



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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How to send submissions via the Web Client

Guidance for applicants

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The [eSubmission Gateway Web Client](#) is an electronic submission channel that allows the applicants to submit documents supporting all types of applications to the Agency securely over the internet in any electronic format (structured or non-structured). The eSubmission Gateway Web Client users will benefit from an **automated confirmation of the technical validation feedback** (eCTD only) and an automated upload to the Agency's eCTD review system. The use of the eSubmission Gateway and the Web Client is **mandatory** for all human and veterinary submissions, including medical devices.

The various steps that need to be completed in the Web Client submission process are outlined below.

Please note that you will only be able to send submissions via the Web Client if you have successfully registered and received email confirmation with your login details.

1. Preparing your system

a) Please check the version of Java installed on the machine you will be sending the package from. Ensure that you have the **latest version** of Java installed (version 1.8 or later) and that you are using a 32bit version of Java. Some issues have been experienced during testing when 64bit version of Java 1.8 was used.

Please note that Mozilla Firefox and Google Chrome are **not compatible** with the large file applet (due to Java compatibility issues). In order to send submissions **larger than 40mb** you **must** use **IE** (internet explorer).

We recommend to always use the large file applet to ensure that you will receive both receipt and the acknowledgement confirming the receipt of the submission (or rejection) by the EMA.


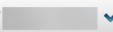
b) To enable sending of larger files if you have a Java warning message shown on the screen


 The local backup monitoring service requires the download of a Java applet. If a Java prompt suggest blocking unsafe components, select "No" or "Don't Block". If this message does not disappear shortly, contact your system administrator for assistance in verifying the version of your Java Runtime Environment (JRE).

Name: Find All folders

Inbox

Or if you have an incorrect file selection dialogue box using IE.

 **EMA Gateway : Production** European Medicines Agency/ 

 The local backup monitoring service requires the download of a Java applet. If a Java prompt suggest blocking unsafe components, select "No" or "Don't Block". If this message shortly, contact your system administrator for assistance in verifying the version of your Java Runtime Environment (JRE).

Send documents

1) Select recipients
Receiver: E-SUBMISSIONS

2) Add documents

#	Type	File Name

Open

This ... > Puusaari (\\FSb\eu... | Search Puusaari (\\FSb\eur...

Organize New folder

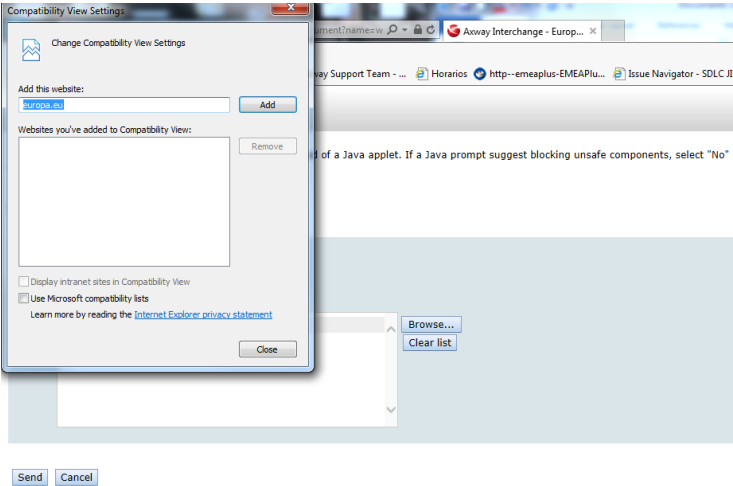
- Puusaari (\\FSb\edmschk) (K:)
- Puusaari (\\FSb\eurdraink) (L:)
- paeds (\\FSA) (N:)
- stage_area (\\fs-prod.eudra.org) (I:)
- Apps (\\FSA) (P:)
- apps (\\ws010) (X:)
- eurs (\\fs-prod.eudra.org) (Y:)
- Network

Name

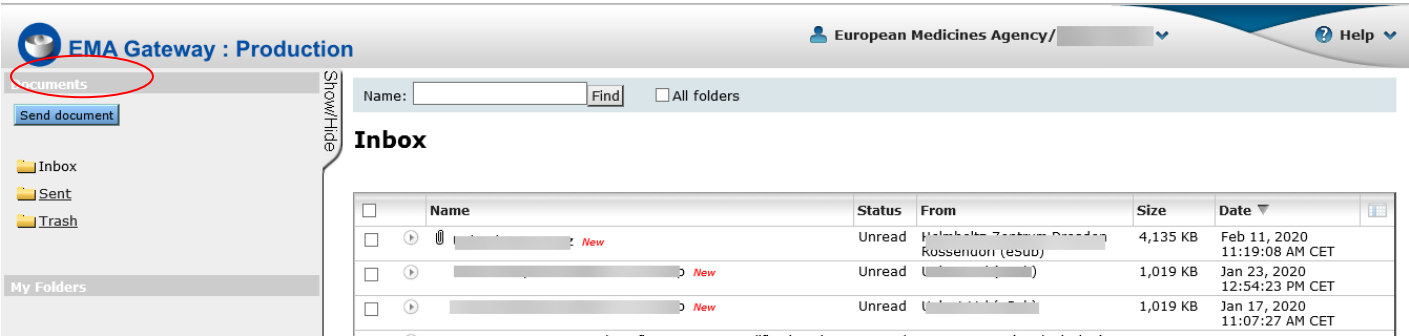
- Wonderpill
- Wonderpill

File name: | All Files



c) Please open the browser 'compatibility settings' and add 'europa.eu' on the Compatibility View (in order to send submissions above 40mb you must use the large file applet with the java browse window). Please note that you can only see the Java selection window when you are using correct version of Java and have enabled the compatibility view (in IE).



d) The java warning message should disappear after a short while (this may take slightly longer first time). Once this warning message has disappeared, you will be able to continue to 'send documents'



e) When the 'Send documents' window first opens you will see this window. Please wait a text 'Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission.' to appear under the 2) Add documents section (this will enable the large file applet allowing submission of larger packages)

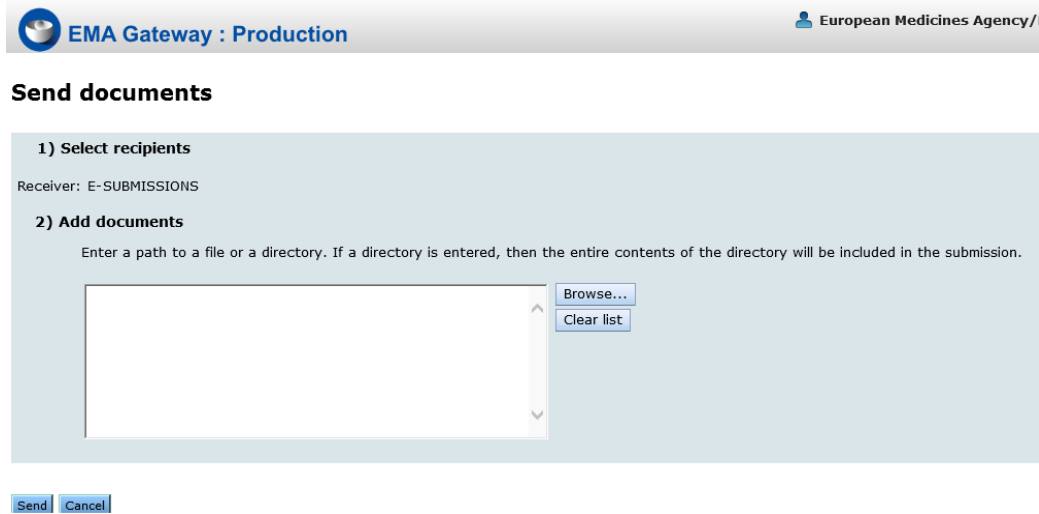
 

Send documents

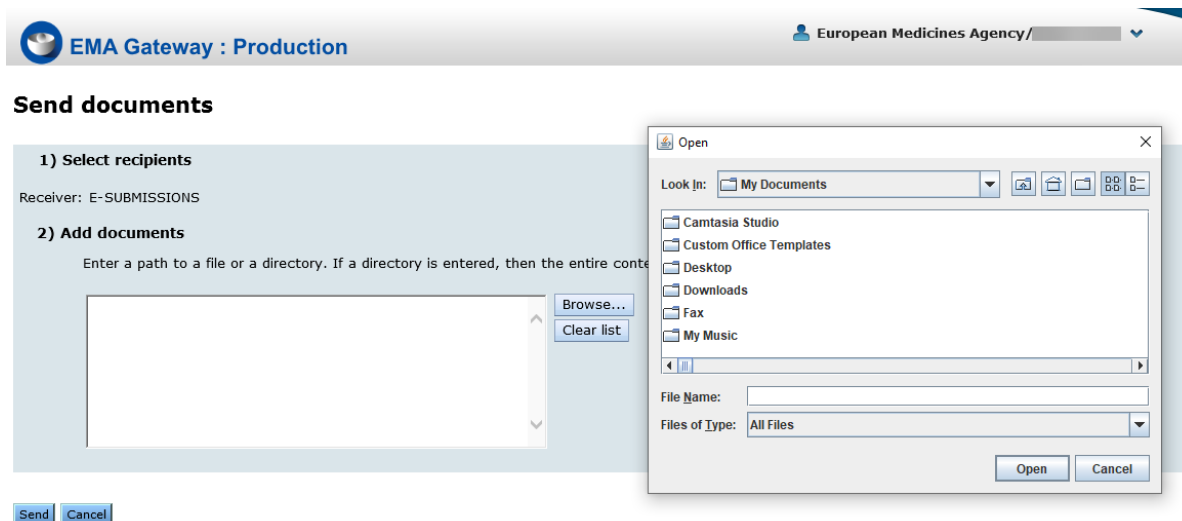
1) Select recipients
Receiver: E-SUBMISSIONS

2) Add documents
Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission.

f) Once the message is visible, you are now able to open the Java pop up window to select the submission package.



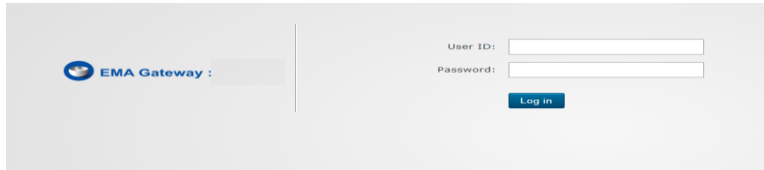
g) The Java window **must** be used in order to send submissions larger than 40mb. This is only possible using IE.



2. Accessing the Web Client

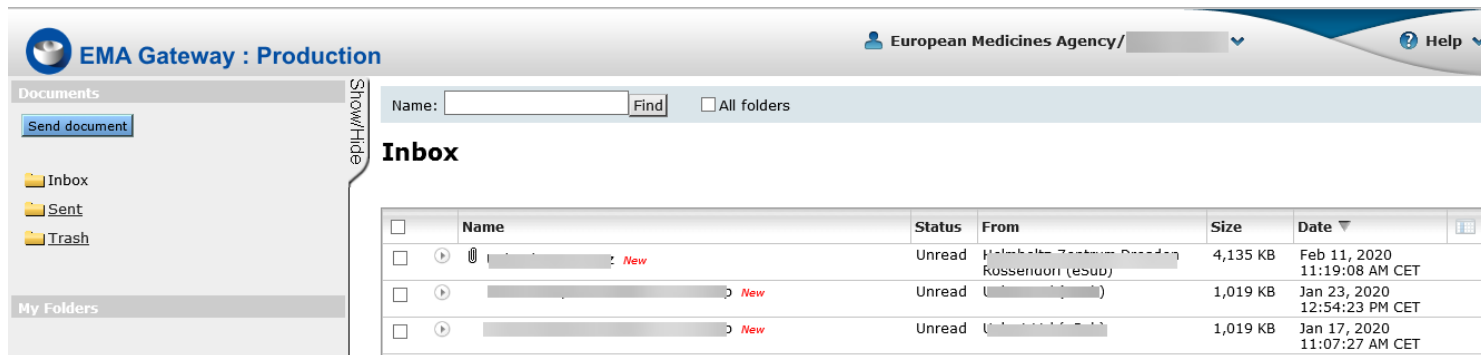
a) Please access the Web Client by clicking the link below for the EMA's Production environment:
<https://pgateway.ema.europa.eu/ui/>

b) You will see the login screen:



c) Please enter the User ID and Password which you chose when you completed the online registration form. This information can be found in the *bottom section* of the PDF attachment you received with the email confirming your registration for the Web Client.

d) You will now be able to view your Web Client account. This is the where you will find the inbox and sent items and where you will receive acknowledgements and receipts for your submissions to the EMA.



<input type="checkbox"/>	Name	Status	From	Size	Date	
<input type="checkbox"/>	[redacted] <i>New</i>	Unread	Helena Zestum-Saunders Rossenroon (esuo)	4,135 KB	Feb 11, 2020 11:19:08 AM CET	
<input type="checkbox"/>	[redacted] <i>New</i>	Unread	[redacted]	1,019 KB	Jan 23, 2020 12:54:23 PM CET	
<input type="checkbox"/>	[redacted] <i>New</i>	Unread	[redacted]	1,019 KB	Jan 17, 2020 11:07:27 AM CET	

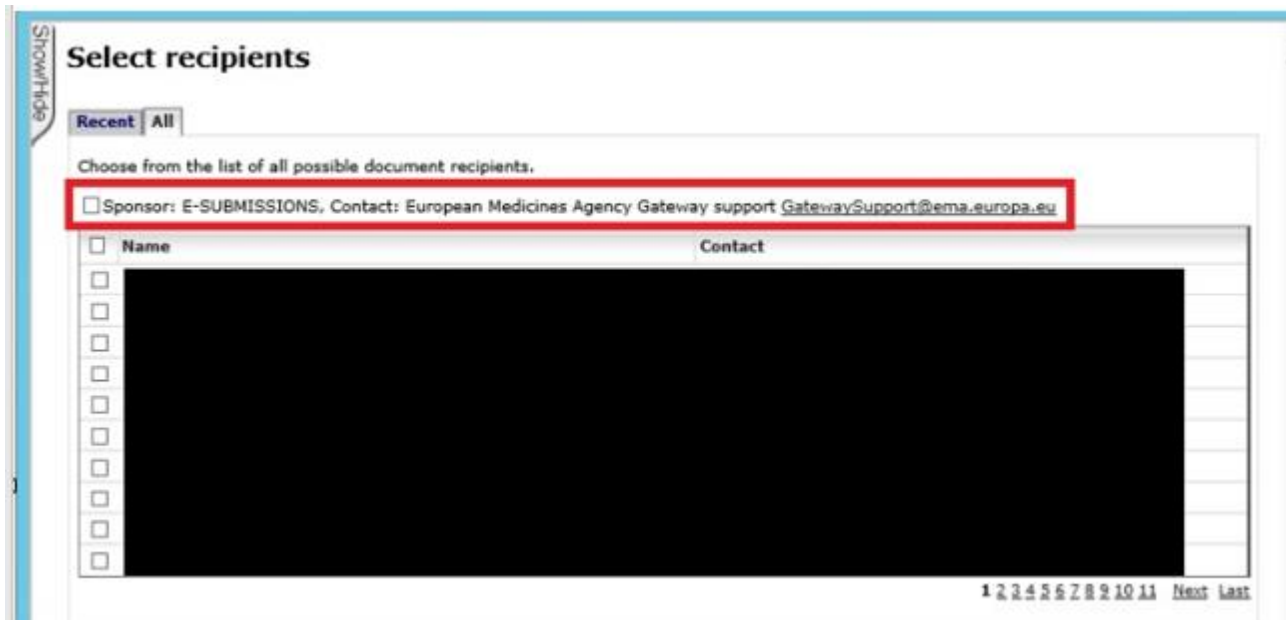
3. Sending Submissions

a) To send a submission to the EMA you will need to select "Send document" from the menu as shown below:



b) Occasionally, you may need to select the recipient, you should always select E-SUBMISSION when sending submissions to the EMA production environment. The recipient is listed as 'sponsor' above the list of other contacts (hidden in this screenshot).

Tick the box and click 'Add' to include the correct recipient.

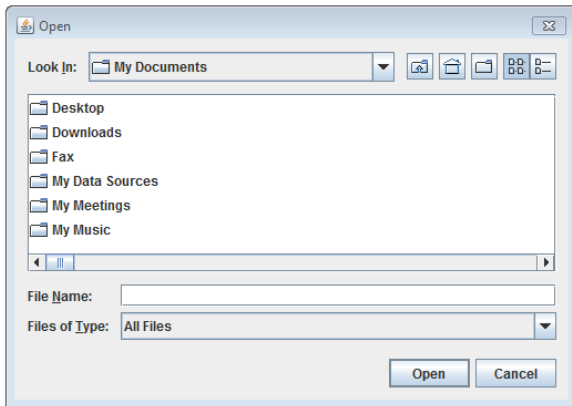




c) You will be shown a screen which will shows you the receiver of the submission. In the production environment the receiver should be set to **E-SUBMISSIONS**

The screenshot shows the 'EMA Gateway : Production' header with the European Medicines Agency logo. Below the header, the section is titled 'Send documents'. It contains two main steps: '1) Select recipients' and '2) Add documents'. Under '1) Select recipients', the receiver is set to 'E-SUBMISSIONS'. Under '2) Add documents', there is a text input field for a file path, a 'Browse...' button, and a 'Clear list' button. At the bottom of the form, there are 'Send' and 'Cancel' buttons.

d) Next, click the **Browse...** button and select the file you wish to submit as shown below:



e) Click **Send** to submit your files to the EMA.

Send documents

1) Select recipients

Receiver: **E-SUBMISSIONS**

2) Add documents

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission.

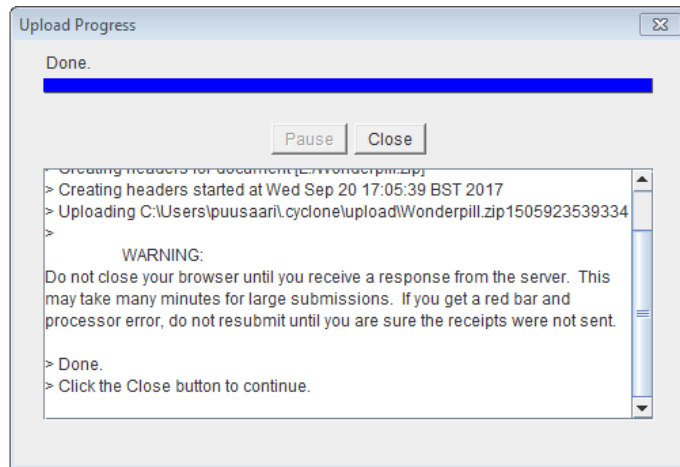
L:/Wonderpill.zip

Browse...

Clear list

Send Cancel

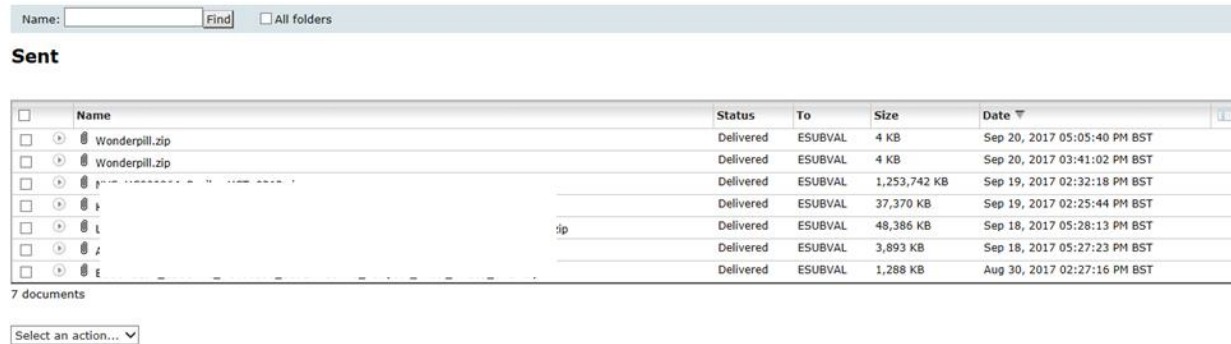
f) During the upload process you will see the following message:



g) Click on the  button.

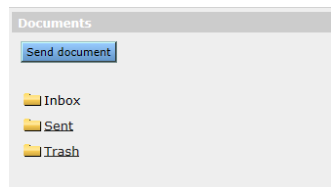
4. Viewing sent submissions

a) Once you close the window after the submission is sent, you will be taken to the sent items folder as shown below:



4.1. Viewing sent submission receipts and acknowledgements

a) To view receipts and acknowledgements select "Inbox" from the "Open folder" menu in the top right of the screen as shown below:



b) You will be able to see the receipt for the submission that was just sent:

Inbox

Name	Status	From	Size	Date
Receipt for Wonderpill.zip.txt <i>New</i>	Unread	ESUBVAL	2 KB	Sep 20, 2017 05:05:40 PM BST
From: gatewaysupport@ema.europa.eu (gatewaysupport@ema.europa.eu) To: Delivered: Sep 20, 2017 05:05:40 PM BST First download: Type: Receipt Show original document Related document: Wonderpill.zip Download View as text Rename document				
Receipt for Wonderpill.zip.txt	Read	ESUBVAL	2 KB	Sep 20, 2017 03:41:02 PM BST
FAIL_ACK_EMEA_H_C_002640_0063 <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 03:17:25 PM BST
FAIL_ACK_UNKNOWN_SUBMISSION_TYPE <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 02:35:22 PM BST

- c) When the submission has been successfully processed by the EMA's review system you will receive an acknowledgement in the Web Client inbox as shown:

Inbox

Name	Status	From	Size	Date
Receipt for Wonderpill.zip.txt <i>New</i>	Unread	ESUBVAL	2 KB	Sep 20, 2017 05:05:40 PM BST
Receipt for Wonderpill.zip.txt	Read	ESUBVAL	2 KB	Sep 20, 2017 03:41:02 PM BST
FAIL_ACK_EMEA_H_C_002640_0063 <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 03:17:25 PM BST
FAIL_ACK_UNKNOWN_SUBMISSION_TYPE <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 02:35:22 PM BST
Receipt for NVS_HC000964_Rasilez HCT_0212.zip.txt <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 02:33:13 PM BST
SUCCESS_ACK_EMEA_H_C_002422_0065 <i>New</i>	Unread	ESUBVAL	2 KB	Sep 18, 2017 06:04:13 PM BST
From: gatewaysupport@ema.europa.eu (gatewaysupport@ema.europa.eu) To: Delivered: Sep 18, 2017 06:04:13 PM BST First download: Type: XML Download View as text Rename document				
SUCCESS_ACK_vet-psur_EMEA_V_C_000156_2707 <i>New</i>	Unread	ESUBVAL	1,009 bytes	Aug 30, 2017 02:28:49 PM BST

7 documents

Select an action...

- d) If your submission was processed unsuccessfully a failure acknowledgment will be shown in the Web Client inbox as shown below:

Inbox

<input type="checkbox"/>	Name	Status	From	Size	Date ▾
<input type="checkbox"/>	Receipt for Wonderpill.zip.txt <i>New</i>	Unread	ESUBVAL	2 KB	Sep 20, 2017 05:05:40 PM BST
<input type="checkbox"/>	Receipt for Wonderpill.zip.txt	Read	ESUBVAL	2 KB	Sep 20, 2017 03:41:02 PM BST
<input type="checkbox"/>	FAIL_ACK_EMEA_H_C_002640_0063 <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 03:17:25 PM BST
<input type="checkbox"/>	FAIL_ACK_UNKNOWN_SUBMISSION_TYPE <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 02:35:22 PM BST
From: gatewayssupport@ema.europa.eu (gatewayssupport@ema.europa.eu) To: ; Delivered: Sep 19, 2017 02:35:22 PM BST First download: Type: XML Download View as text Rename document					
<input type="checkbox"/>	Receipt for NVS_HC000964_Rasilez HCT_0212.zip.txt <i>New</i>	Unread	ESUBVAL	2 KB	Sep 19, 2017 02:33:13 PM BST
<input type="checkbox"/>	SUCCESS_ACK_EMEA_H_C_002422_0065 <i>New</i>	Unread	ESUBVAL	2 KB	Sep 18, 2017 06:04:13 PM BST
<input type="checkbox"/>	SUCCESS_ACK_vet-psur_EMEA_V_C_000156_2707 <i>New</i>	Unread	ESUBVAL	1,009 bytes	Aug 30, 2017 02:28:49 PM BST

7 documents

Select an action... ▾

5. Error codes

If your submission was unsuccessful you will be able to find out the reason for this by viewing the error code inside the acknowledgement message. The error codes list is regularly updated and is available here: [Error codes list](#)

If you experience any issues during using the Web Client please contact:

[EMA Service Desk portal](#)