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How to register for the Web Client

Guidance for applicants



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The various steps that need to be completed in the registration process are outlined below. Please note that you will only be able to access the Web Client if you have successfully registered and received email confirmation that registration has been completed.

1. Accessing the online registration form

a) Please access the registration form via

https://esubregistration.ema.europa.eu/registration

This link will enable you to register for both the External Compliance Testing and production environments. During UAT you will submit files to the External Compliance Testing environment.

2. Completing the online registration form

- a) Please follow the on screen instructions displayed in "9" and complete the registration form.
- **b)** The first page of the completed form will look like the example below:

bmission Regist	tration - Step 1					
e provide the follow	ving information:					
Organisation Name		Organisation	Organisation Address:			
XYZ Pharma		Street:	Pharma Straat			
Product (inver	ited) name(s):	City:	Amsterda	m		
Please provide at le	ast one.	Postal Code:	1083			
Wonderpill		Country:	Netherlands			
Person Author on behalf of th	ised For Communication	9				
Person Author on behalf of th Title:	ised For Communication le Applicant: Mr	9 Contact Poin	t For IT Ma	atters:	(
Person Author on behalf of th Title: Name:	ised For Communication e Applicant: Mr David	Contact Poin Title:	t For IT Ma	atters:	(
Person Author on behalf of th Title: Name: Family Name:	ised For Communication e Applicant: Mr David Morgan	Contact Poin Title: Name:	t For IT Ma Mrs Rita	atters:		
Person Author on behalf of th Title: Name: Family Name: Department:	ised For Communication le Applicant: Mr David Morgan Marketing Authorisation	Contact Poin Title: Name: Family Name:	It For IT M a Mrs Rita Ronald	atters:	(
Person Author on behalf of th Title: Name: Family Name: Department: Telephone:	ised For Communication Applicant: Mr David Morgan Marketing Authorisation +31 88 781 600	Contact Poin Title: Name: Family Name: Email:	t For IT Ma Mrs Rita Ronald rita.ronald	atters:		
Person Author on behalf of th Title: Name: Family Name: Department: Telephone: Telefax:	ised For Communication the Applicant: Mr David Morgan Marketing Authorisation +31 88 781 600 +31 88 781 601	Contact Poin Title: Name: Family Name: Email:	t For IT Ma Mrs Rita Ronald rita.ronald	atters:		
Person Author on behalf of th Title: Name: Family Name: Department: Telephone: Telefax: Email:	ised For Communication Applicant: Mr David Morgan Marketing Authorisation +31 88 781 600 +31 88 781 601 vid.morgan@xyzpharma.com	Contact Poin Title: Name: Family Name: Email:	t For IT Ma Mrs Rita Ronald rita.ronald	atters:		

c) Once the registration form has been correctly completed, click "Next" to complete the second page as shown below:

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH				
Submission Registration - Step 2				
Organisation Routing Id in Test: ESUBT- 9				
Register to : This value is required.				
Web Client				
Gateway AS/2				
Gateway AS/3				
Please type in the letters displayed above:				
pyright © 2012 European Medicines Agency				

- d) Please enter the "Organisation Routing ID" of your choice for test & production (as per instruction shown in "9"). The routing IDs for test and production must be between 3-10 characters.
- e) Next, select Web Client and enter your proposed password for the test and production environments.

The password must be at least 6 characters with

- At least one upper-case letter and one lower-case letter
- At least one number (0-9)
- **f)** Next, check the information you entered on this screen carefully. Also click the "Back" button to review the information you entered on the first screen.

g) Type in the letters displayed on the image underneath the password and click "Submit".

EUROPEAN MEDICINES AGENCY	
bmission Registration - Step 2	
Organisation Routing Id in Test: Organisation Routing Id in Production:	ESUBT- TEST 9 ESUBP- PROD 9
Register to : Web Cli	ent 💌
Web Client C	onfiguration
TESTING	PRODUCTION
ele;	out
Please type in the le elehout Back	tters displayed above:
right © 2012 European Medicines Agency	

3. Submitting a completed online registration application

a) When "Submit" is clicked, you will receive the message below to confirm that you are sure you want to proceed. If you would like to change any of the details entered click on "Cancel" as once you click "OK" there is no opportunity to go back and amend any of the entered information.

Message from webpage	
Please proceed	d only if you are sure that all input values are correct
	OK Cancel

b) A message will appear confirming that your online registration application has been sent as shown below:



c) You will also receive an auto-generated email from the Agency confirming the receipt of your application and your password (as shown below). The email will be sent to the email address you mentioned in the communication section of your online registration form.

🖂 🛃 ı 😈 🍐 🗇 🗧 European Medicines Agency - Application for registration to eSubmissions. Reference #:245 - Message (HTML)						• **			
File Messa	ge McAfee E-mail Scan								۵ 🕜
ignore X & Junk → Delete	Reply Reply Forward More *	Image: Meeting Invites Image: To Manage Image: Meeting Invites Image: To Manage Image: Team E-mail Image: To Manage Image: Team E-mail	r	Move	Pules ▼ MOneNote Actions ▼	 Mark Unread Categorize ▼ Follow Up ▼ 	Translate	orightary Hand Hand Hand Hand Hand Hand Hand Hand	Zoom
Delete	Respond	Quick Steps	Gi.		Move	Tags 🕞	Ed	liting	Zoom
From: eSubmissionGWFH@ema.europa.eu Sent: Mon 29/10/2012 15:31 To: e Koneri Satish Sent: Mon 29/10/2012 15:31 Cc: Subject: European Medicines Agency - Application for registration to eSubmissions. Reference #:245 Sent: Mon 29/10/2012 15:31 Message EsubmissionApplicationDetails_245.pdf (21 KB) EsubmissionApplicationDetails_245.pdf (21 KB)									
Your application for registration to the eSubmission Gateway has been submitted succesfully. Your reference number is:245. Your application will be processed in the next 20 working days.									

4. Confirmation that registration has been completed

a) When your profile has been enabled you will receive an email confirmation. You may then transfer files via the External Compliance Testing Environment link using the test credentials you supplied in your application initially. These details are also provided in the PDF attachment of the email confirmation you receive.

5. Password Management

a) At the time of registration an email is sent to all applicants containing the password they specified in the online registration form. When you log in to the Web Client you will be able to change your password. This is at the discretion of the user and not a mandatory requirement.

Please note that if you do change your password from within the Web Client, the EMA will not be able to re-issue the password if it is lost or forgotten. In this instance you will need to contact the EMA service desk via the online portal <u>https://servicedesk.ema.europa.eu/</u> for your password to be reset.

We advise that you keep the email containing the PDF attachment in an appropriately secure location for future reference.

If you experience any issues with the online registration please contact: <u>EMA service desk</u>