



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Gateway and Web Client – Training on the use of XML delivery files for Veterinary submissions

Webinar training on v1.0





Outline of Today's training session

- eSubmission Gateway and Web Client background and latest news
- Benefits of using XML delivery file
- Scope of the pilot
- How to create a delivery file
- Create delivery file screen DEMO / details
- Filenaming
- How to include delivery file in the submission
- Submission using the web client
- How to avoid problems
- Good to know
- Next release
- Gateway website
- Gateway support
- Useful links



eSubmission Gateway and Web Client background and latest news (1/2)

- The eSubmission Gateway and the [eSubmission Web Client](#) are electronic submission channels that allow the applicants to submit documents supporting all types of applications for human and veterinary medicines to the Agency securely over the internet
- The EMA is introducing use of XML delivery files for all procedure types following a successful implementation of XML delivery files for human PSUR submissions.
- The XML delivery files are replacing the filenaming conventions for eSubmission Gateway. Both are used to provide submission 'metadata' to allow automated feedback to the applicant on the status of the submission. Submissions for human domain also contain an automated technical validation check and feedback to applicant, automated upload to the EMAs review system and sharing the submissions with the network via the Common Repository and PSUR Repository. For veterinary submissions some of these additional features will be implemented in future.
- The use of XML delivery files will replace the filenames for all submissions over a period of time.



eSubmission Gateway and Web Client background and latest news (2/2)

- An updated version of the XML delivery file creation user interface will be introduced around 1 July 2016 to comply with the updated eCTD EU Module 1 specification which introduces concept of 'submission type' and 'submission unit' – even though the Veterinary domain does not use eCTD this change is also implemented on the Veterinary side to keep the user interface harmonised and to provide additional information on the details of the submission to support the related business processes.
- Mandatory use of the eSubmission Gateway for Veterinary submissions will commence from 1 January 2017. Mandatory use of the XML delivery file for Veterinary submissions will be communicated at later stage.



Benefits of using XML delivery files

- Use of delivery files is implemented to improve and **harmonise** the submission process for all applicants;
 - There is **no need** to use **filenaming** conventions when delivery files are used
 - There is **no need to include receiver and sender routing ID** information in the delivery file – this will be automatically detected when the submission is sent via the Gateway (production or test)
 - **Built in business rules** guides the users to make correct selections
 - Product selection from EMA product database where applicable
 - Simple, intuitive user interface
 - Reduces errors



Veterinary

- Annual Re-assessment
- Corrigendum
- Extension
- Initial MAA
- Lifting of suspension
- Post-Authorisation Measure (PAM, including Condition of MA)
- Reformat of dossier
- Renewal
- Risk Management Plan (RMP)
- Specific Obligation
- Supplemental info (including Responses to LoQ and LoOI)
- Transfer of MA
- Type IA variation (single and IG)

- Type IB variation (single and WS)
- Type II variation (single and WS)
- Withdrawal
- Referrals
- Active Substance Master File (ASMF)

Currently out of scope - continued use of the existing filenaming conventions

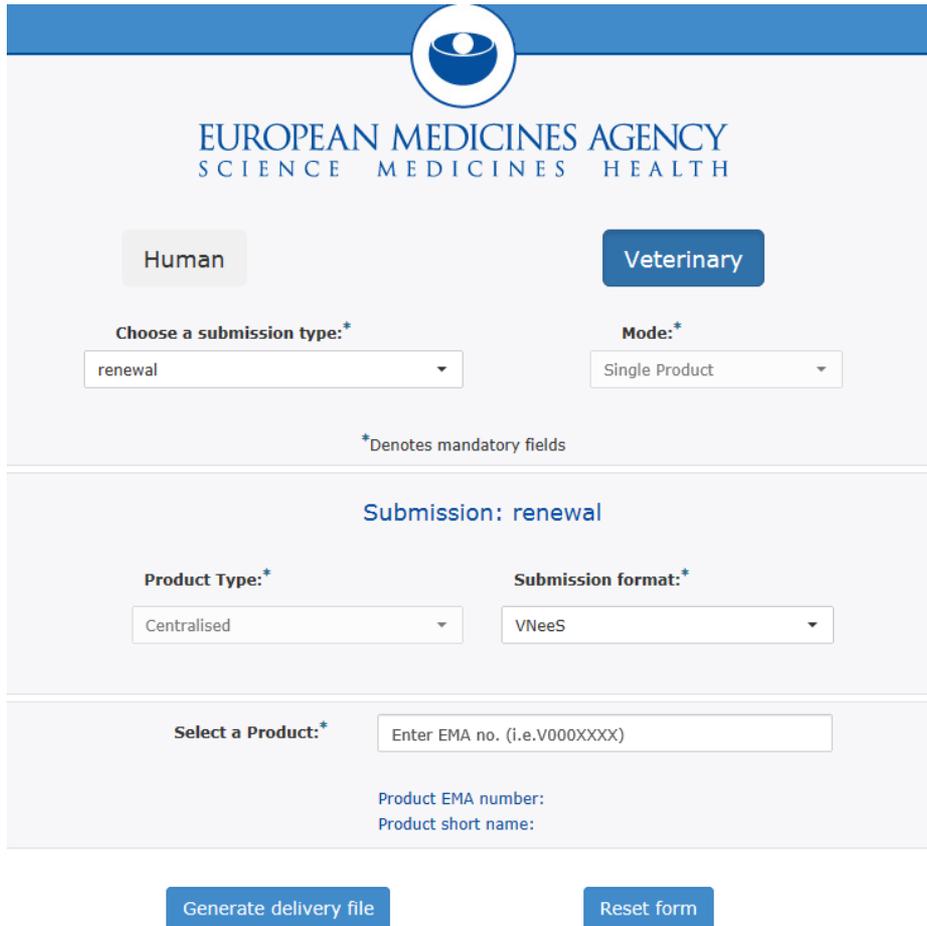
- Veterinary MRL submissions
- Veterinary PSURs



How to create a delivery file

- Each submission requires its own delivery file and submission via the eSubmission Gateway – as previously using the file naming conventions.
- No change for the submission rules

Create delivery file screen (1/9)



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Human Veterinary

Choose a submission type:*
renewal

Mode:*
Single Product

*Denotes mandatory fields

Submission: renewal

Product Type:*
Centralised

Submission format:*
VNeoS

Select a Product:*
Enter EMA no. (i.e.V000XXXX)

Product EMA number:
Product short name:

Generate delivery file Reset form

The screen is divided into different sections:

The user will be required to complete each field in each section.

The required data input depends on the selected submission type.

Choose a submission type:*

initial-maa

va

CAP

var-type1a

var-type1b

var-type2

Mode:*

Single Product

Single Product

IG(grouping of variations)

WS

Select the **submission type** by **typing** any part of the regulatory activity name in field or **select** the value from the **dropdown** list

Supplemental information (e.g. RSI, LoQ, LoOI) should be used for all submissions after the **initial** submission for any regulatory activity, for example validation responses, responses, comments, closing and consolidation sequences.

Depending on the selected **Submission type** available 'mode' will be different.

Business rules will guide the user to select the correct mode.

Product Type:*

Centralised ▼

Centralised

Centralised/National

Depending on the **Submission type** and **mode** different options are available for product type. Where selection is possible, please ensure that you have selected the correct option in order to reveal the correct product selection.

Submission format:*

VNeS ▼

VNeS

Other

Depending on the **Submission type, mode** and **product type** different options are available for **submission format**.

Where selection is possible, please ensure that you have selected the correct option to support the processing of the application at the EMA.



Select a Product:*

Generate delivery file

- V0002781
- V0004185
- V0002645
- V0002804
- V0002626
- V0002759
- V0002286

Select a Product:*

Generate delivery file

- Nobilis IB4-91-EMEA/V/C/000036
- Nobilis OR inac-EMEA/V/C/000062
- Nobilis Influenza H5N2-EMEA/V/C/000118
- Nobilis IB Primo QX-EMEA/V/C/002802

Product selection is linked to the **procedure type** and depending on the procedure type a different list of products is available for selection.

Procedures containing **Centrally Authorised Products** are connected to an EMA product database, Siamed, through which all CAPs are retrieved.

To search and select a product, start typing **any part** of the **EMEA product number** or the **product name**.

For **initial MAA application** you should search for the number in format V0001234. For any subsequent submissions for that same procedure or for any other post-authorisation activity the product number is in format V/C for Veterinary products. When veterinary product is selected from the list for initial MAA submission, the product name is **not** shown to provide data protection for the applicant.

The EMA product number is available on the Eligibility Confirmation Letter as 'project number' e.g. V0001234.

This Project Number (known as Product Reference for Human applications) remains the same throughout the product lifecycle and it should be used regardless what type of submission is being transmitted.



Select worksharing number:*

Nothing selected

ws/00

WS/0009

WS/0025

WS/0046

In order to facilitate the planning of a worksharing procedure, MAHs are advised to inform the Agency at least 3 months in advance of the submission of a variation or group of variations to be subject to a worksharing procedure, together with an explanation as to why the holder believes that a worksharing procedure is suitable, by means of a 'letter of intent'.

More information on '[Worksharing](#)' can be found from the Regulatory Post-Authorisation Guide (search in 'human' or 'veterinary' guidance as appropriate).

A [letter of intent template](#) must be filled and sent to vet.applications@ema.europa.eu to obtain the WS number.

Please note that requesting the worksharing arrangement in advance is mandatory. The WS number has to be included in the xml delivery file.

Select the worksharing number by typing any part of the WS number in the search field.

The number is provided in format WS/0012

IG (Grouping of variations):

Please note that requesting this high level number in advance is mandatory for submissions sent via the eSubmission Gateway or Web Client since this number has to be included in the xml delivery file.

This 'high-level' procedure number can be obtained from the Agency shortly before submission by sending your request with a copy of the draft cover letter to:
[vet.applications@ema.europa.eu](mailto:veter.applications@ema.europa.eu).

More information on '[Grouping of variations](#)' can be found from the Regulatory Post-Authorisation Guide (select 'human' or 'veterinary' as appropriate).

Select the IG number by typing any part of the IG number in the search field.

The number is provided in format IG/0012

Select grouping number:*

Nothing selected

00|

IG/0016

IG/0027

IG/0042

Referrals Article *

Nothing selected ▾

- Article13
- Article30(3)
- Article33(4)
- Article34
- Article35
- Article45
- Article78

Referrals:

Select the referrals Article from the list of referrals shown in a dropdown menu.

The **product type** should be either 'Centralised' or 'National' depending on the type of referral selected. For Article 45 procedure, only Centralised products are possible.

Enter the EMA referral number in the format shown below, the product or referral name and the MAH name in the **free text field**.

Referral: *

EMA Referral Number: V-A-123

Product/referral name: *

MAH Name: *

Known issue: product type field erroneously shows also a 'Centralised/National' option, but it will be removed as a fix by Friday.

Create delivery file screen - ASMF (8/9)



Choose a submission type:*
asmf

Mode:*
various CAPS
Single Product
various CAPS
various CAPS and NAPs

*Denotes mandatory fields

Submission: asmf

Product Type:*
Centralised

Submission format:*
VNeoS
VNeoS
Nees
Other

Select ASMF:*
Enter ASMF id. or substance name

Select ASMF:*
sev

EMEA/ASMF/02742-SEVOFLURANE

Select a Product:*
sevoflo-EMEA/V/C/000072

SevoFlo-EMEA/V/C/000072

For ASMF submissions indicate in the 'mode' field if the submission concerns a single product, various CAPs or various CAPs and NAPs.

For ASMFs submitted in support of veterinary products, the ASMF format can be either in VNeoS or NeoS (CTD). If your ASMF was submitted on paper but you are submitting a convenience copy electronically, you can choose "Other" as submission format.

Enter the ASMF number by typing in the search field any part of the ASMF number or the substance name. The more you type the more the list is filtered.

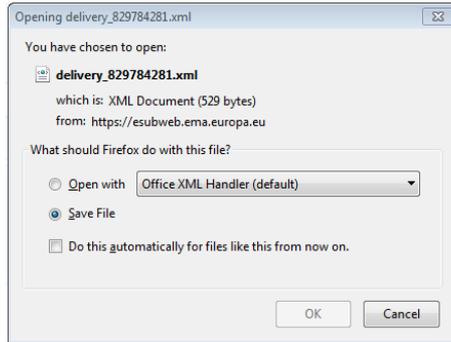
Select a CAP by typing any part of the EMEA product number. All ASMF submissions must be related to a CAP. If the submission relates to multiple CAPs or multiple CAPs and NAPs always select a CAP as the lead product.

Create delivery file screen (9/9)



Generate delivery file

Reset form



Save the xml delivery file in a named folder or a location where you can easily identify it especially if you are creating multiple delivery files for associated submissions.

To proceed click the 'Generate delivery file' button or 'Reset form' to clear the form to prepare a new delivery file for different procedure.

All delivery files are created with unique name. An example of the **unique** name is: delivery_123456789

It is possible to **rename** the delivery file. The only requirement with renaming is that the filename of the **delivery file must** contain word '**delivery**'. The number of characters is not restricted.

The saving of the delivery file is different depending which browser you use!

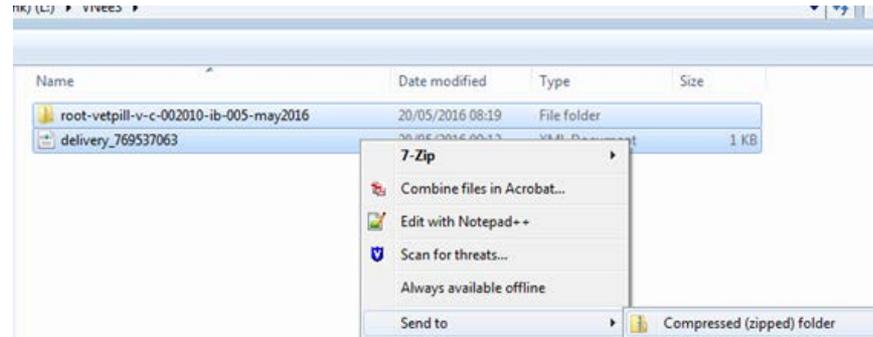




- Submission **metadata is provided via XML delivery file**, however package should ideally have a **meaningful** name (for submission support and archiving purposes)
- File names **will not be validated** for submissions via the Gateway
- File name examples:
 - VC000999_Vetpill.zip
 - VC000999 Vetpill responses.zip
- There is no requirement for underscores or spaces.
- Additional information e.g. 'responses' can be included in the file name
- Folders inside the zip containing submissions (e.g. root-vetpill-emea-v-c-000123-ib-001-june2016) should follow the VNeS guideline if relevant for your submission type.

How to include delivery file in the submission (1/3)

- To ensure that the submission is successful it is important to place the xml delivery file in the correct place in the folder structure and to ensure that the structure is not superfluous i.e. it should not contain additional empty folders on top level.
- When creating the zip, ensure that you only have the submission folder (e.g. root-vetpill-emea-v-c-000123-ib-001-june2016) and the xml delivery file in a folder -> create the zip

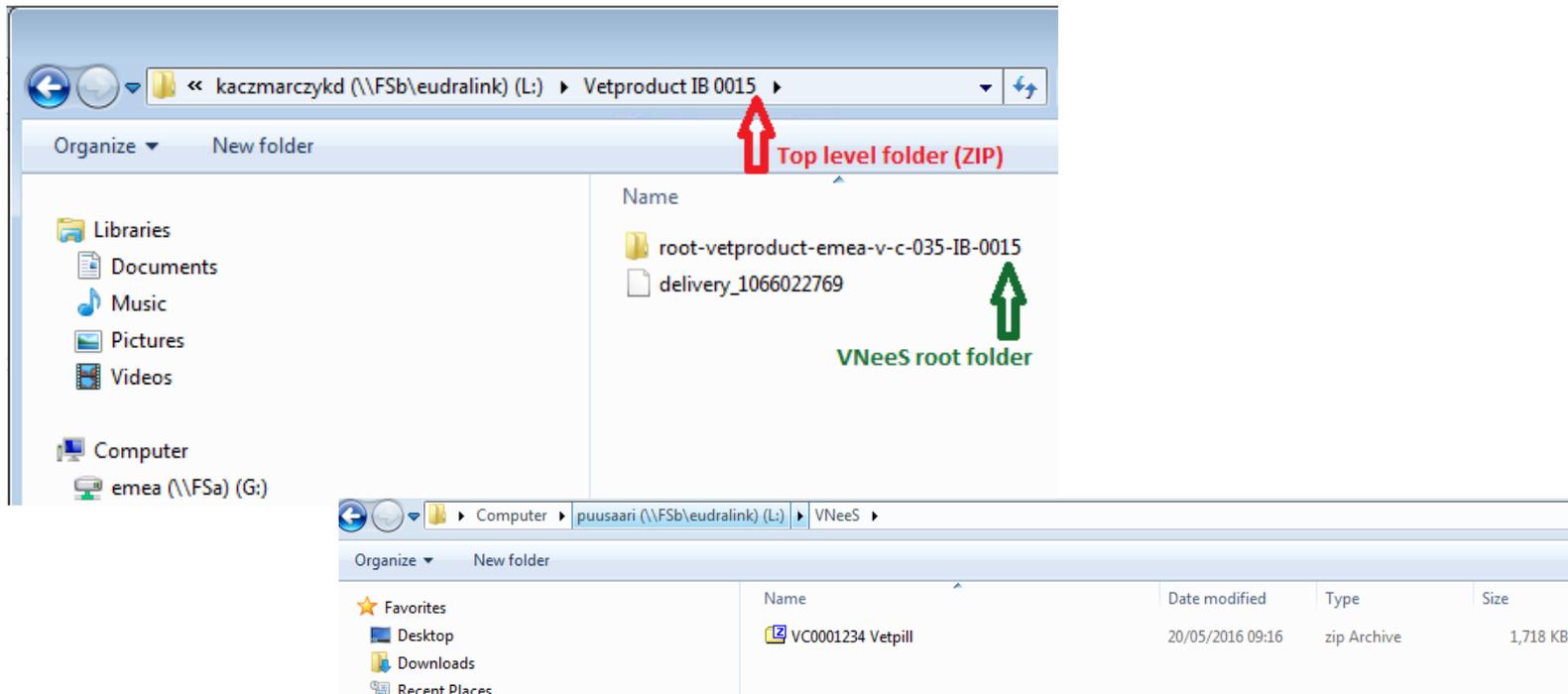


- Check that the zip file only contains the submission folder and the delivery file and that the zip is not placed inside another folder
- You can rename the zip to give it a simple, meaningful name. The zip package filename is not checked by the system but may help identifying the submission in case you experience technical problems and require assistance

How to include delivery file in the submission (2/3)



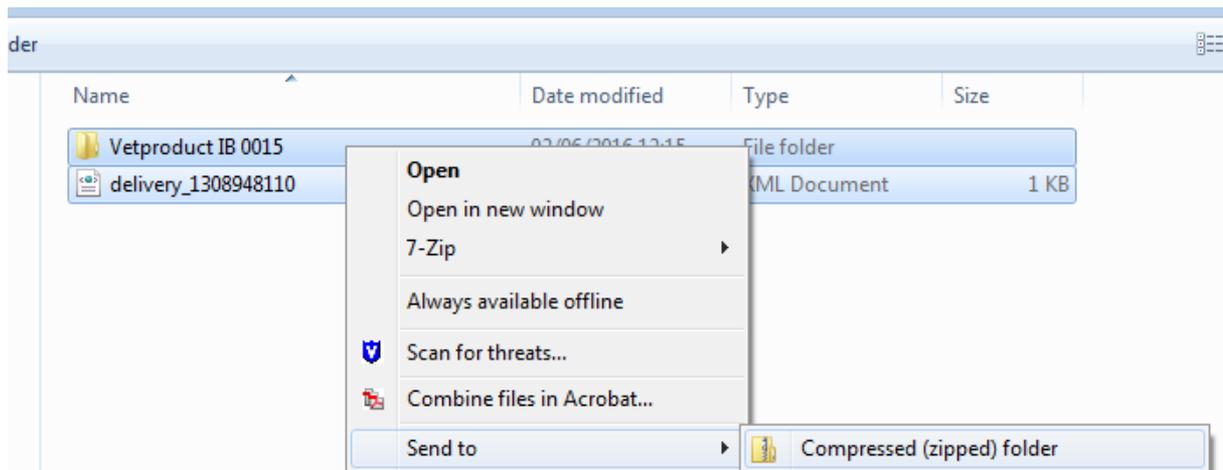
- Ensure that the xml delivery file is placed in the top level folder, in the same level as the submission folder. Both the submission folder and the xml delivery file must be in the top level folder – ensure that the folder structure is not superfluous as this will cause a rejection – if there are additional folders in the structure the Gateway Filehandler cannot recognise the delivery file and the submission will fail.



How to include delivery file in the submission (3/3)



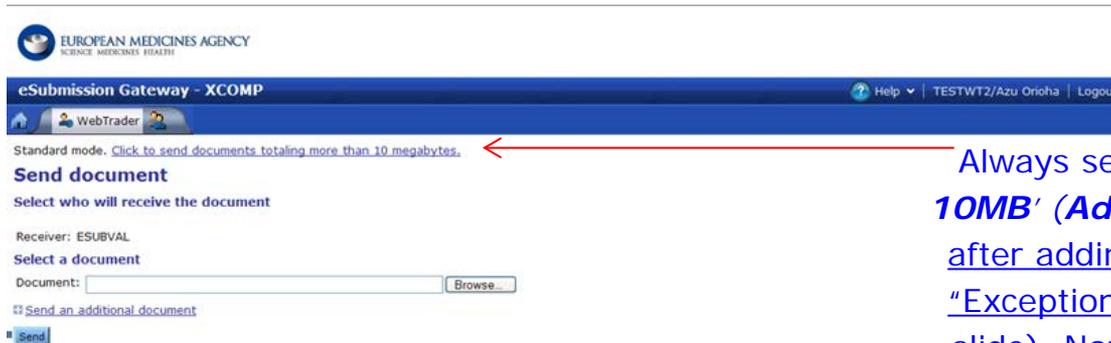
- For some small veterinary submissions to the Agency such as small variations or PAMs, it is possible for the whole submission to be provided in a single PDF file. In this case, place the single file in a folder with a meaningful name (no restrictions). When creating the zip, ensure that you only have the submission folder and the xml delivery file in a folder -> create the zip



1. Ensure you are using the correct version of Java (version 1.5.0.15 or higher)
2. Ensure you have created a [XML delivery file](#) and inserted it inside the zip package
3. Logon with the credentials supplied in communication from the registration team

Details for eSubmissions web client

eSubmissions webclient url:
User ID: ESUBPEMAPSUR-admin
proposed password:



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eSubmission Gateway - XCOMP Help | TESTWTZ/Azu Orioha | Logout

WebTrader

Standard mode. [Click to send documents totaling more than 10 megabytes.](#)

Send document

Select who will receive the document

Receiver: ESUBVAL

Select a document

Document:

[Send an additional document](#)

Always select the '**Send documents more than 10MB' (Advanced Mode)**. This [link will appear only after adding the eSubmission gateway URLs in the "Exception Site List" in Java Console](#) (refer to next slide). Note that Acknowledgements are delivered only when you use the Advanced Mode.

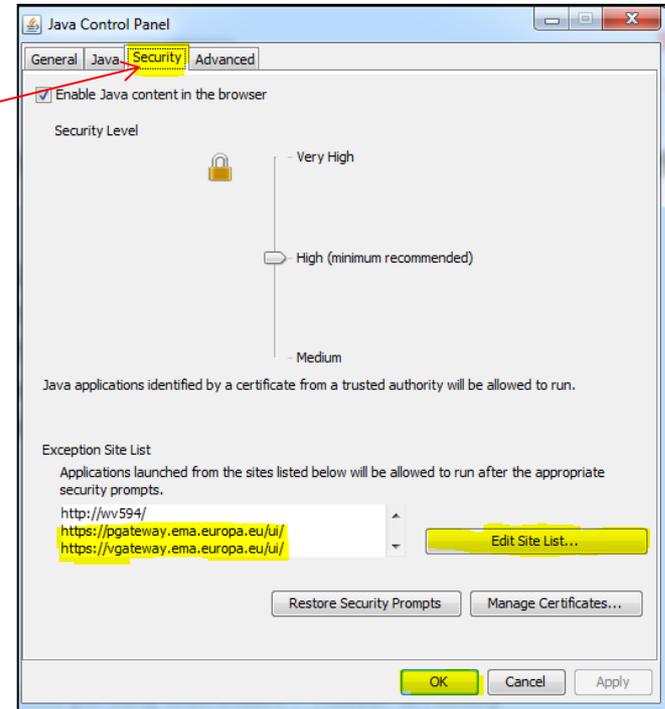
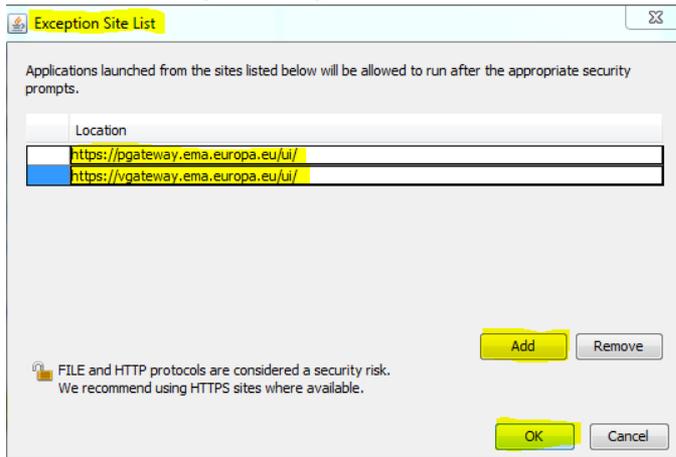
Submission using the Web Client (2/2)

To use the Webclient, **Add eSubmission Gateway Sites in the Exception Site List in the Java Console**

To note that you'll need 'Local Administrator Rights' to configure those settings.

1. Go to **Start Menu** and click on **Control Panel**
2. Click on **Java**
3. Go to the **Security tab**
4. Click the '**Edit Site List...**' button
5. Add following 2 URLs in the "Exception Site List":

- <https://pgateway.ema.europa.eu/ui/>
- <https://vgateway.ema.europa.eu/ui/>





- Only one package and delivery file should be included per zip file
- Always use the “Advanced Mode” for **all** transmissions via the Web Client, also for submissions smaller than 10MB to receive the receipts and acknowledgements from the eSubmission Gateway / Web Client
- If you have any queries/issues/concerns regarding the use of the delivery files, please contact the EMA IT Service Desk: <https://servicedesk.ema.europa.eu>
- There is no change to how the eSubmission Gateway is used
- VNeedS **validation** should be done **prior** to the zipping the submission folder and the delivery file together. The delivery file should not be validated.



- You may generate the delivery file as many times as you wish and rehearse creating delivery files for any procedures without any impact to EMA. The EMA does not receive the delivery files unless they are included in the submission package that is sent via eSubmission Gateway / Web Client
- It is not possible to 'group' different submissions types for example variation and renewal – each submission type requires its own delivery file and submission – there is no change to this in comparison to using filenaming conventions
- The **Receipt** is sent once the submission has been successfully received by the EMA Gateway Web Client. It is a simple text file with reception timestamp and is comparable to 'courier signature'. Receipt is sent only when using the "Advanced Mode".
- The final "**Acknowledgement**" is an **xml file** sent after the system has completed processing the submission. It contains the result of the validation (SUCCESS or FAILURE). In case of a failure, a detailed description of the error is included in it.
- Depending on the submission size and Web Client Gateway queue, both automated messages can take anything between 5 mins ~ 24 hours for the delivery back to sender
- The eSubmission Gateway **does not** replace CESP for National, MRP and DCP submissions. For Centralised veterinary submissions, the use of Gateway only covers submission to the EMA.

- Amendment of Submission Type to align with the [updated eCTD EU M1](#) (submission type and submission unit) – even though the VET submissions do not follow eCTD this change is introduced also for vet submissions to harmonise the process and to provide more metadata for future automation

Submission type	Submission unit
MAA	Initial
MAA	Validation-response
MAA	Responses
MAA	closing

Next release – preview to the main change

HumanVeterinary

Choose a submission type:*

Choose a Submission-Unit*

initial

- No selection
- initial
- validation-response
- response
- additional-info
- closing
- consolidating
- corrigendum
- reformat

Mode:*

Product

Submission format:*

Select a Product:*

Product EMA number:

Product short name:

Generate delivery fileReset form



Gateway web site

eSubmission Gateway and Web Client:

<http://esubmission.ema.europa.eu/esubmission.html>

- Links to the create delivery file UI and the Web Client
- User documents
- Multimedia tutorials
- Training dates
- Who to contact

Additional veterinary-specific information is also published on the Veterinary eSubmissions website: <http://esubmission.ema.europa.eu/tiges/vetesub.htm>



Gateway Support

- Technical validation issues (e.g. missing or 'Failure' Acknowledgements): <https://servicedesk.ema.europa.eu>
- Gateway registration queries: <https://servicedesk.ema.europa.eu>
- Use of the EMA **service portal** <https://servicedesk.ema.europa.eu>



- **Gateway Registration Documentation** (contact info, forms, guidance documents): <http://esubmission.ema.europa.eu/esubmission.html>
- **Gateway Registration team:** <https://servicedesk.ema.europa.eu>
- **Technical issues during webclient set-up:** <https://servicedesk.ema.europa.eu>
- **Technical validation issues** (e.g. 'Failure' Acknowledgements): <https://servicedesk.ema.europa.eu>
- **EU Guidance on VNeS:** <http://esubmission.ema.europa.eu/tiges/vetesub.htm>
- **EU Guidance on NeS:** <http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html>
- **Dossier Requirements for veterinary CAPs:**
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/11/WC500014483.pdf



Thank you for your attention

Further information

<https://servicedesk.ema.europa.eu>

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