



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. Available for all applicants, this solution is particularly relevant for Small and Medium sized Enterprises (SMEs) and companies with lower IT budgets and low submission volumes.

## **Q2. What is the objective of electronic Submissions via the Web Client?**

Currently electronic submissions are received by the European Medicines Agency via CD-ROMs and DVDs from the Applicants. The Gateway Web Client offers Applicants an easier and quicker way of submitting eCTD submissions securely over the Internet. The online service is already offered by the European Medicines Agency for Eudravigilance and is now available for the Centralised Procedure covering all eCTD submissions related to the authorisation and maintenance of medicinal products, including new marketing authorisations, variations, renewals, PSURs, active substance master files (ASMF) and Plasma Master Files (PMF).

The use of the Web Client improves the Agency's efficiency in handling the submissions received and in making them available quickly within the European Review System (EURS).

## **Q3. Which types of applications can I submit via the EMA eSubmission Web Client?**

The eSubmissions Gateway Web Client service is offered for all Centralised Procedure applications for Human Products, submitted in eCTD format only e.g. new marketing authorisations, variations, renewals, PSURs, active substance master files (ASMF) and Plasma Master Files (PMF). Currently all other submission types such as Referrals, Scientific Advice and Paediatrics are outside the scope of the eSubmissions Gateway Web Client.

## **Q4. What does my company need to do in order to use the Web Client?**

Before being able to use the Web Client you will need to ensure that:

- 1) [Online registration](#) has been completed and account(s) have been activated.
- 2) The filename convention described in this document is used correctly when uploading zip files.

## **Q5. How will the Web Client benefit SMEs and other applicants?**

Currently applicants who are not connected to the eSubmission Gateway and/or the Web Client 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.

**Q6. What is the criteria used to define small and medium sized companies?**

The Agency applies the definition of micro, small and medium-sized enterprises provided in Commission Recommendation 2003/361/EC. Therefore companies must:

- be established in the EEA, and
- employ less than 250 employees, and
- have an annual turnover of not more than €50 million or an annual balance sheet total of not more than €43 million. Further details can be found here.

**Q7. When will the Web Client be ready to use?**

The EMA is launching the Web Client on 15<sup>th</sup> of January 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/Web Client.

If you would like register to use the Gateway or the Web Client, please visit the registration [web page](#).

**Q8. 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.

**Q9. 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.

**Q10. Can consultancy companies and other third parties use the Web Client on behalf of Marketing Authorisation Holders (MAHs)?**

The Web Client application is open to all applicants. 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.

**Q11. When registering a consultancy, what products should we include in the registration form?**

When registering a consultancy it is not mandatory to include product name in the registration form, it is sufficient to state that you are a consultancy in the product name field. There is however no problem with providing a name of a product of one of your clients if you wish to do so.

**Q12. 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.

**Q13. How are Product Team Leaders and other relevant Product Team Members informed that a Gateway / Web Client submission has been received and "clocked-in" by EMA's product application business support team (PA-BUS)?**

The EMA's internal registration and distribution processes are constantly changing to accommodate the new delivery methods.

Product Team Leaders (PTLs) are informed within 1 working day from the time of delivery of a valid eCTD sequence.

**Q14. 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 ESTR I (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:

| <b>Feature</b>   | <b>Web Client</b> | <b>eSubmission Gateway</b> |
|--|-------------------|----------------------------|
| 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 (MDN) / receipt   | ✓                 | ✓                          |
| Provides confirmation of the submission's technical compliance   | ✓                 | ✓                          |
| Compliant with ESTR I (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                        | ✓ | ✓ |

**Q15. Do we have to use the Web Client for all submissions or is it possible to submit some via the Web Client and some via the current CD media process?**

It is possible for applicants to still use the former method of sending CDs / DVDs for different products after they have registered for the Web Client, however, the EMA would like to encourage use of the Gateway and the Web Client as much as possible. It is also possible to use both, the Gateway and the Web Client, but the applicants must not use both for the same submission as this will lead to negative validation and can cause delays in the handling of your application.

**Q16. Is it mandatory to fill in the eCTD envelope for each submission sent via the Web Client?**

Yes, the current [eCTD guidance](#) applies to all submissions regardless of the submission channel used (CD/DVD, Gateway, Web Client).

## 2. Archival file formats and maximum size

**Q17. Do submissions need to be sent as zip files?**

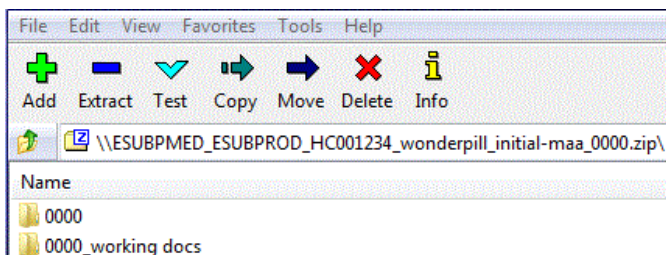
The eCTD submission should be archived as a zip file (Encryption and Password should be disabled on the zip file). As soon as the eCTD submission is received by the Gateway Web Client, it is encrypted. Other archival file formats are not allowed. The compressed application file must comply with the ZIP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

**Q18. Does the applicant have to zip the files or does the software do it automatically before the submission is sent?**

No, the applicant has to zip the files prior to sending it. The system does not accept packages that are not zipped.

**Q19. Do we need to structure our folders within the zip file in a particular way?**

You must ensure that the sequence number folder is a root folder in the zip file as shown below. This is required to help ensure that your submission passes the Web Client's technical validation.



**Q20. How should I provide working documents?**

When working documents are submitted together with the eCTD sequence, the EMA recommends naming the folder 'xxxx-working docs' where the number (xxxx) equals the number of the eCTD sequence being submitted.

You must ensure that the sequence number folder is a root folder in the zip file within the same Web Client transmission. This is required to help ensure that your submission passes the technical validation.

**Q21. Does the EMA recommend any zip software to compress the submission sequence folder?**

Any software that can create a valid zip archive can be used. Some examples are winzip, 7z, winrar, the windows archive utility etc.

**Q22. Is there a maximum size for a submission made via the Web Client?**

Currently, the larger 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 recommend that you use the large file option for all submissions to ensure you always receive a receipt.*

We have tested the Web Client up to 15GB (Unzipped). If you have a submission bigger than 5GB, please [contact us](mailto:eCTD@ema.europa.eu) (eCTD@ema.europa.eu), so that appropriate measures can be put in place to successfully receive your submission. Additionally, it is recommended that any submissions that are bigger than 5GB are sent outside "peak hours" when the traffic is lower.

### 3. File naming conventions

(for further details and common examples please refer to Annex 1.)

**Q23. What is the file naming format for submitting electronic Submissions via the EMA eSubmission Web Client?**

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  |
|------------------------|---|----------------|----------|
| <b>SenderRoutingId</b> | Routing ID for Sender as registered by the Gateway for identification MDN & acknowledgement messages. | Upper          | ESUBPXYZ |

|                          |  |                         |   |
|--------------------------|--|-------------------------|---|
| <b>ReceiverRoutingId</b> | Gateway routing ID to differentiate this eSubmission from other application transmissions. | Upper                   | ESUBPROD  |
| <b>EMEA Product No</b>   | e.g. EMEA/H/C/000000<br>(This must be a 6 digit number)                                    | Upper                   | EMEAHC000999or<br>H011111 (Initial application) |
| <b>Product Name</b>      | maximum 30 characters  | Upper / Lower           | Wonderpill                                      |
| <b>Submission Type</b>   | See list of Submission types below   | Upper / Lower           | initial-maa                                     |
| <b>Sequence Number</b>   | 0000-9999  | N/A (should be numeric) | 0020  |
| <b>.zip</b>              | .zip   | Lower                   | .zip  |

### Filename Example:

#### In the case of Initial MAA:

ESUBPXYZ\_ESUBPROD\_H011111\_Wonderpill\_initial-maa\_0000.zip

ESUBPXYZ\_ESUBPROD\_HC001111\_Wonderpill\_supplemental-info\_0001.zip

**(Applicants are advised that the use of the EMA product number is mandatory. The number can be found in the EMA Eligibility confirmation letter)**

#### List of Submission Types:

[http://esubmission.ema.europa.eu/eumodule1/docs/EU%20M1%201.4.1/EU%20M1%20v141\\_Spec%200\\_Nov2011\\_FINAL.pdf](http://esubmission.ema.europa.eu/eumodule1/docs/EU%20M1%201.4.1/EU%20M1%20v141_Spec%200_Nov2011_FINAL.pdf)

EU Module 1 Specifications 1.4 (Appendix 1: The EU Module 1 XML Submission) – see “Type”. e.g. initial-maa, var-type1a, etc. (page 20)

#### Notes:

- Please use an underscore between each data item within the filename. The filename should not contain an underscore other than as a separator for the different components of the filename as shown below
- 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.

### **Q24. What is the difference between Hxxxxxxx and HCxxxxxx EMA product number that has to be used in the filenaming convention?**

The Hxxxxxxx number is found in the Eligibility confirmation letter. This EMA product number consists of the letter H, followed by seven numerical digits. The HC number is only given after the application has been received by the EMA. This EMA product number contains letters HC (or occasionally “W” or “D” or “K”) followed by **six** numerical digits. For the submission of the Initial sequence (0000) of a new MAA, the applicant should use HXXXXXX (six numerical digits, removing the first zero) and for any subsequent submissions, use HCXXXXXX.

Example:



In the Eligibility confirmation letter H0001234

In your filename this will become H001234

In subsequent submissions HC001234

**Q25. 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:**

**Worksharing:** ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_WSxxxx\_00xx.zip

**Type IA Groupings (IGs):** ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_IGxxxx\_00xx.zip

Please go to Annex 1 for further explanatory notes.

**Q26. I received a 'failure' acknowledgment message; do I need to change my filename and the sequence number? Would this create duplication?**

If your 'failure' acknowledgement is the result of using incorrect file name, please ensure that filenaming convention is followed and amend accordingly.

However, if you receive 'failure' acknowledgement due to eCTD technical validation, the same filename should be used. There will not be duplication as the initial package has not been uploaded in the review system.

For example if the initial submission (sequence 0000) failed, the corrected submission should also be sequence 0000.

**Q27. How will the submission type in the file name affect validation? Will it lead to negative technical validation if incorrect submission type is used?**

It is recommended that the EU Module 1 Specifications 1.4 (Appendix 1: The EU Module 1 XML Submission) – see "Type". e.g. initial-maa, var-type1a, etc submission types are used, however it will not result in negative technical validation.

**Q28. What filenaming convention, should be followed in the case of ASMFs that are submitted in relation to a Centrally Authorised Product?**

*In these cases only, please use submission type: 'ASMF' in your Web Client filename:*  
ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_ASMF\_00xx.zip

Please note that the eCTD Specification should be followed in the content of the submission.

**Q29. Is there a filename convention for working documents folder?**

The EMA recommends using 'xxxx-working docs', where the number (xxxx) equals the sequence number.

**Q30. Does the EMA have any plans to revisit the filename convention to make it easier for the applicants?**

It is very important to get the filename correct. The EMA has carefully reviewed the mandatory elements and minimum requirements for the filename to allow the automated validation and the upload to the review system.

If you have any problems with the filename convention, please contact [eCTD@ema.europa.eu](mailto:eCTD@ema.europa.eu).

## **4. Connection and registration process**

**Q31. How do companies register to use the Web Client in the production environment?**

Registration for the Web Client can be completed online via a dedicated [web page](#).

**Q32. Is it possible to test the Web Client before sending real submissions in the production environment?**

Applicants are encouraged to submit test submissions in the External Compliance environment prior to submitting in PRODUCTION. Please ensure you have included relevant details (for test environment configuration) in the online application form at the time of registration. If you experience any issues, please contact the EMA (as appropriate from section 7 of this document).

**Q33. 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.

**Q34. We are already set up as we have used the Gateway before – do we still need to register?**

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. If you have **not** registered for the eSubmission Web Client previously, you will need to register before being able to submit files.

**Q35. Will we be able to register multiple users with individual passwords? Or can we only have one registered user?**

We recommend 1 registered user per company.

**Q36. Is it possible to have one master account, per company, registered to use the Web Client?**

We suggest that one registration is made per company, although it is up to the company concerned to manage the user credentials and share them internally with the relevant colleagues.

**Q37. The online registration form requires entry of a "Centrally Authorised Product Name". As a consultancy, we ourselves are not Marketing Authorisation Holders. What should we enter for this field during the registration process?**

If you are registering to use the Web Client as a consultancy please indicate this in the product name field of the online registration form.

**Q38. Can I only submit applications for products I have registered on the eSubmission Web Client application form?**

No, you can submit all eCTD applications for all your products via the Web Client once the registration process has been completed.

**Q39. How do I update the list of registered products?**

There is no need to update the list of registered products. This is only requested so that during the registration the EMA registration team can confirm that the applicant has a product in the centralised procedure.

If you register before you have submitted your first initial submission for the centralised procedure, please indicate this in the field.

**Q40. Do I need to include a hard copy Cover Letter / Registration form with submission sequences sent via the European Medicines Agency Web Client?**

There is no need for applicants to send an additional signed cover letter / Registration form in paper format as the transmitted dossier should already contain a signed and scanned electronic cover letter and relevant data (e.g. date and time). Date and time are stored on the Gateway server and the eCTD submission is loaded into EURS, where all the information can be retrieved at a later stage as required.

Please use the EMA published [cover letter template](#) for the submission in the context of the Centralised Procedure.

**Q41. Do I need to send additional Media (CD, DVD) along with my Web Client submissions?**

No, there is no need to send additional media along with the Web Client submission. Applicants must **not** send a duplicate submission electronically or via CD/DVD as this might lead to delays in the handling of applications.

**Q42. Is it still required to send eCTD sequences on hard media (CD/DVD) to the Rapporteur, Co-Rapporteur and all CHMP members for eCTD submissions in the Centralised Procedure when at the same time eSubmission Web Client is used for submission to the Agency? Or do all CHMP members have access to the Web Client?**

Yes, you must continue to send the submissions to the Rapporteur and Co-Rapporteur in accordance with the submission requirements of each National Competent Authority.

The EMA is working on the development of a Central Repository which will enable member states to view submissions electronically. Prototype testing for this solution is expected to start within the first half of 2013.

**Q43. Is it possible to change the registered contact person and some other contact information (organisation name, email address etc.)?**

For any updates related to your user account please contact [GatewaySupport@ema.europa.eu](mailto:GatewaySupport@ema.europa.eu).

**Q44. 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](mailto: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

### ***Q45. Are there any technical requirements for Web Client users?***

The browser must have J2SE Java Runtime Environment (JRE) 1.5 or above. This is required to run various applets within the user interface.

### ***Q46. 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

### ***Q47. Do we need to get a change made to our firewall to access the Web Client?***

It is recommended to work with your IT Infrastructure Team to allow access to `vgateway.ema.europa.eu:4081` Our IP address is 195.144.18.238

### ***Q48. 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 any additional toolbars 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.

### ***Q49. Are there any disk space requirements when using the Web Client?***

Web Client users are required to have available space on their local machine that is greater than the size of the file they are uploading.

### ***Q50. What is the best way to manage the back-up files created when we use the large file option in the folder ".cyclone\backup"?***

We recommend that these files are deleted when you obtain a receipt. The back-up files are stored in the event of failure during upload. Once the submission has been received they are not required.

**Q51. Why didn't I get an acknowledgement for the submission I sent via the Web Client?**

If you did not receive an acknowledgement or receipt it could be due to the following reasons:

- Check that the routing ID is correct and does not contain any additional spaces

You should assume that the application has **not** been received by the EMA if you haven't received the acknowledgement. Please allow 5 minutes to 4 hours to receive the acknowledgement. If you have not received this, please contact EMA's gateway support at [gatewaysupport@ema.europa.eu](mailto:gatewaysupport@ema.europa.eu).

**Q52. 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, harmonised eCTD validation criteria for all submissions. For failed submissions the error description can be found in the 'failure' acknowledgement (xml) and the submission has to be sent again.

**Q53. How long do we have to wait to receive an acknowledgement?**

The waiting time depends on the size of the submission and the system load at the time the submission was sent. It might take from 5 minutes to 4 hours depending of the size of the submission.

**Q54. Do we get receipts and acknowledgements for all submissions sent via the Web Client?**

Receipts are provided when the large file option is selected; however, all submissions will receive an acknowledgement confirming the technical compliance of each submission. *We recommend that you use the large file option for all submissions to ensure you always receive a receipt.* It is only when a positive acknowledgement is received that you can be certain that your submission has been successfully received and uploaded in to the EMA's review system.

**Q55. What is the difference between an acknowledgement and a receipt?**

The purpose of the receipt is to confirm that your submission has been delivered to the EMA (a bit like the signature provided to a courier delivering a package). Receipts are only provided when the large file option is selected.

Acknowledgements are provided for all submissions to confirm that they are technically compliant and have been imported in to the EMA's review system. For failed submissions the error description can be found in the 'failure' acknowledgement (xml) and the submission has to be sent again.

You should assume that the application has **not** been received by the EMA if you haven't received the acknowledgement. Please allow 5 minutes to 4 hours to receive the acknowledgement. If you have not received this, please contact EMA's gateway support at [gatewaysupport@ema.europa.eu](mailto:gatewaysupport@ema.europa.eu).

**Q56. Do I need to wait for the acknowledgement of the sequence to be received before sending the next sequence?**

It is best to await acknowledgements rather than sending multiple sequences all at once. This is especially relevant if one submission relates to another sequence. For example if sequence 0030 is related to sequence 0028, we must receive 0028 first.

**Q57. What should we do if a negative acknowledgement is received?**

You should carefully review the error description in the acknowledgement, make necessary changes and resubmit the package. Please only contact the EMA on [ectd@ema.europa.eu](mailto:ectd@ema.europa.eu) if you are unable to resolve the issue. Should you need to contact the EMA, please include as much description of the error as possible and/or the eCTD validation report for comparison.

**Q58. In which format the error information will be included in the acknowledgement, text format (words) or in XML code (<text>)?**

The error report is in XML and the DTD schema is available from the [eSubmission website](#).

**Q59. Would you identify number of file and folder received at your end similar to what FDA sends in their second acknowledgement receipt?**

No, the EMA does not yet have this feature.

**Q60. Will the acknowledgement have a specific file naming convention? Or will we just need to identify via partnership routing naming?**

The product number and the sequence number are always included in the acknowledgement.

**Q61. Is there configuration setting in user inbox where an email can be forwarded once Acknowledgement is received in the inbox (instead of manually verifying after every few minutes if the Acknowledgement has been received)**

The inbox must be checked manually. Unfortunately the Web Client is not able to forward the acknowledgements to an email address as of yet.

**Q62. Do the 'SUCCESS' or 'FAILURE' acknowledgments follow the P/F or Best Practice classifications in the Validation Criteria, i.e. wouldn't BP criteria errors result to a 'FAILURE'?**

Only the 'Pass/Fail' criteria is used to establish whether a submission is 'SUCCESS' or 'FAILURE'.

Please note that you may also receive 'Failure' acknowledgement if the incorrect filename is used.

**Q63. Is the DTD/Schema for the acknowledgement file available?**

The xml definition schema (xsd) is available and it will be published online on the eSubmissions website.

**Q64. Is there any requirement for attaching Digital certificate for Web Client submissions?**

No, there is no need to attach digital certificates in the Web Client submissions.

**Q65. What if I realise there was a content error in the submission after receiving a successful acknowledgement and we wish to retract the submission and resubmit with correct content?**

Good care should always be taken prior to sending a submission, however, in the unlikely case that erroneous information was included in the submission package, please contact the EMA within hours, to request deletion from the review system. Retraction or deletion of a submission is dependent on the processing stage of that particular sequence.

**Q66. Which validation tool does EMA use? Which tool should we use to ensure the validation criteria is exactly the same?**

The EMA is using EURS validator. The TIGes validation rules should have been implemented in harmonised manner in all tools so applicants are free to choose which validation tool they prefer to use for their submissions.

**Q67. How do I ensure that I do not miss a submission deadline?**

When using the large file option, the Web Client sends an automatic receipt to the applicant as soon as the gateway has received the entire electronic submission file in eCTD format. The receipt is equal to the signature upon delivery by the courier and only confirms that the package has been received by the EMA. It does not confirm that a valid submission has been received. It is however, the timestamp in the receipt that is the time that confirms the delivery of the package to the agency. In the view of meeting the submission deadline the EMA must receive a technically valid package by midnight (23.59 hours) UK time on the day of the submission deadline. It is the responsibility of the applicant to ensure that a valid submission is provided to the agency.

Receipts are only provided when the large file option is selected; however, all submissions will receive an acknowledgement confirming the technical compliance of each submission. *We recommend that you use the large file option for all submissions to ensure you always receive a receipt.*

The timestamp of the automatic acknowledgement has to show that the eCTD file has been entirely and correctly received by the EMA before the expiration of the submission deadline (midnight).

Therefore it is recommended that the applicant sends the electronic submission file well in advance of the actual deadline. This is particularly relevant for submissions that are larger than 5GB.

## 6. Glossary

### **Term**

|                                      |   |
|--------------------------------------|---|
| Applicant                            | A pharmaceutical company or its agent that is submitting information in support of an <b>application</b>  |
| ESTRI Gateway Procedure              | Electronic Standards for the Transfer of Regulatory Information<br>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 <b>'sequence'</b>  |
| 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 Web Client 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 concerning Web Client/Gateway set-up or the transmission failures of files in the production or test environment please contact: [gatewaysupport@ema.europa.eu](mailto:gatewaysupport@ema.europa.eu)

If you have any questions concerning 'negative acknowledgement' of eCTDs (eCTD Validation Compliance checks) please forward your query or comment with the validation report to [eCTD@ema.europa.eu](mailto:eCTD@ema.europa.eu)



## Annex 1.

### Detailed examples of filenames for different application types

The use of Product Number H/C/xxxxxx is applicable after the Initial MAA is submitted to the EMA. Prior to the Initial MAA submission, Hxxxxxx is to be used, however only the last six numerical digits are to be taken into account.

This number is always available on the Eligibility confirmation letter as 'Product Reference'. E.g. if the Eligibility Confirmation Letter indicates Product number H0002271 please eliminate first digit (0) from H0002271 to reflect H002271 in the filename.

The above 6digit Product Number (or Product Reference) remains the same throughout the life-cycle of a product and it should be used regardless what type of submission is being transmitted.

There are examples below for different types of submissions for Wonderpill Hxxxx123 from MAH :

**Initial MAA:**

ESUBPXYZ\_ESUBPROD\_Hxxx123\_Wonderpill\_initial-maa\_0000.zip

**Response to LOQ/RSI/LOI :**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_supplemental-info\_00xx.zip

**Type IA variation application**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_var-type1a\_00xx.zip

**Type IB variation application - single**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_var-type1b\_00xx.zip

**Type IB variation application – grouping (several scopes)**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_var-type1b\_00xx.zip      same as for single

**Type II variation application - single**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_var-type2\_00xx.zip

**Type II variation - grouping of several scopes** (if it's a mixture of different variation types, the 'highest' is to be applied e.g. one scope is for type IB, two scopes are for type II a further scope for a type IA )

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_var-type2\_00xx.Zip

**Extension application:**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_extension\_00xx.zip

**Periodic Safety Update reports (including RMP):**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_psur\_00xx.zip

**Renewal application :**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_renewal\_00xx.zip

**Closing (decision) sequence for Type II :**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_supplemental-info\_00xx.zip

**Response to Validation Issues :**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_supplemental-info\_00xx.zip

**Follow Up Measure :**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_fum\_00xx.zip

**Withdrawal of MA or variation application (consolidation sequence):**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_withdrawal\_00xx.zip

**Worksharings and IA Groupings (IG)**

For Worksharing and Type IA Grouping (several products affected by the same Type IA changes/scope(s)) applicants are required to obtain a "EMEA/H/C/WSxxxx" or "EMEA/H/C/IGxxxx" number (via email to [PA-BUS@ema.europa.eu](mailto:PA-BUS@ema.europa.eu)) in advance of submitting their Work-sharing or IA Grouping.

**Worksharing:**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_WSxxxx\_00xx.zip

**Type IA Groupings (IGs)**

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_IGxxxx\_00xx.zip

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

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

Example:

ESUBPXYZ\_ESUBPROD\_HCxxx123\_Wonderpill\_WSxxxx\_00xx.zip on 01-01-20xx - technically valid submission

ESUBPXYZ\_ESUBPROD\_HCxxx12**4**\_Wonderpill\_WSxxxx\_00xx.zip on 01-01-20xx - technically valid submission

ESUBPXYZ\_ESUBPROD\_HCxxx12**5**\_Wonderpill\_WSxxxx\_00xx.zip on 01-01-20xx - technically valid submission

ESUBPXYZ\_ESUBPROD\_HCxxx12**6**\_Wonderpill\_WSxxxx\_00xx.zip on 01-01-20xx - technically **invalid** submission

ESUBPXYZ\_ESUBPROD\_HCxxx12**7**\_Wonderpill\_WSxxxx\_00xx.zip on 01-01-20xx - technically valid submission

**Resubmission:**

ESUBPXYZ\_ESUBPROD\_HCxxx12**6**\_Wonderpill\_WSxxxx\_00xx.zip on 10-01-20xx - technically valid submission

This means that the official submission date for this Work Sharing procedure will be **10**-01-20xx. This also means that if the re-submitted element will arrive after the submission deadline, it will follow the applicable timetable and not the missed one.