



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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eSubmission Gateway Web Client Guidance for applicants

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1. The eSubmission Gateway Web Client – General Questions

Q1. What is the Web Client?

The Web Client is an online system which enables applicants to send their eCTD submissions via the internet. This solution is particularly relevant for Small and Medium sized Enterprises (SMEs) and companies with lower IT budgets and low submission volumes.

Q2. How will the Web Client benefit SMEs and other applicants?

Currently applicants who are not connected to the eSubmission Gateway can only submit applications on a physical support (CD or DVD). This might be particularly relevant for registered SME applicants. The Web Client offers an alternative option in order to give equal submission options to all applicants regardless of their IT budget and volume of applications/ submissions. As a result submissions will be faster for participating companies as the need for specialist delivery modes such as hard copy mail are eliminated.

Q3. When will the Web Client be ready to use?

The EMA is planning to launch the Web Client in early 2013 with an enhanced support period running for 3 months following the launch of this service. Applicants can continue to submit applications on a physical support (CD or DVD) after the solution is launched in production if they choose to, however the EMA strongly recommends the use of the eSubmission Gateway or the Web Client solution to all applicants for the submission of all sequences, for all eCTD applications within the centralised procedure. Applicants must **not** send duplicate submissions using both CD or DVD and Gateway. If you would like to join a mailing list of companies to be contacted when the Web Client registration web page is live please email: natasha.brown@ext.ema.europa.eu.

Q4. What is the cost for companies who wish to use the Web Client?

There is no cost to Web Client users as the solution is available via the internet.

Q5. How secure are submissions sent via the Web Client?

The Web Client uses Hypertext Transfer Protocol Secure (HTTPS) to ensure that submissions are sent securely. Users will be required to use a strong username and password authentication when setting up their Web Client profile. In future we hope to work towards providing digital signature functionality within the eAF.

Q6. Can consultancy companies and other third parties use the Web Client on behalf of Marketing Authorisation Holders (MAHs)?

It is possible for consultancies to register and send submissions on behalf of various MAHs. In this case, it is not necessary for each MAH to register separately; we only require registration for the consultancy.

Q7 Can we use both the eSubmission Gateway and the Web Client to send submissions?

Applicants must **not** use both solutions for the same submission. If duplicate submissions are sent we will only receive the first submission and the applicant will receive an acknowledgement of failure with error messages for the second submission. It is however possible to register as a user for both systems.

Q8. Why is the EMA offering 2 different services? Which one is more suitable for my needs, the eSubmission Gateway or the Web Client?

Features of the Web Client

The Web Client is a free solution that offers an alternative option in order to give equal submission options to all applicants regardless of their IT budget. The Web Client uses Hypertext Transfer Protocol Secure (HTTPS) to ensure that submissions are sent securely. Users will be required to use a strong username and password authentication when setting up their Web Client profile.

The Web Client requires manual uploading of submissions and is therefore more suitable for lower transmission volumes

Features of the eSubmission Gateway

The EMA eSubmission Gateway enables applicants to submit all eCTD format applications via a secure Internet connection. It is based on the ESTR1 (Electronic Standards for the Transfer of Regulatory Information) gateway standard, which defines a secure data exchange service for regulatory information. There is a cost involved to set up the Gateway service.

The Gateway allows multiple submissions to be sent concurrently with an optimum transmission speed. Applicants with larger submission volumes or automated workflows might wish to benefit from the automated features provided by the connection to the eSubmission Gateway.

A summary of the main features is shown below:

Feature	Web Client	eSubmission Gateway
Removes the need for submitting CDs / DVDs to the EMA	✓	✓
Allows the technical possibility (after relevant registration) to connect to other EMA Gateway communities		✓
Allows eCTD submissions	✓	✓
Encrypts submissions upon receipt by EMA Gateway	✓	✓
Free solution	✓	
Suitable for consultancies / affiliate companies as well as Marketing Authorisation Holders	✓	✓
Provides automated message delivery notification – check correct term		✓
Provides confirmation of the submission's technical compliance	✓	✓
Compliant with ESTR (Electronic Standards for the Transfer of Regulatory Information)		✓
Uses HTTPS (Hypertext Transfer Protocol Secure)	✓	
Accessible remotely via a website	✓	
Automated upload of submissions via custom development		✓
Suitable for transmitting multiple submissions*	✓	✓
Suitable for larger submission volumes		✓
Allows transmissions up to 15GB	✓	✓

*The Web Client supports multiple submissions when each file is individually selected, the Gateway allows for automation to enable multiple submissions to be sent without the need for manual intervention.

2. Archival file formats and maximum size

Q9. Do submissions need to be sent as zip files?

The eCTD submission should be archived as a zip file (Encryption and Password should be disabled on the zip file). As soon as the eCTD submission is received by the Gateway, it is encrypted. Other archival file formats are not allowed. The compressed application file must comply with the ZIP open format.

Q10. Is there a maximum size for a submission made via the Web Client?

Currently, the largest submissions received by the EMA are usually no bigger than 3-4 GB. Applicants can upload multiple files at once if they are less than 10 MBs each. Files greater than 10 MBs in size will need to be uploaded one by one.

We have tested the Web Client up to 15GB (Unzipped). If you have a submission beyond this limit, please contact us so that appropriate measures can be put in place to successfully receive your submission.

3. File naming conventions

Q11. What is the file naming format for submitting electronic Submissions via the EMA eSubmission Gateway?

The filename is used as a means of identifying specific information, allowing the Agency to automate processing of the submission once received.

The filename is broken down into different parts as described in the table below:

Data	Remarks	Case sensitive	Example
SenderRoutingId_	Routing ID for Sender as registered by the Gateway for identification & MDN message. This will be supplied to the Applicant by Gateway support	Upper	XYZ
ReceiverRoutingId_	Gateway routing ID to differentiate this eSubmission from other application transmissions.	Upper	ESUBPROD
EMEA Product No_	e.g. EMEA/H/C/000000	Upper	EMEAHC000000 or Hxxxxxxx (Initial application)
Product Name	maximum 30 characters	Upper / Lower	Wonderpill
Submission Type	See list of Submission types below	Upper / Lower	initial-maa
Sequence Number	0000-9999	N/A (should be numeric)	0020
.zip	.zip	Lower	.zip

Filename Example:

XYZ_ESUBPROD_HC000xxx_Wonderpill_initial-maa_0020.zip

OR in the case of an Initial Marketing Authorisation Application:

XYZ_ESUBPROD_Hxxxxxxx_Wonderpill_initial-maa_0020.zip

(applicants are advised that the use of this number is mandatory and it can be found in the EMA Eligibility confirmation letter)

List of Submission Types See link: <http://esubmission.ema.europa.eu/eumodule1/index.htm>

EU Module 1 Specifications 1.4 (Appendix 1: The EU Module 1 XML Submission) – see “Type”. e.g. initial-maa, var-type1a, etc.

Notes:

- Please use an underscore between each data item within the filename.
- Do not use an underscore anywhere else other than between each data item of the filename.
- Do not use special characters or spaces in the individual data items of the filename. Acceptable characters are: a to z (upper or lower case), 0 to 9 and “-”(hyphen).

- The maximum number of characters of the filename should be 180.
- The "Type" (see above) should be selected from the list [\(link\)](#) provided.

Q12. What is the file naming format for submitting Worksharing and Type IA (IG) Grouping applications? How should I submit Worksharing applications?

For Worksharing and Type IA Grouping applications, applicants are required to obtain a "EMEA/H/C/WSxxxx" or "EMEA/H/C/IGxxxx" number (via email to PA-BUS@ema.europa.eu) in advance of submitting their Work-sharing or IA Grouping.

Filename Example:

In this case the following file naming convention is to be used:

MAH_ESUBPROD_HCWSxxxx_ProductName_var-type2_00xx.zip or

MAH_ESUBPROD_HCIIGxxxx_ProductName_var-type1a_00xx.zip

When there is a combination of different types of variations (Grouping), the variation Type should be the 'highest type' in the group.

Applicants are required to ensure that each product for the Worksharing is sent in separate zips. The Worksharing number and application type should be always correctly referred to. Additionally, it is imperative that all products within Worksharing /IA Grouping are sent at the same time to ensure that they arrive together.

If one product in the Worksharing/IA Grouping fails during the transmission, only this part of the Worksharing /IA Grouping has to be re-sent. Content validation will only start when ALL parts of the Worksharing / IA Grouping have reached the Agency. The submission date of the Worksharing / IA Grouping will be the date of the last submitted product.

4. Connection and registration process

Q13. How do companies register to use the Web Client in the production environment?

Registration for the Web Client is completed online via a dedicated web page. Online registration instructions will be published on the [eSubmission website](#). If you would like to join a mailing list of companies to be contacted when the registration web page is live please email: natasha.brown@ext.ema.europa.eu.

Q14. How far in advance of a submission deadline do companies need to register to use the Web Client?

We recommend that you complete the online registration form at least 20 working days before your submission deadline. Registration is only required once and after it has been completed submissions can be sent via the Web Client.

Q15. We are already set up as we have used the Gateway before – do we still need to register?

Registration is required as the eSubmissions Gateway community is its own community, and is not a part of EVTEST or any other existing community. If you have not registered for the eSubmission Gateway Web Client previously, you will need to register before being able to submit files. Applicants registered to use the eSubmission Gateway will need to re-register to obtain relevant user username and password if they wish to use the eSubmission Web Client.

Q16. What happens if we forget our password? Will we be required to re-register?

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 GatewaySupport@ema.europa.eu 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.

5. Technical questions

Q17. Are there any technical requirements for Web Client users?

The browser must have J2SE Java Runtime Environment (JRE) 1.5. This is required to run various applets within the user interface. If you need JRE 1.5.0_05 or later, go to the following URL and download and install the JRE: <http://java.sun.com/j2se/1.5.0/download.jsp>

Q18. Which browser is recommended for use with the Web Client?

The following browsers are recommended for use with the Web Client:

- Microsoft Internet Explorer 7 or later
- Mozilla Firefox 3 or later
- Google Chrome 6 or later

Q19. Will pop-up blocking software interfere with the Web Client?

Pop-up blocking software for your browser may interfere with the Web Client. You may want to disable or uninstall such software. Moreover, some browser plug-ins or add-ons designed to enhance web server performance may interfere with the user interface.

If you use Internet Explorer do not install the Yahoo toolbar in your browser, as this has been demonstrated to interfere with the user interface.

Applicants are expected to comply with unique connection identifiers for sending and receiving.

Q20. How will companies know that submissions sent via the Web Client have been successful?

Users will receive an acknowledgement confirming the receipt and pass/fail of the technical compliance check as per the current eCTD validation criteria for all submissions. For failed validations an error report will be attached.

Q21. Can multiple submissions be sent at the same time?

The Web Client supports multiple submissions under 10 MB when each file is individually selected for upload as a zip file. Please ensure that the submissions are zipped in accordance with the filename convention described in Q11.

6. Glossary

Term

Applicant	A pharmaceutical company or its agent that is submitting information in support of an application
ESTRI Gateway	Electronic Standards for the Transfer of Regulatory Information
Procedure	The centralised registration procedure for the authorisation and maintenance of medicinal products in the European Union. There are 4 types of procedures that operate within the EU – The eSubmissions via the Gateway is only dealing with the Centralised Procedure
Submission	A single set of information and/or documents supplied by the applicant as a part of, or the complete, Application. In the context of eCTD, this is equivalent to 'sequence'
External Compliance Test Environment	External Compliance Test Environment is used to test the compliance of a new trading partner from pharmaceutical industry with the EMA's eSubmission Gateway system
Production environment	Production environment is used for live production
Web Client	A Web Client is a computer communication system, in which client computers send requests to the server computer for data from its database, and the server returns the results to the clients via Internet/WWW

7. Contact us

For technical queries in the production environment: gatewaysupport@ema.europa.eu

If you have any further non-technical questions that are not adequately addressed by this document, please forward your query or comment to eCTD@ema.europa.eu