EMA eSubmission Gateway and Web Client: Questions and answers on Veterinary Applications

This question and answer document aims to address the commonly-asked questions and provide guidance regarding technical and practical aspects of the European Medicines Agency's eSubmission Gateway and Web Client for Veterinary electronic submissions

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Objectives of eSubmissions via the Gateway and Web Client

Q1. What are the eSubmission Gateway and Web Client?

The EMA eSubmission Gateway enables applicants to submit via a secure Internet connection. It is based on the ESTRI (Electronic Standards for the Transfer of Regulatory Information) gateway standard, which defines a secure data exchange service for regulatory information.

The Web Client is an online system which enables applicants to send their electronic 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.

It is possible to submit **all types of Veterinary submissions** (e.g. Initials, Post Authorisation Procedures, ASMF, Referrals etc.) via the eSubmission Gateway / Web Client from 1st of April 2014.

Q2. What is the objective of electronic Submissions via the EMA eSubmission Gateway/Web Client?

The Gateway and Web Client offer Applicants an easier and quicker way of submitting electronic submissions securely over the Internet. The service is already offered by the European Medicines Agency for Eudravigilance and has been available for the Human Centralised Procedure since 9th of January 2012 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 scope is extended to cover all Referral procedures, all **Veterinary submissions** and Paediatric submissions from 1st of April 2014.

The use of the Gateway / Web Client has significantly improved the Agency's efficiency in handling the submissions received and in making them available quickly within the Agency's review tool. Moreover, when using the Gateway / Web Client, the submission of hard-copy cover letter is **not** required.

Q3. Which types of applications can I submit via the eSubmission Gateway/Web Client?

From 1st of March 2014 eSubmissions Gateway / Web Client service is mandatory for all Human Centralised Procedure eCTD format applications for Human Products, e.g. new marketing authorisations, variations, renewals, PSURs, active substance master files (ASMF) and Plasma Master Files (PMF).

From 1st of April 2014 it will be possible to send all types of veterinary submissions to the EMA via the eSubmissions Gateway / Web Client.
The EMA will further extend the use of these tools to all other submission types which currently are outside the scope of the eSubmissions Gateway.

Q4. What does my company need to do in order to use the eSubmission Gateway / Web Client?

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

> *1) Online registration has been completed and account(s) have been activated.*
>
> *2) The filename conventions are described in the Annex 2 are used correctly when uploading zip files.*

Q5. How will the Web Client benefit veterinary SMEs and other veterinary applicants/MAH?

Currently applicants from veterinary companies who are not connected to the eSubmission Gateway and/or the Web Client can only submit applications by CD/DVD or Eudralink, together with a hard-copy signed cover letter. 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. This might be particularly relevant for registered SME applicants. As a result submissions will be faster for participating companies as the need for specialist delivery modes are eliminated. The submission of hard copy cover letter is <u>not</u> required when submitting via the Web Client.

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 in principle:

• 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 can the Veterinary applicants/MAH use the Gateway/Web Client?

The EMA launched the eSubmission Gateway on 9th of January 2012 and the Web Client solution on 15 January 2013, the service is extended for the use of Veterinary applicants on 1st of April 2014.

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 this free solution is available via the internet for all registered users.

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 eSubmission Gateway / Web Client on behalf of Marketing Authorisation Holders (MAHs)?

The eSubmission Gateway and the Web Client applications are 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. Can we use both the eSubmission Gateway and the Web Client to send submissions?

It is possible to register as a user for both systems. Applicants however, must **not** use both solutions for the same submission. Sending duplicate submissions may cause delays in start of the procedure.

Q12. How are Product Managers and other relevant staff informed that a Gateway / Web Client submission has been received and "clocked-in" by EMA's Veterinary applications team?

Upon successful transmission of a submission via the Gateway/ Web Client, the Vet Applications team receives a notification. The notification is then circulated to the relevant colleagues, including Product managers.

Please note that the EMA's internal registration and distribution processes are constantly evolving to accommodate new delivery methods.

Q13. 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 eSubmission Gateway

The EMA eSubmission Gateway enables applicants to submit all veterinary applications via a secure Internet connection. It is based on the ESTRI (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.

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 by the applicant and is therefore more suitable for lower transmission volumes.

A summary of the main features is shown below:

Feature	Web Client	eSubmission Gateway
Removes the need for submitting CDs / DVDs / Eudralink message / paper to the EMA	✔	✔
Allows the technical possibility (after relevant registration) to connect to other EMA Gateway communities		✔
Allows veterinary and VNeeS 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	✔	✔
Compliant with ESTRI (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 25GB	✔	✔

Q14. Do we have to use the eSubmission Gateway / Web Client for all submissions?

It is strongly recommended to use the eSubmission Gateway or the Web Client from 1st of April 2014 for all Veterinary submissions.

Veterinary submissions on physical media (CD/DVD) or via Eudralink with hard copy cover letter will continue to be accepted as an alternative method for the time being. However, it is essential that applicants only use one submission method and do not submit duplicate submissions on physical media, or Eudralink as this might cause a delay in processing the application.

Q15. Is it mandatory to use VNeeS format for all Veterinary eSubmissions sent via the Gateway/Web Client?

When applicable, yes, it is mandatory to use the VNeeS format for electronic veterinary submissions. For further details, please refer to the current version of the Guideline on eSubmissions for Veterinary Products on the Vet eSubmission website.

Archival file formats and maximum size

Q16. What archival file formats are available for submission via the Gateway / Web Client?

The submission package should be archived as a zip file (Encryption and Password should be disabled on the zip file). As soon as the submission package 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.

Q17. Does the applicant have to zip the files or does the software do it automatically before the submission is sent?

The applicant has to zip the files prior to sending them. The system does not accept packages that are not zipped.

***Q18. 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.

Q19. Is there a maximum size for a submission made via the Gateway/Web Client?

We have tested the eSubmission Gateway and Web Client up to 25GB (unzipped). If you have a submission bigger than 25GB, please contact us at esubmission@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.

Q20. Do we need to structure our folders within the zip file in a particular way?

You must ensure that the top level folder is a "root folder" in the zip file as shown below. It allows appropriate identification of the submission when validated in the Gateway / Web Client system.
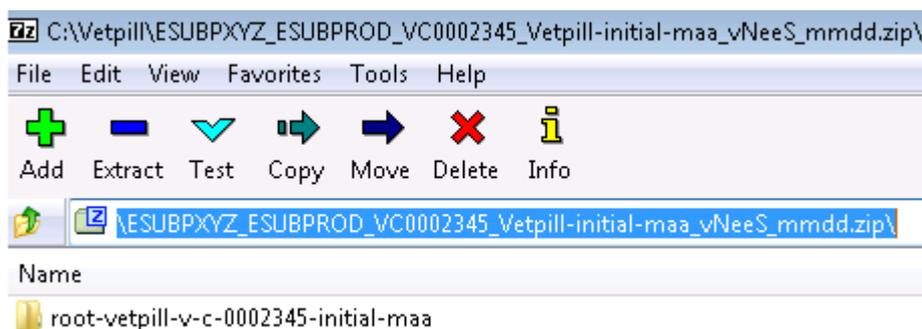
File naming conventions

(For further details and common examples please refer to Annex 2)

Q21. What is the file naming format for submitting electronic Submissions via the eSubmission Gateway/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
SenderRoutingId	Routing ID for Sender as registered by the Gateway, to route MDN receipt & Acknowledgement messages back to the sender.	Upper	ESUBPXYZ
ReceiverRoutingId	Routing ID for EMA's eSubmission Gateway Community, it's required for routing a transmission to its intended destination e.g. eSubmission Test and Production environments use "ESUBVAL" & "ESUBPROD" respectively.	Upper	ESUBPROD
EMA Product No for Centrally Authorised Veterinary Products	e.g. EMEA/V/C/0000000 (This must be a 7 digit number)	Upper	VC0000999 or V0011111 (Initial application)
Product Name and Procedures Type	Maximum 30 characters. See list of Submission types (for Veterinary submissions) below. Do not use an underscore between the product name and the procedure type	Upper / Lower. Lower	Vetpill initial-maa
Submission Date	Must be a four digit numeric value mmdd, for example 15th of March is 0315	N/A (should be numeric)	0315
.zip	.zip	Lower	.zip

Filename Example:

In the case of Initial MAA:

Initial MAA:

ESUBPXYZ_ESUBPROD_V0001234_Vetpill-initial-maa_vNeeS_mmdd.zip

ESUBPXYZ_ESUBPROD_VC0001234_==Vetpill-supplementary-info==_vNeeS_mmdd.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

Notes:

- The fourth part of the filename (==highlighted in yellow==) cannot have more than 30 characters, so if an application has got a long product name and long procedure type name, where the filename is likely to be over 30 characters, the name of the product or the name of the procedure should be shortened.

- Please note that the last part (sixth part) of the filename should be in the form of the date format mmdd. So for example for an application submitted on the 13 March 2014, the last part will show "0313".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 an underscore between the product name and the procedure type.

- 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.

Q22. What is the difference between Vxxxxxxx and VCxxxxxxx EMA product number that has to be used in the filenaming convention?

The Vxxxxxxx number is found in the Eligibility confirmation letter. This EMA product number consists of the letter V, followed by seven numerical digits. The VC number is only given after the application has been received by the EMA. This EMA product number contains letters VC followed by **seven** numerical digits. For the submission of a new MAA, the applicant should use VXXXXXXX (seven numerical digits) and for any subsequent submissions, use VCXXXXXXX (also seven numerical digits).

Example:

In the Eligibility confirmation letter V0001234

In your filename this will is V0001234

In subsequent submissions VC0001234

Q23. What is the file naming format for submitting Worksharing and IG (Type IA variations) applications? How should I submit Worksharing applications?

For Worksharing and IG (Type IA variations) (several products from the same MAH affected by the same changes/scope(s)), applicants are required to obtain a "EMEA/V/C/WSxxxx" or "EMEA/V/C/IGxxxx" number (via email to vet.applications@ema.europa.eu) in advance of submitting their Worksharing or IG procedure.

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 / IG (Type IA variations) are sent on the same day to ensure timely start of the procedure.

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

Filename Example:

Worksharing: ESUBPXYZ_ESUBPROD_VCxxxx123_<mark>Vetpill-WS-xxxx</mark>_vNeeS_mmdd.zip

IG (Type IA variations) Example: ESUBPXYZ_ESUBPROD_VCxxxx123_<mark>Vetpill-IG-xxxx</mark>_vNeeS_mmdd.zip

Please go to Annex 2 for further explanatory notes.

Q24. I received a 'failure' acknowledgment message; do I need to change my filename? Would using same filename create duplication?

If your 'failure' acknowledgement is the result of using incorrect file name, please ensure that filenaming conventions described in Annex 2 are followed and amend it accordingly.

Q25. How will the submission type in the file name affect validation? Will it lead to negative validation if incorrect submission type is used?

It is recommended that the proposed submission types from the Annex 2 are used, however it will not result in negative validation.
For further details on the filenaming conventions, please see Annex 2.

Connection and registration process

Q26. What is the connection and registration process required for sending submissions via the Gateway?

First-time users must first register online via the registration web page.

Once registered, test files must be sent for initial testing of connectivity in the External Compliance/Test environment before being enabled in the production environment.
To note: Applicants already registered for EMA's Eudravigilance (EV) Gateway community will have to re-register to use eSubmission gateway channel.

Once testing against the External Compliance/ Test environment is successful, the EMA will enable the applicant's Production profile and VNeeS submissions may be transmitted in the Production environment.

More guidance can be found under: http://esubmission.ema.europa.eu/esubmission.html

Q27. My company has multiple names (i.e. Pharma Company and Pharma Company Europe) – do I need to register both as separate companies?

There is no need to register them as separate companies; the same gateway identifier can be used for all companies from the same group.

Q28. We are a consultancy/service provider representing multiple Marketing Authorisation Holders (MAHs). Does each MAH need to register to use the eSubmission Gateway / Web Client?

It is not necessary for each MAH to register. We only require one registration for the consultancy only; there is no need to register for each client.

Q29. 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.

Q30. Can we have multiple users after the registration is complete?

Once the registration is complete and testing has been verified you do not need to register multiple users.

Q31. Can I only submit applications for products I have registered on the eSubmission Gateway / Web Client application form?

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

Q32. 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.

Q33. How long does it take to register?

The registration process can take up to 10 working days to be completed. It is crucial that the relevant technical information is provided to the EMA in order to complete the process.

MDN and Acknowledgements

Q34. What is the Message Delivery Notification (MDN)?

An automated Gateway MDN (Message Delivery Notification) message is sent to the applicant acknowledging receipt of the transmission. The MDN 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 technically valid (VNeeS) submission has been received.

Please note: If the MDN message is not received the Applicant should stop transmitting and immediately contact the EMA Gateway support. The eSubmission should not be sent repeatedly and automated repeated transmission must be avoided.

Q35. What is an acknowledgement?

Acknowledgements are provided for all Gateway and Web Client transmissions confirming that they have been received by the EMA. For failed submissions the error description can be found in the 'failure' acknowledgement (xml) and the submission has to be sent again.

Q36. What is the difference between an acknowledgement and a MDN (message delivery notification)?

The purpose of the MDN is to confirm that your submission has been delivered to the EMA (a bit like the signature provided to a courier delivering a package). Acknowledgements confirm that the submissions have been received by the EMA. The acknowledgement includes an error description.

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 24 hours to receive the acknowledgement. If you have not received this, please contact EMA's gateway support at gatewaysupport@ema.europa.eu.

Q37. Do we get MDNs (message delivery notification)/receipts and acknowledgements for all submissions sent via the Gateway / Web Client?

Yes, all submissions sent via the Gateway/Web Client will receive a MDN/Receipt and a separate acknowledgement (xml) message confirming the receipt of each transmission. It is only when a positive acknowledgement is received that you can be certain that your submission has been successfully received.

Q38. How long should we wait before attempting resubmission if the MDN has not been received?

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 24 hours depending of the size of the submission. If you have not received the MDN after 24 hours, please contact EMA's gateway support at gatewaysupport@ema.europa.eu.

Q39. Which receipt should the applicant/MAH archive, the MDN or the acknowledgement as the official timestamp?

The MDN 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 MDN 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.

Q40. If an MDN has been received does it mean that the EMA can open the submission successfully?

No, applicants sending Veterinary submissions must wait until they receive an acknowledgement confirming the receipt of the application.

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 24 hours to receive the acknowledgement. If you have not received this, please contact EMA's gateway support at gatewaysupport@ema.europa.eu.

It is strongly recommended to send a test submission in the test environment before using the Gateway / Web Client for the first time to confirm the receipt of the MDN and the Acknowledgement.

For Veterinary submissions you will receive MDN receipt, followed by an Acknowledgement.
The applicants should wait for the usual validation letter if this is normally received before proceeding with sending submissions to (Co)Rapporteur and other member states.

Q41. Why didn't I get an acknowledgement for the submission I sent via the Gateway / 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 or typos

- Please check with IT support (Security) to ensure that the firewall access has been allowed to the following:

   pgateway.ema.europa.eu:4081

   IP address 195.144.18.218

   A violation of above security rule will prevent the delivery of ACKs from EMA's gateway system.

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 24 hours to receive the acknowledgement. If you have not received this, please contact EMA's gateway support at gatewaysupport@ema.europa.eu.

Q42. Is there any specific technical configuration required to receive the MDN or the acknowledgment?

It is recommended to send a test submission in test environment to confirm the receipt of the acknowledgement prior to sending your first submission in production.

When using the eSubmission Web Client, the user must always select the *'send documents more than 10MB'* option to use "Large file applet". Note that receipts (MDN) are sent only when you use this option, and **this link will appear in the Web Client tool only with correct Java Version. The web trader's browser must have J2SE Java Runtime Environment (JRE) 1.5 or 1.6.** The web trader also must deploy **Java Cryptography Extension (JCE) Unlimited Strength Jurisdiction Policy Files 5.0 or 6.0.**

Q43. Our gateway has not been set up to receive acknowledgements. What happens with the acknowledgements you will be sending but not received by us? Do you follow the current workflow?

Applicants are encouraged to configure their systems so that acknowledgements are received. It is recommended to send a test submission to confirm the receipt of the acknowledgement and configure the Production environment accordingly.

Q44. 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. Dependent on the submission size and transmission queue it can take anytime between 5 minutes to 24 hours maximum. If you have not received the acknowledgement in this time you should assume that the application has **not** been received by the EMA.

Q45. Do I need to wait for the acknowledgement of the submission to be received before sending the next submission?

It is best to await acknowledgements rather than sending multiple submissions all at once.

Q46. What should we do if a negative acknowledgement is received?

You should carefully review the error report attached in the acknowledgement, make necessary changes in the filename and resubmit the package. Please only contact the EMA on esubmission@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 include the Acknowledgement when applicable.Please review Annex 2 to see the correct filenames for different procedure types.

Q47. 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.

Q48. Does the EMA identify the number of files and folders received, similar to what the FDA sends in their second acknowledgement receipt?

No, the EMA's Gateway does not yet have this feature.

Q49. Will the acknowledgement have a specific filenaming convention? Or will we just need to identify via partnership routing naming?

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

Q50. 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. Retraction or deletion of a transmission is dependent on the processing stage of that particular submission.

Common Technical questions

Q51. Do we need to inform the agency before sending a test submission?

There is no need to contact the EMA before sending test submission in the test environment. All applicants that have registered to use the Gateway / Web Client are also automatically registered to the External Compliance/Test environment.
The EMA strongly recommends new users to make full use of the test environment available before sending first submissions in the production environment.

Q52. What happens if the EMA eSubmission Gateway / Web Client is not responding? Is there a plan how to deal with downtime of the eSubmission Gateway service?

The EMA eSubmission Gateway / Web Client has been implemented as a high availability system. The eSubmission Gateway / Web Client service is included in the Agency's business continuity plan which foresees the recovery of the service in case of a disaster in less than 24 hours.

Downtime caused by planned maintenance periods will be announced 2 weeks before the planned maintenance for the production environment and 1 week before for the external compliancy test environment.

If you have to urgently send a submission and the eSubmission Gateway / Web Client is not working, please contact eSubmission@ema.europa.eu and provide your telephone number for a call back during office hours.

Q53. How will applicants know if there is a technical issue with their submission?

Users will receive correspondence from the vet applications team who will run the VNeeS checker and communicate issues to the users.

Q54. Is the DTD/Schema for the acknowledgement file available?

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

Q55. Which validation tool does EMA use? Which tool should we use to ensure the validation criteria is exactly the same?

The EMA is using VNeeS checker. For further information and latest version of the VNeeS checker, please see the [Vet eSubmission website.](#)

Technical questions relevant to eSubmission Web Client only

Q56. Is there any specific technical configuration required to receive the MDN?

When using the eSubmission Web Client, the user must always select the *'send documents more than 10MB'* option to use "Large file applet". Note that receipts (MDN) are sent only when you use this option, and **this link will appear in the Web Client tool only with correct Java Version JRE 1.5 or 1.6**

Always select the *'send documents more than 10MB'* option to use "Large file applet", Note that receipts (MDN) are sent only when you use this option, and **this link will appear only with correct Java Version JRE 1.5 or 1.6.** The web trader also must deploy Java Cryptography Extension (JCE) Unlimited Strength Jurisdiction Policy Files 5.0 or 6.0.

Q57. Are there any technical requirements for Web Client users?

The browser must have J2SE Java Runtime Environment (JRE) 1.5 or 1.6. This is required to run various applets within the user interface.

That guarantees the LFA (Large File Application applet) will work.

The web trader also must deploy Java Cryptography Extension (JCE) Unlimited Strength Jurisdiction Policy Files 5.0 or 6.0.

Q58. 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

Q59. 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:
For **Test environment (ESUBVAL)** allow access to:

vgateway.ema.europa.eu:4081
IP address is 195.144.18.238

For **Production *environment (ESUBPROD),*** allow access to:
pgateway.ema.europa.eu:4081
IP address 195.144.18.218

A violation of above security rule will prevent the delivery of Acknowledgements from EMA webclient.

Q60. 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.

Q61. 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.

Q62. 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.

Technical questions relevant to eSubmission Gateway only

Q63. Which Gateway solution is used by the EMA?

At the EMA we are using a product called Axway Synchrony Gateway Interchange (version 5.xx).

Q64. Which protocols should I use when transmitting eSubmissions via the EMA Gateway?

For information on Protocol types, please refer to the eSubmission website (http://esubmission.ema.europa.eu/esubmission.html).

Q65. Where can I obtain certificates to enable mutual authentication to the EMA Gateway? Does EMA recommend an RSA based algorithm application or a service to generate a public key?

The EMA provides its public key in a certificate to the companies, and the company provides its public key to the EMA. The company can purchase a certificate from recognised certificate providers, such as VeriSign, Thawte, Globalsign, etc. Most gateways provide the ability to generate a certificate which can also be used. The EMA's certificate is generated by the Axway Gateway. Your private key should never be made available to anyone.

Q66.What is the recommended asymmetric key length (RSA algorithm)?

2048 bits is the best choice for encryption key length.

Q67. What is the difference between AS2 and AS3 Gateway?

AS2 (Applicability Statement 2) is a specification about how to transport data securely and reliably over the Internet over http.

AS3 (Applicability Statement 3), is a standard by which vendor applications communicate over the Internet using File Transfer Protocol (FTP).

Q68. Where do I obtain the EMA Gateway certificate from?

External Compliance Testing Environment:

An encryption certificate is needed to complete the online registration. Please download the EMA root certificate from the Public Website of the European Medicines Agency: (http://esubmission.ema.europa.eu/esubmission.html).

Production Environment:

An encryption certificate is needed to complete the completed forms. Please download the EMA root certificate from the Public Website of the European Medicines Agency (http://esubmission.ema.europa.eu/esubmission.html).

General questions

Q69. Do I need to include a hard copy Cover Letter / Registration form with submission sent via the Gateway / 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 / Web Client server and the VNeeS submission is loaded into EMA's review tool, where all the information can be retrieved at a later stage as required.

Q70. What is the cost of the eSubmission Gateway for industry partners?

The cost depends on the complexity of the configuration but usually starts at €10-15.000. Included in this cost is the software licence for the Gateway and a number of days of consultancy for the installation/configuration of the Gateway. There may be additional costs purchasing and setting up the necessary hardware/servers.

Q71. Is it still required to send veterinary eSubmissions on hard media (CD/DVD) / Eudralink to the Rapporteur, Co-Rapporteur and all CVMP members for submissions in the Centralised Procedure when at the same time eSubmission Gateway / Web Client is used for submission to the Agency? Or do all CVMP members have access to the Gateway / 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.

There are number of NCAs who now accept Centralised Procedure submissions via the CESP channel. Please see the details on the CESP website.

Q72. Do we have to use the Gateway / Web Client for all submissions or is it possible to submit some via the Gateway / Web Client and some via the CD/DVD media/ Eudralink process?

For the time being, it is possible to use both, the Gateway /Web Client and submission via CD/ DVD/ Eudralink, but you must not use different submission modes for the same submission as this will cause delays in the handling of your application.

Q73. We are already set up as we have used the Gateway / Web Client before – do we still need to register?

Registration is required as e-Submissions has its own community of users, and is not a part of EVTEST or any other existing community. The eSubmission Gateway has its own transport URL and certificate.

Glossary

Term	Definition
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.
External Compliance Test Environment	External Compliance Test Environment is used to test the compliance of a new applicant from pharmaceutical industry with the EMA's eSubmission Gateway system
Production environment	Production environment is used for live production
Web-based client	A Web-based client/server network 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

Contact us

To register:

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

For technical queries and failures with regards to gateway set-up or Acknowledgements deliveries in the Test or Production environment:

gatewaysupport@ema.europa.eu

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