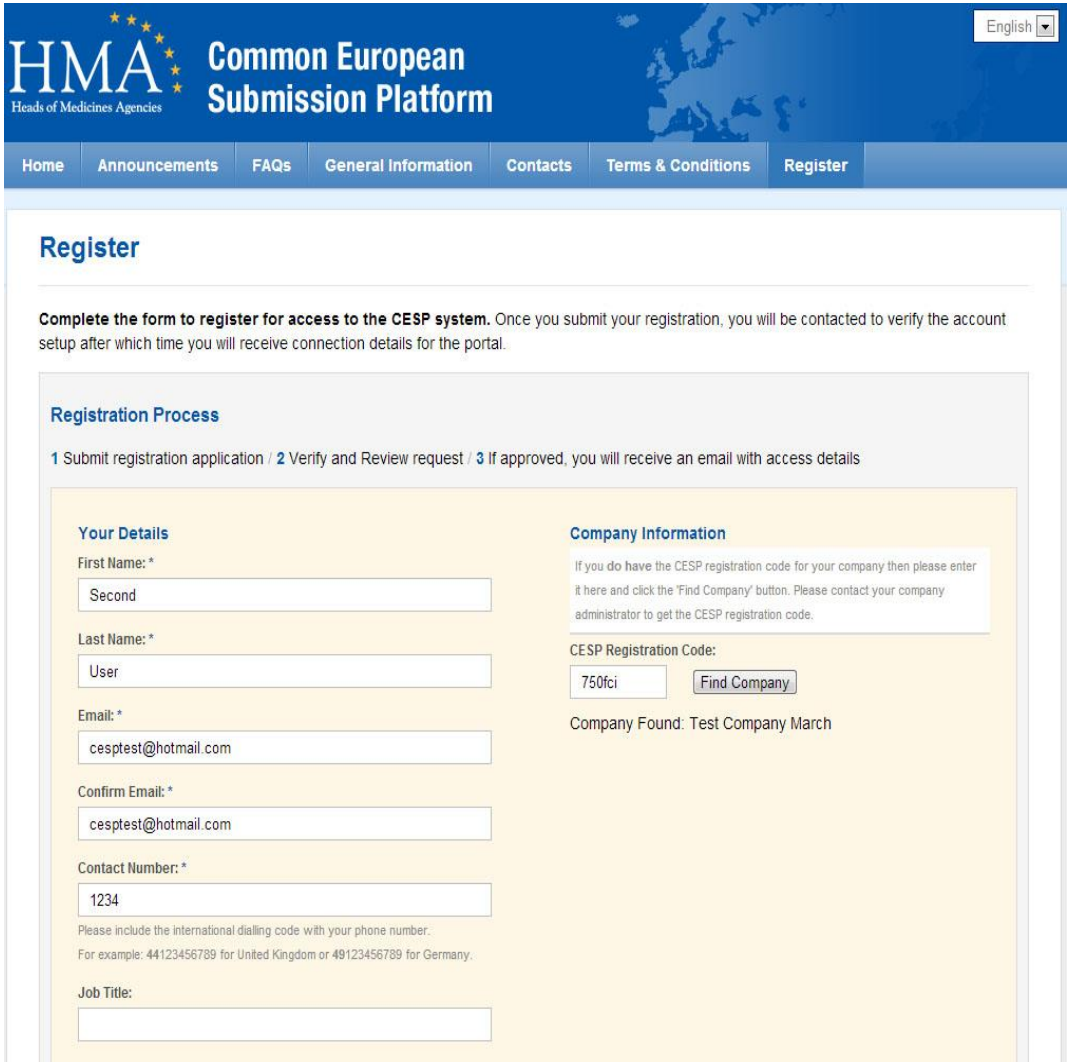
1. You can manage each user in the system by selecting the ‘edit’ beside there name.
2. You can manually add a new user by selecting the ‘Create New User’ button

   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.

Registering a New User step

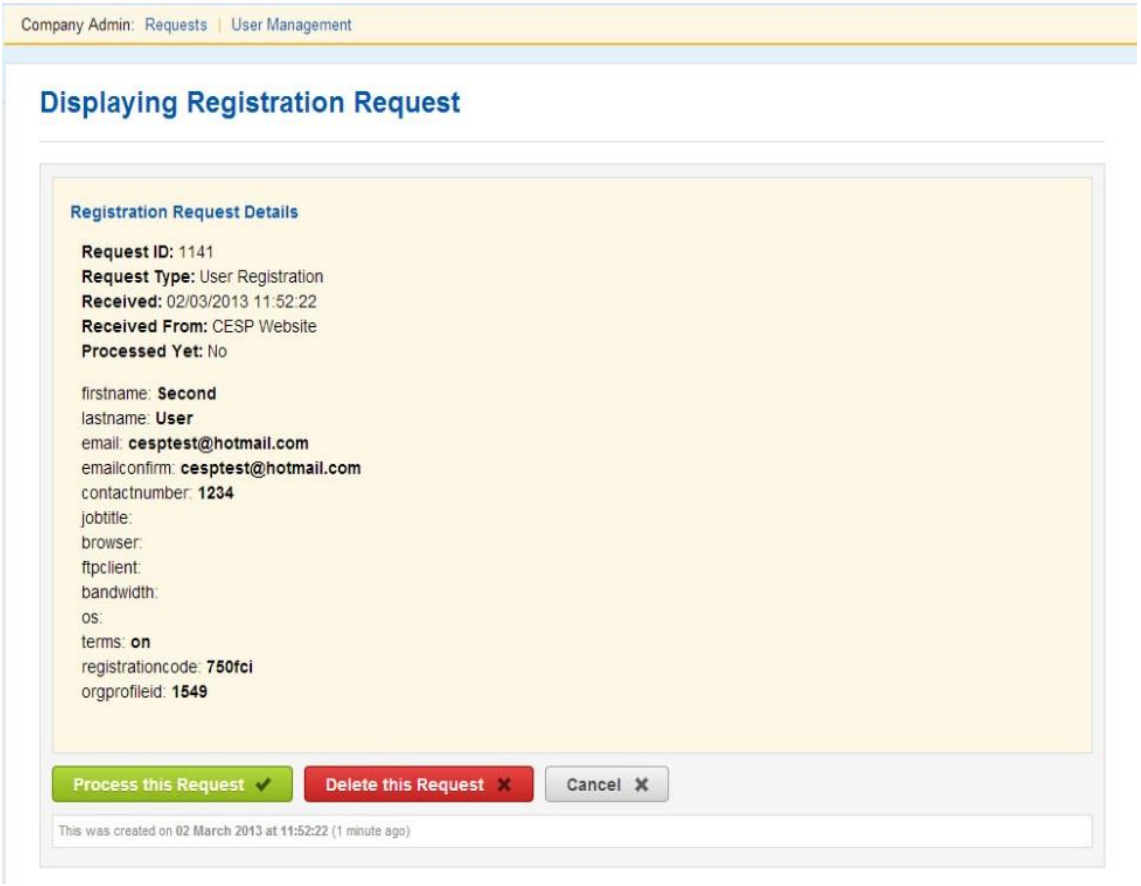
- User completes the registration available on the website
- Enter your CESP registration code provided by your company administrator .
- Select ‘Find Company’.
- You will be displayed the company name associated with the code.
- Complete the form as required and select submit.
- Your request will be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



HMA Heads of Medicines Agencies Common European Submission Platform

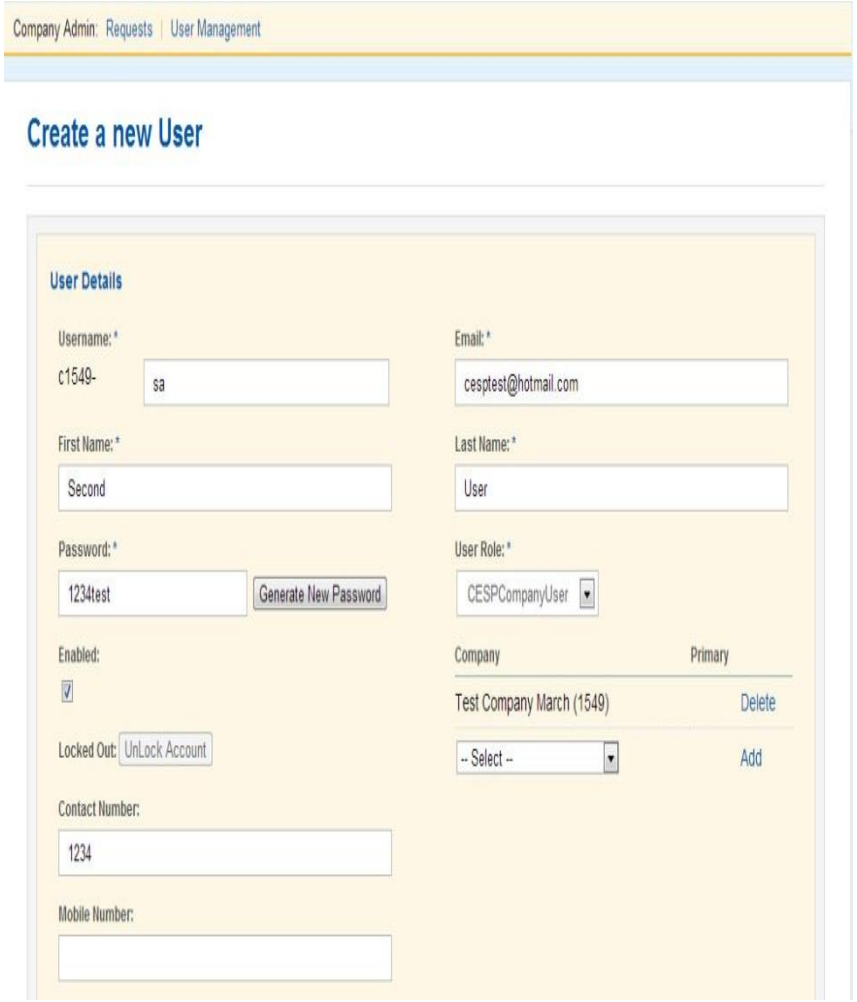
Processing a New User Request step 1

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

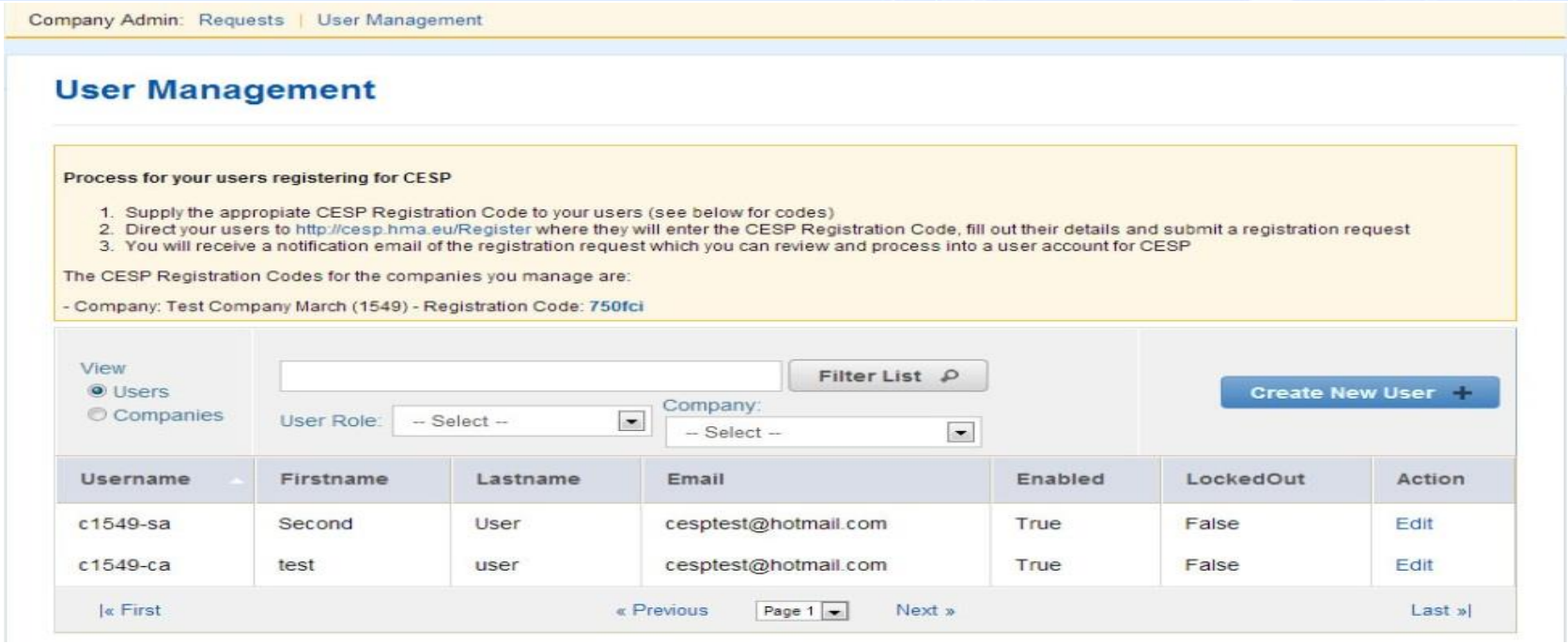


Processing a New User Request step 2

- 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.

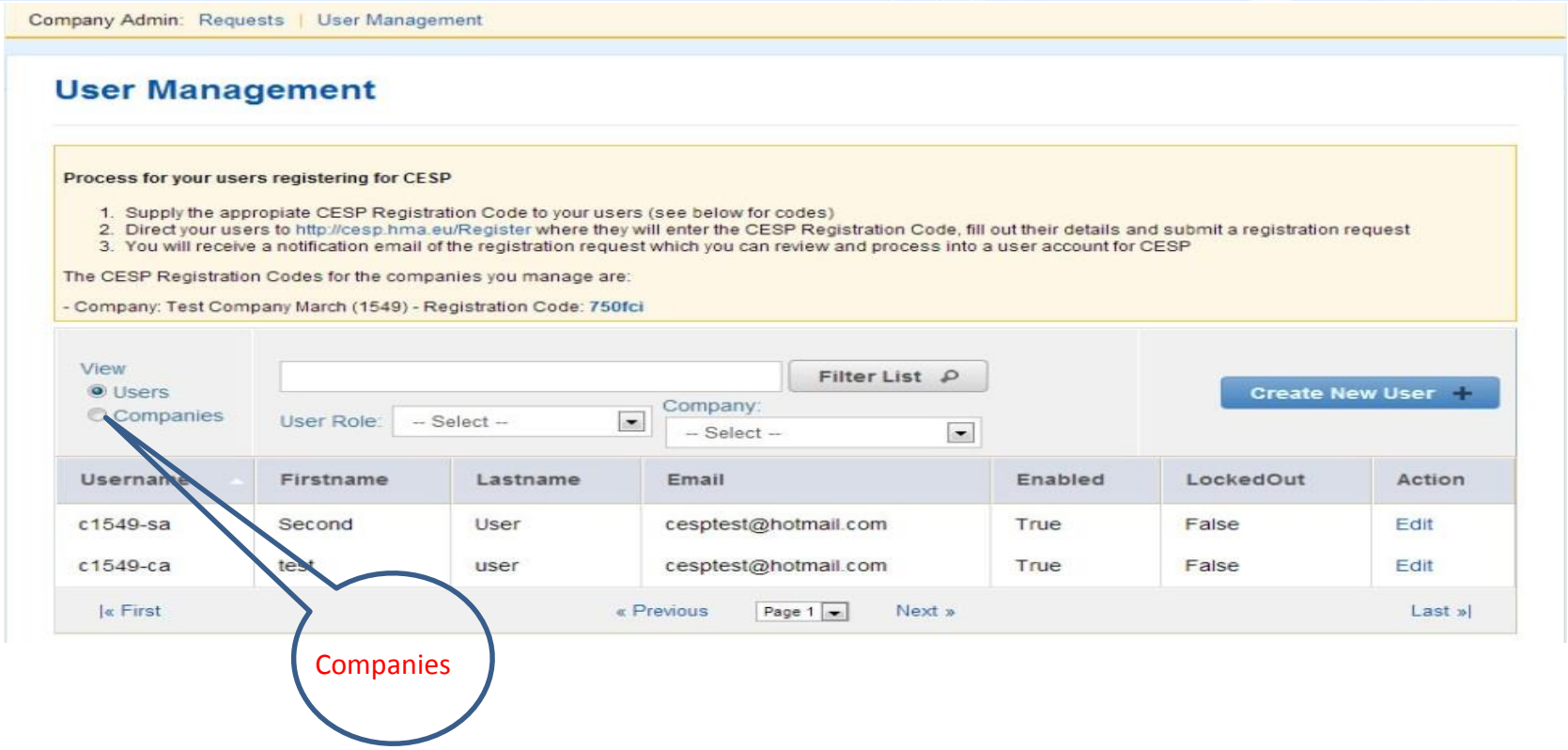


Processing a New User Request step 3



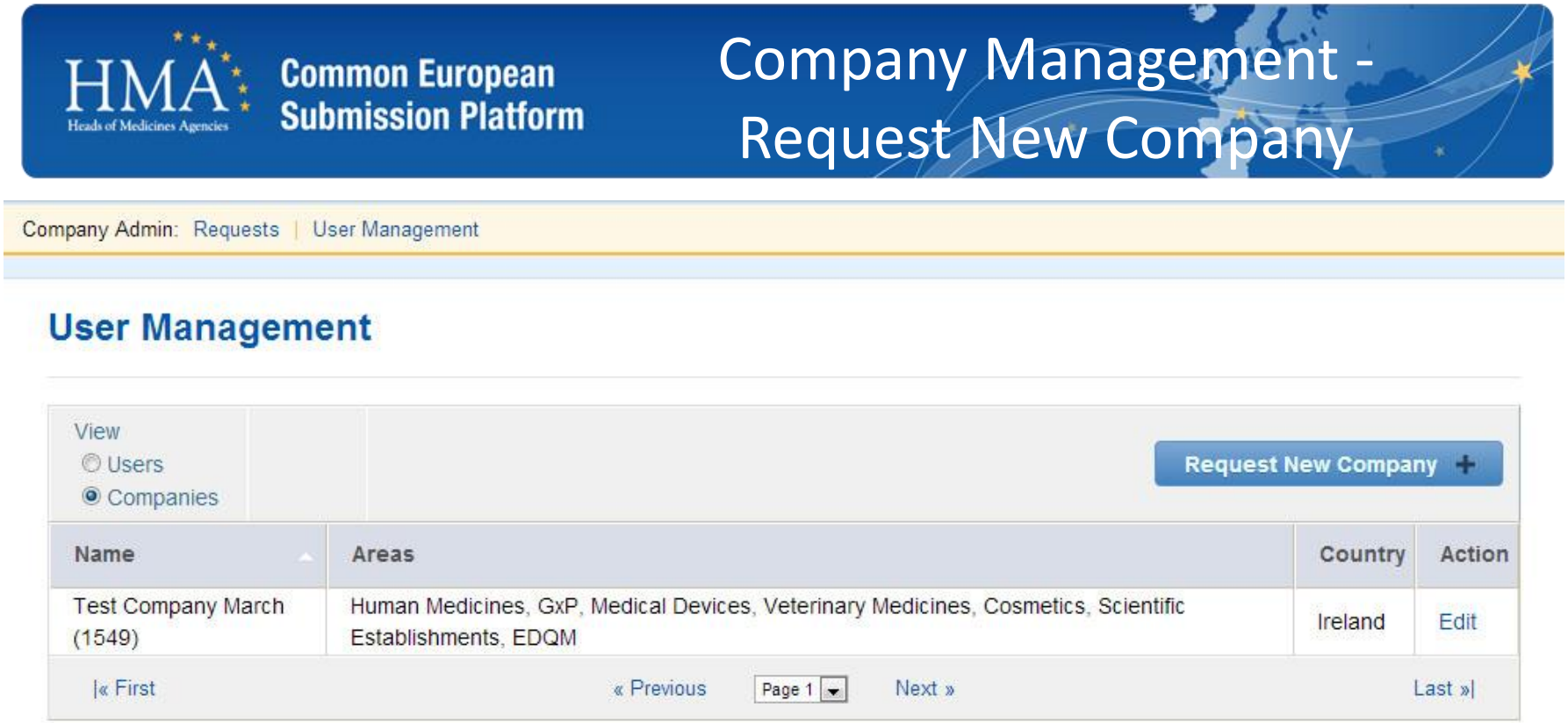
- User is displayed for that company

Company management



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

Company Management - Request New Company



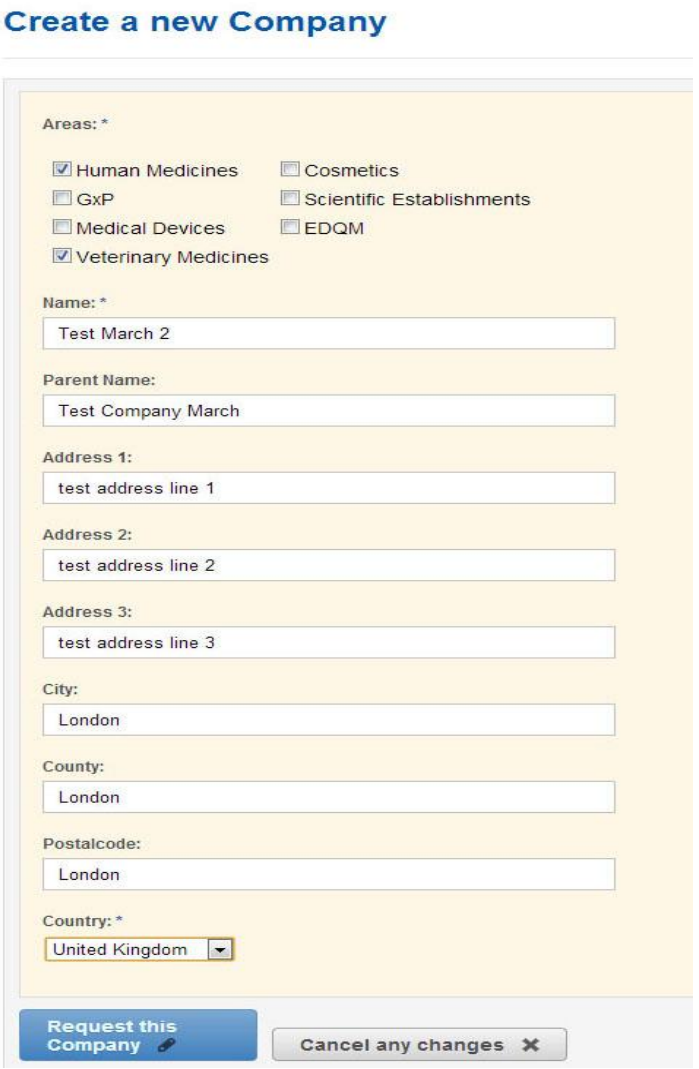
- Current listing of companies is displayed
- Select the “Request New Company” Button

HMA Heads of Medicines Agencies — Common European Submission Platform

Company management

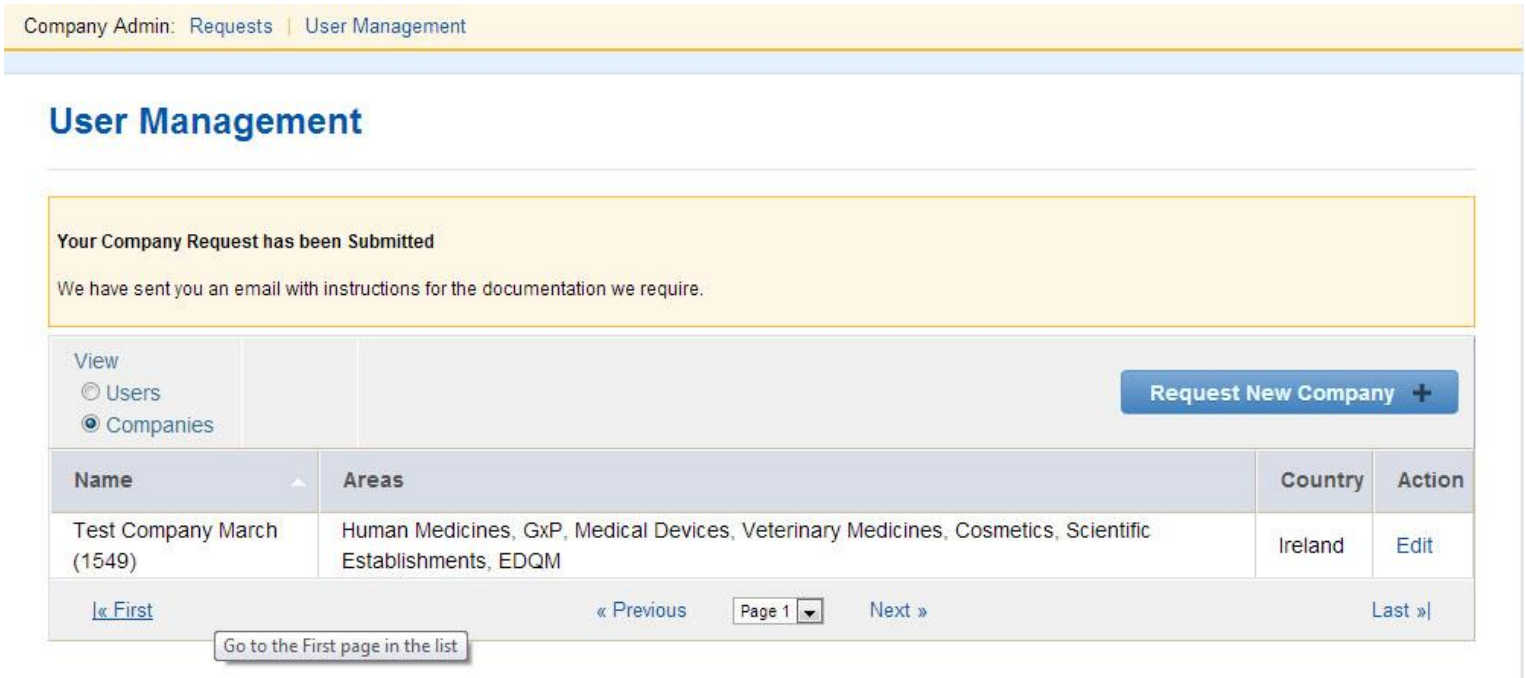
Request New Company – slide 2

- 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



HMA Heads of Medicines Agencies **Common European Submission Platform**

Company management

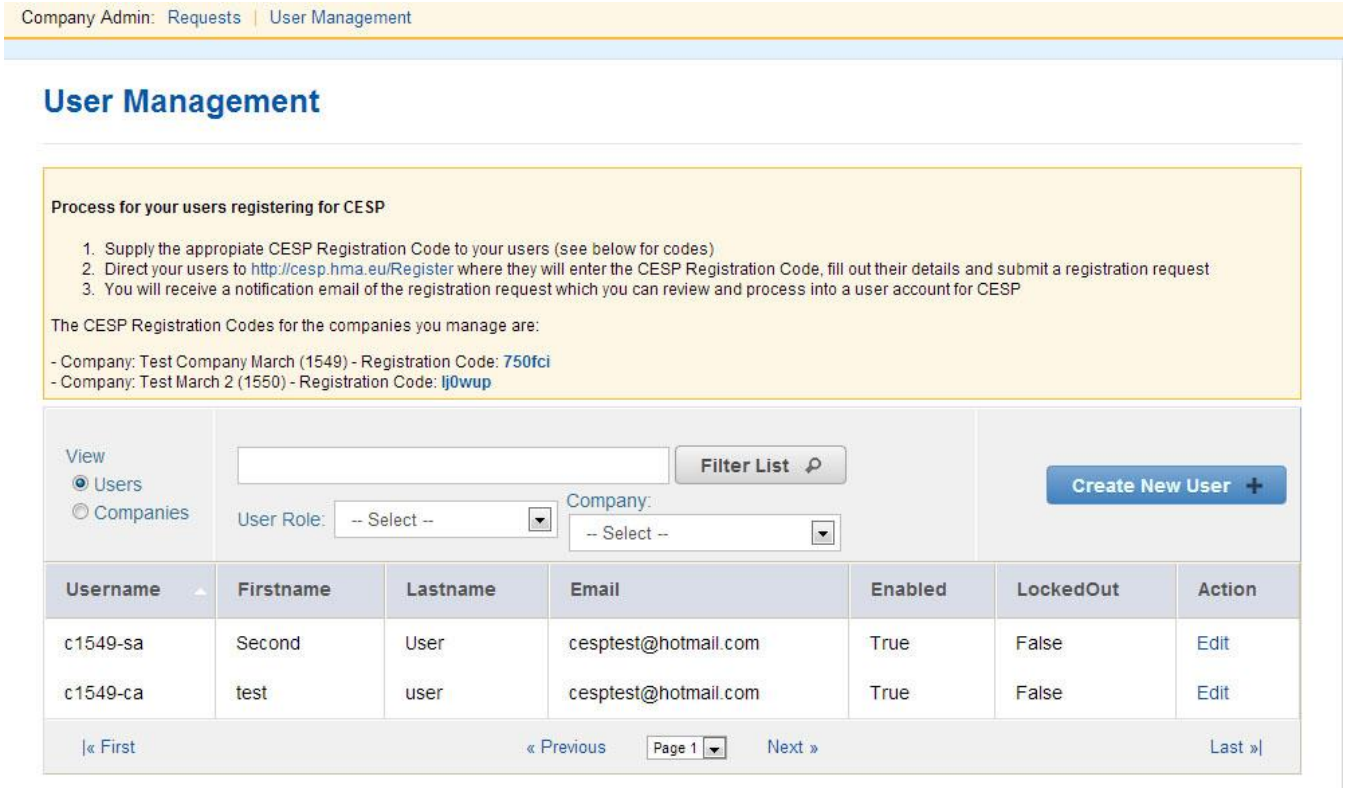


- Email will be sent to the CA requesting confirmation of company details
- Complete the information in the email and return to system administrator

HMA Heads of Medicines Agencies

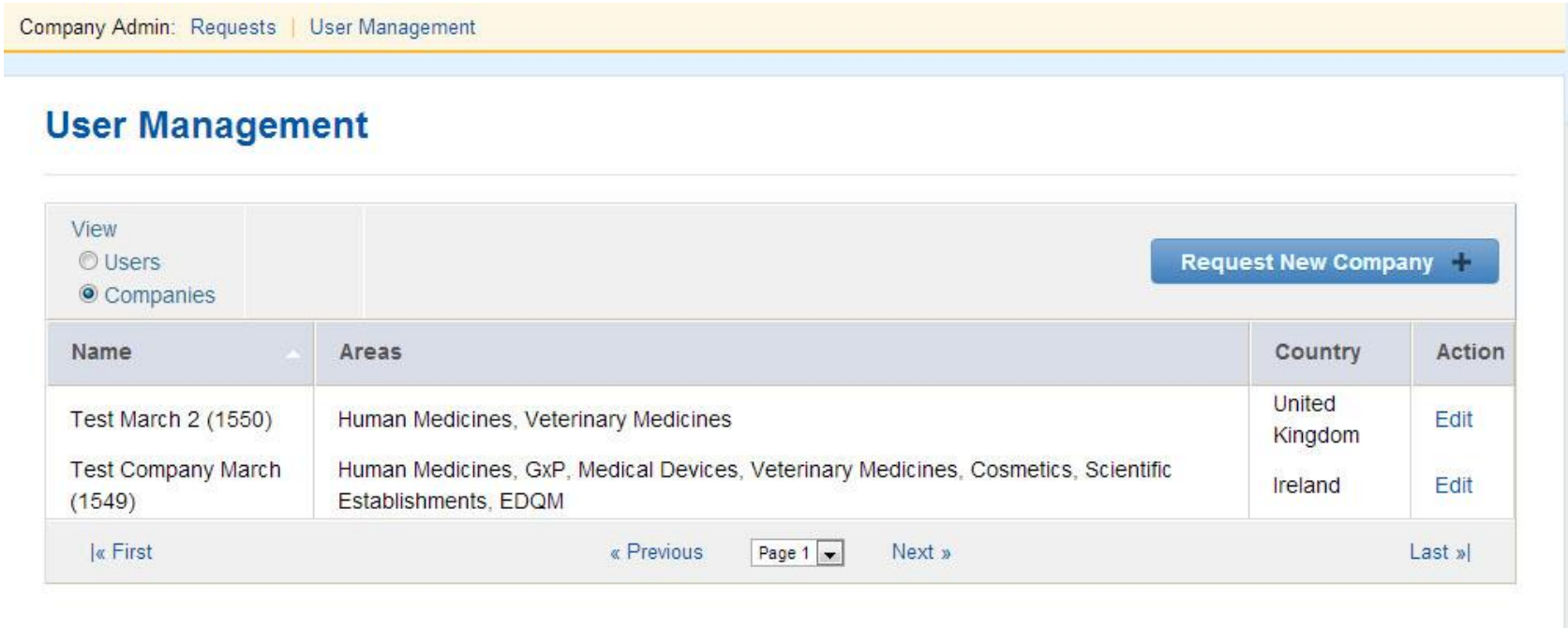
Common European Submission Platform

Company management



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

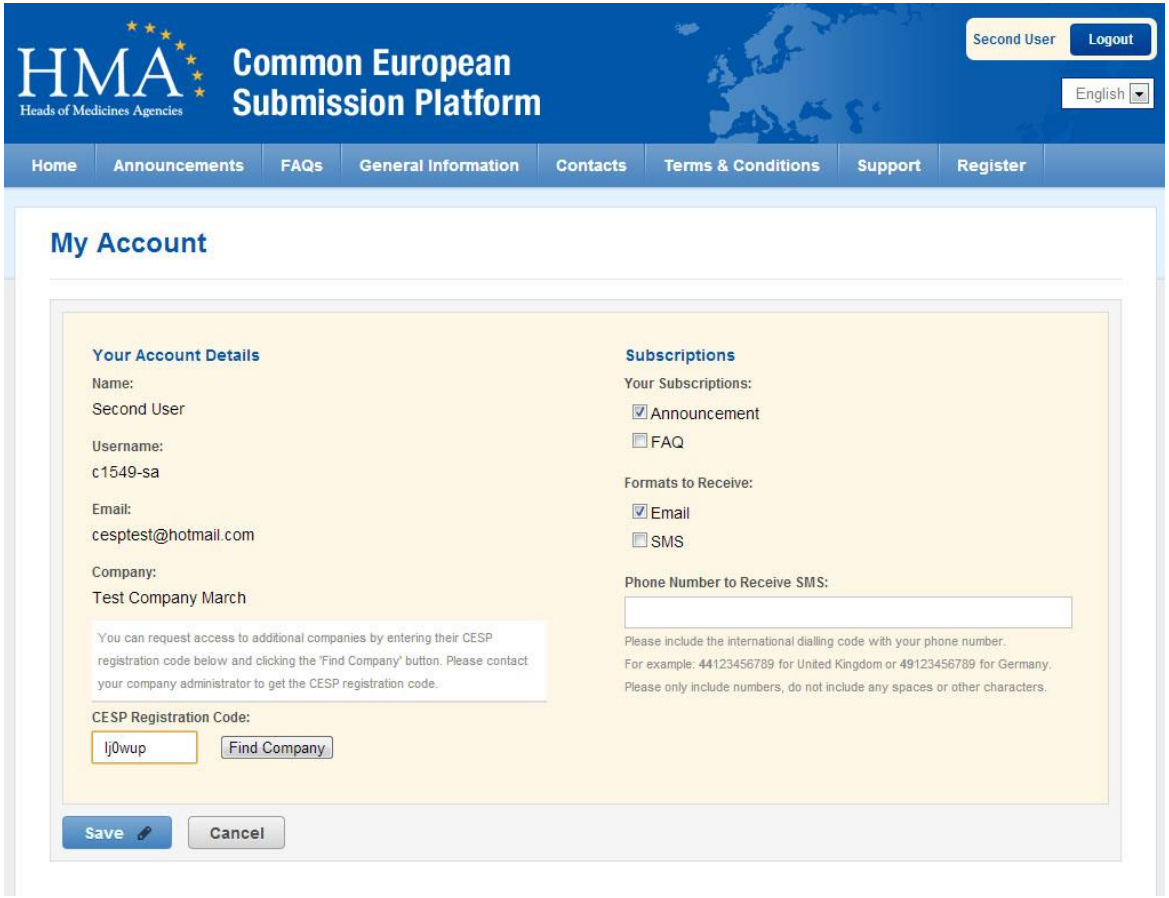
Company management



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

Granting users access to a Company

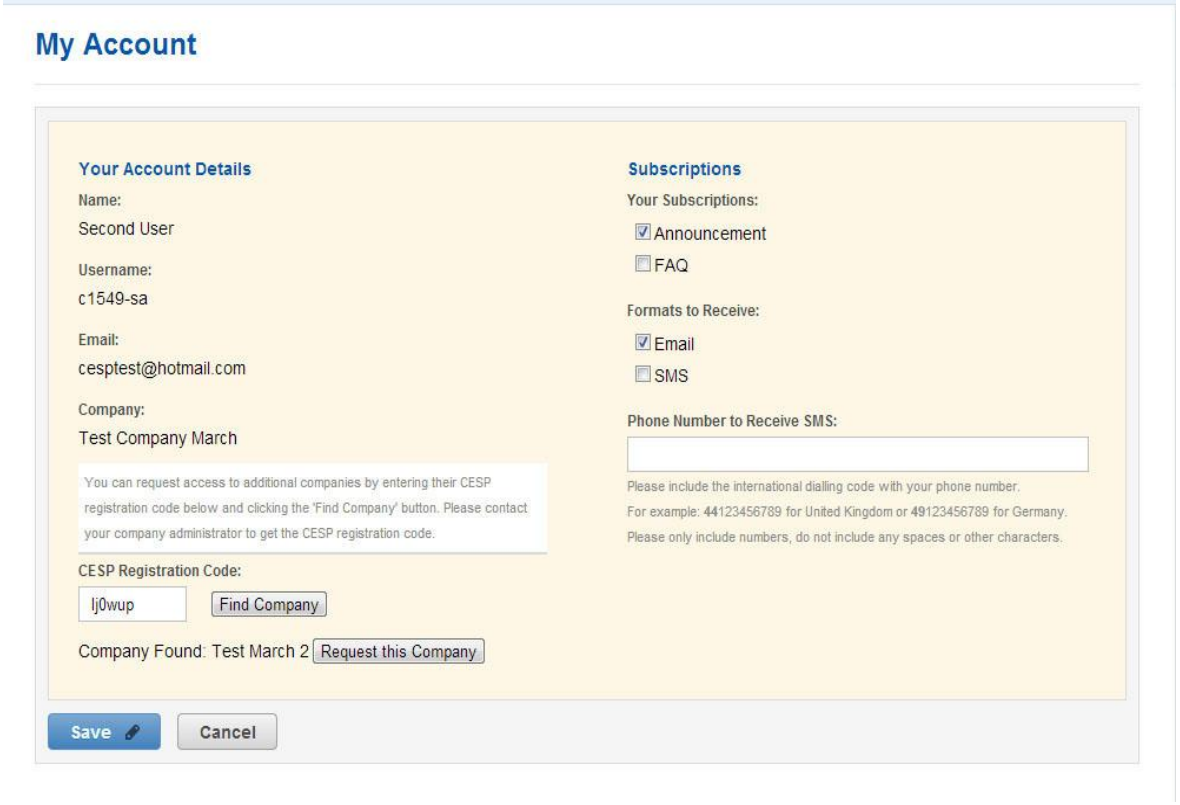
- You can grant existing users access to this company by providing them with the registration code.
- Each user can then enter this registration code in the cesp registration code section of the “My Account” screen and press find company



HMA Heads of Medicines Agencies Common European Submission Platform

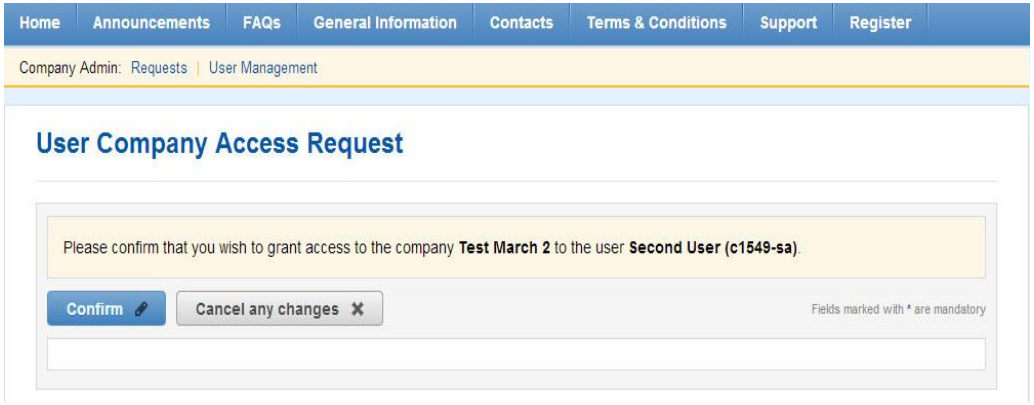
Granting users access to a Company

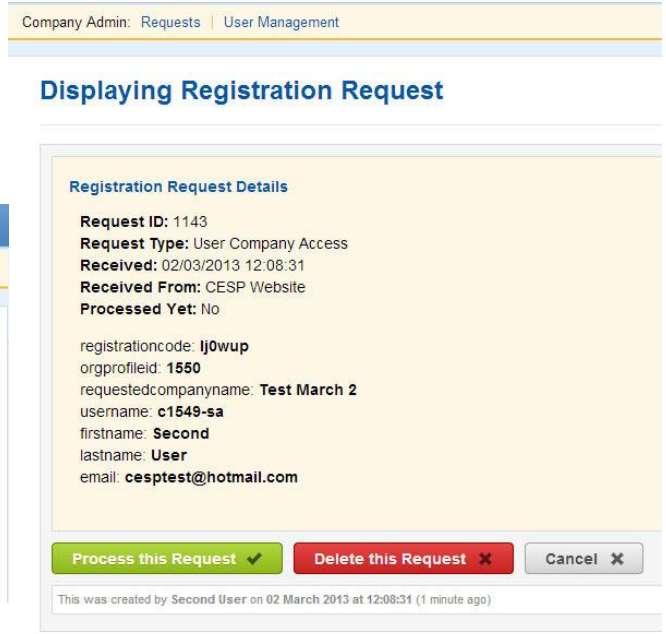
- When a valid company is found the user can select the “request this company” button
- This sends the request to the company administrator



Granting users access to a Company

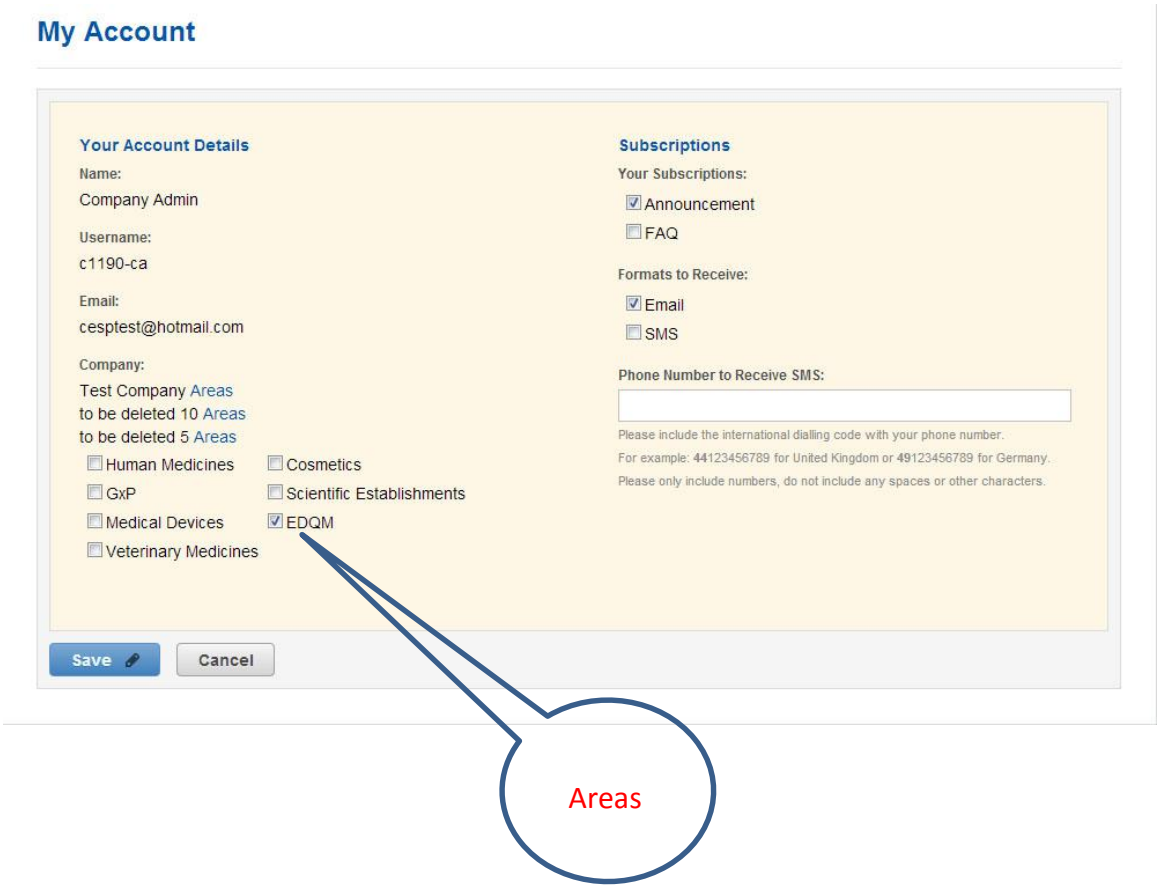
- CA can view and process the request





Adding a New Area to your Profile

- 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.



HMA Heads of Medicines Agencies Common European Submission Platform

Setting up affiliates

- 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.

HMA Heads of Medicines Agencies Common European Submission Platform

Setting up consultancies

- 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.

HMA Heads of Medicines Agencies Common European Submission Platform

Support Desk Information

- 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