



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mandatory use of eSubmission Gateway for all veterinary submissions to EMA

Webinar for Industry

Presented by Kristiina Puusaari on 1 December 2016

An agency of the European Union



eSubmission Gateway and Web Client background and latest news

- Background and news
- Changes in vet submission
- Mandatory use – extent of change

Submission using XML delivery file

- Filenaming vs. XML delivery
- Benefits of using XML delivery files
- Scope of the system

How to use XML delivery:

- How to create a delivery file
- Create delivery file screen DEMO –MRLs and vet PSURs
- Filenaming

- How to include delivery file in the submission
- Submission using the Web Client

Avoiding problems

- How to avoid problems
- Good to know
- Gateway website
- Gateway support
- Useful links



eSubmission Gateway and Web Client background and latest news

Mandatory date for all submissions to EMA – 1 Jan 2017



- 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 extending the mandatory use of eSubmission Gateway to all Veterinary submission types following successful mandatory use for Human submissions in 2014.
- Use of XML delivery files has been introduced for all procedure types following a successful implementation of XML delivery files for human PSUR submissions. The final new submission types for MRLs and veterinary PSURs will be introduced on Monday 5th December 2016
- The XML delivery files replace the filenaming conventions for eSubmission Gateway. They 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

- An updated version of the XML delivery file creation user interface will be introduced on 5 December 2016 – making it possible to generate an XML delivery file instead of using filenaming conventions for **Maximum Residue Limits (MRL)** and for veterinary **Periodic Safety Update Reports (PSUR)** submissions
- **Mandatory use of the eSubmission Gateway for all Veterinary submissions will commence from 1 January 2017**
- The use of XML delivery files is strongly recommended for all Veterinary submissions
- The use of the XML delivery file for Veterinary submissions will become mandatory on 1 April 2017. The Statement on Intent will be published on the [eSubmission website](#) shortly
- [Statement of Intent for the extension of the Common Repository for Veterinary submissions](#) has been published on the EMA website

Time	Milestone	Available material on eSubmissions website:
April 2014	eSubmission Gateway extended to all veterinary submissions – use of “filenaming convention”	Announcement EMA eSubmission Gateway and Web Client - extended scope Questions and Answers on Veterinary Gateway Applications - eSubmission Gateway and Web Client Error codes Annex 2 - A guide to filenaming convention
May 2016	XML delivery technology pilot launched for majority of veterinary procedural submissions (excluding supplementary information, MRLs and PSURs)	User guide to XML delivery file creation Recording - Training on the use of XML delivery files for Veterinary submissions (03.06.2016) Presentation - Training on the use of XML delivery files for Veterinary submissions (03.06.2016)
July 2016	The XML delivery pilot extended to submissions of all types of supplementary information by introduction of an additional ‘submission-unit type’ functionality	Updated User guide to XML delivery file creation What’s new in XML delivery – presentation for veterinary applicants Presentation from the Training on the use of the XML delivery files for submissions via eSubmission Gateway / Web Client (21. 07. 2016) Recording from the interactive Q&A session on the use of the updated XML delivery files for submissions via eSubmission Gateway / Web Client (21.07.2016) Presentation from the interactive Q&A session on the use of the XML delivery files for submissions via eSubmission Gateway / Web Client (25 & 26. 07. 2016) Recording from the interactive Q&A session on the use of the updated XML delivery files for submissions via eSubmission Gateway / Web Client (26.07.2016)

- The only change is that submissions to EMA **can no longer be accepted via CD/DVD/Eudralink** for all vet procedure types. There are no changes to the other aspects of each of the procedure type:
- All Veterinary submissions are covered by the new mandatory use:
 - Initial marketing authorisation (MA) and extension applications;
 - Applications for variations to the MA, renewals, transfers, annual reassessments, post-authorisation measures and other post-authorisation applications;
 - Veterinary referrals, including Article 45, assessed by the CVMP;
 - Maximum Residue Limits (MRL) applications;
 - Submissions of new or updated Active Substance Master Files (ASMF) in relation to veterinary centrally authorised products; and
 - Submission of Periodic Safety Update Reports (PSURs) for veterinary centrally authorised products



- Only submission to EMA is affected
- For submission to each National Competent Authority, current submission channels still apply as per available guidance:

25 November 2016
EMA/466102/2007-Rev.28
Veterinary Medicines Division

Dossier requirements for submission of marketing authorisation and maximum residue limit (MRL) applications to the European Medicines Agency to members of the Committee for Medicinal Products for Veterinary use (CVMP)

SOP/V/4023 – Annex I
August 2016
Veterinary Medicines Division

Standard operating procedure for management of periodic safety update reports (PSURs) for centrally authorised veterinary medicinal products: Annex I – contact details of national competent authorities (NCAs) for PSUR submission



Submission using XML delivery file

To replace filenaming conventions

File naming:

October 2016
EMA/120761/2014 Rev.2

Annex 2

Note: XML delivery files should now be used for all submissions via the eSubmission Gateway

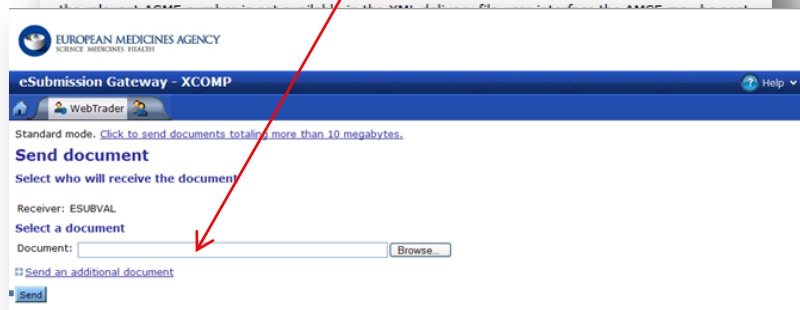
Detailed examples of filenames for e-Submission Gateway/Web Client submissions for those veterinary application types for which the XML delivery files are currently not available

Filename example for submission of MRL and PSUR for Vetpill VCxxxx123:

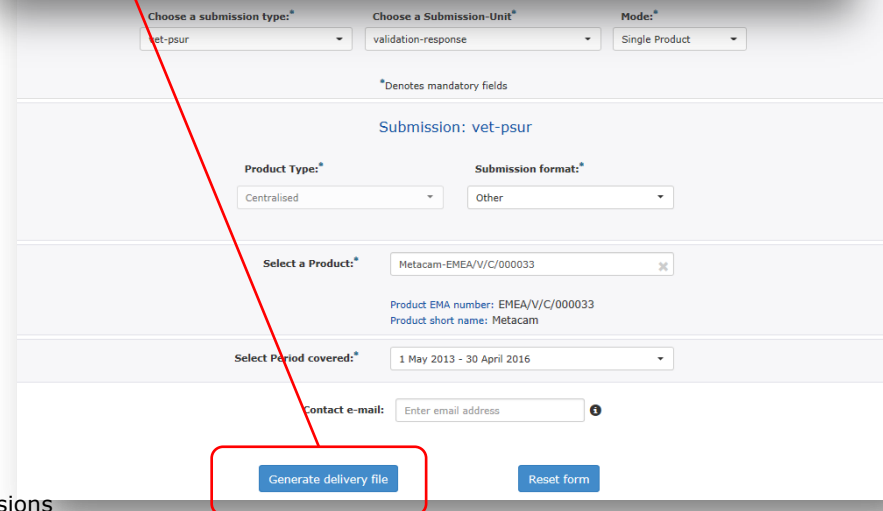
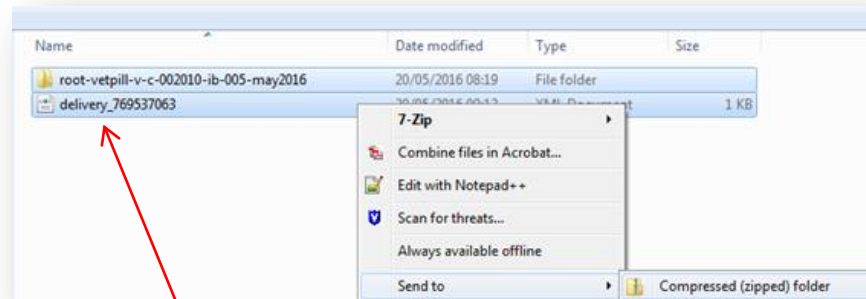
ESUBPXYZ_ESUBPROD_VCxxxx123_Vetpill_VNeeS_mmd.zip

Active Substance Master File (ASMF):

XML delivery files can be used for majority of ASMF submissions. In the exceptional case where



XML delivery:





- 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** guide the users to make correct selections
 - Product selection from EMA product database where applicable
 - Simple, intuitive user interface
 - Reduces errors
 - Will enable automatic processing and is a prerequisite to extend the Common Repository to veterinary submissions coordinated by EMA

Veterinary submission types

- Annual Re-assessment
- Article-45
- Extension
- Lifting of suspension
- MAA
- Post-Authorisation Measures (PAM)
- PASS
- Reformatting/baseline submissions*
- Renewal
- Risk Management Plan (RMP)
- Transfer of MA
- Type IA variation (single and IG)
- Type Iain variation (single and IG)
- Type IB variation (single and WS)
- Type II variation (single and WS)
- Withdrawal
- Referrals
- Active Substance Master File (ASMF)

New (from 5 Dec 2016):

- MRL submissions
- Veterinary PSURs

Covering all submission units;

- Initial
- Validation response
- Response
- Additional information
- Closing
- Consolidating
- Corrigendum
- Reformat*



How to use XML delivery file

Demonstration of new functionality




- Each submission requires its own delivery file and submission via the eSubmission Gateway or Web Client – as previously using the filenaming conventions.
- No change to the submission rules or formats
- Guidance on creation of XML delivery files for majority of submissions (except MRLs and PSURs) is already available on the [Veterinary eSubmission Website](#):

EMA eSubmission Gateway/ Web Client for Veterinary Procedures

- [User guide to XML delivery file creation \(25.07.2016\)](#)
- [What's new in XML delivery – presentation for veterinary applicants \(25.07.2016\)](#)
- [Presentation from the Training on the use of the XML delivery files for submissions via eSubmission Gateway / Web Client \(21. 07. 2016\)](#)
- [Presentation from the interactive Q&A session on the use of the XML delivery files for submissions via eSubmission Gateway / Web Client \(25 & 26. 07. 2016\)](#)
- [Recording from the interactive Q&A session on the use of the updated XML delivery files for submissions via eSubmission Gateway / Web Client \(21.07.2016\)](#)

- Here we will focus on submission of MRL applications and veterinary PSURs



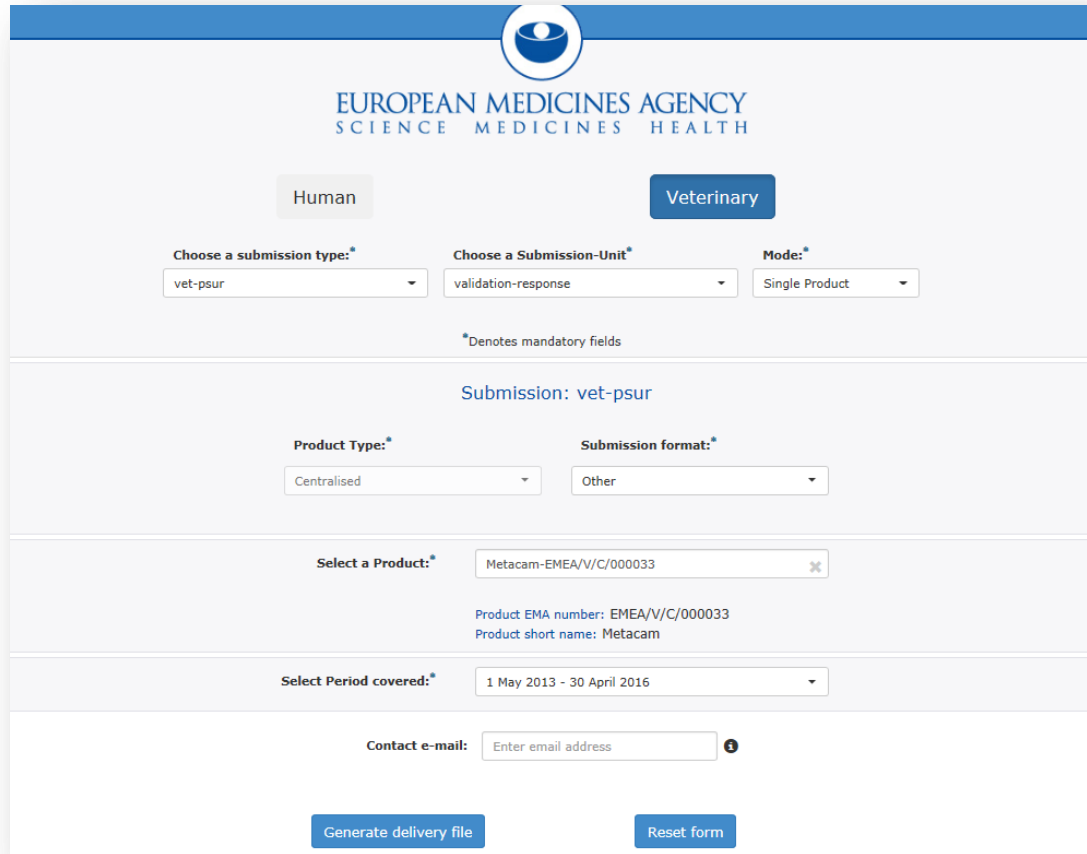
The screenshot shows the 'Create delivery file screen' for the European Medicines Agency. The header features the EMA logo and the text 'EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH'. Below the header, there are two buttons: 'Human' (grey) and 'Veterinary' (blue). Underneath, there are two dropdown menus: 'Choose a submission type:' with 'MRL-full' selected, and 'Choose a Submission-Unit:' with 'No selection' selected. A note below these menus states '*Denotes mandatory fields'. The next section is titled 'Submission: MRL-full'. Below this, there are three input fields: 'Select Substance:*' with a text box containing 'Enter substance name', 'Submission format:*' with a dropdown menu showing 'VNeoS', and 'Procedure number:*' with a text box containing 'Enter procedure No.'. At the bottom, there are two buttons: 'Generate delivery file' (blue) and 'Reset form' (blue).

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.

DEMO 1: Generating XML delivery file for an MRL submission



The screenshot shows the 'Create delivery file' screen for a Veterinary submission. The page features the European Medicines Agency logo and navigation tabs for 'Human' and 'Veterinary'. The 'Veterinary' tab is active. The form includes several dropdown menus for selecting submission type, unit, mode, product type, and submission format. A product selection field is populated with 'Metacam-EMA/V/C/000033'. A period covered dropdown is set to '1 May 2013 - 30 April 2016'. A contact email field is present with a placeholder 'Enter email address' and an information icon. At the bottom, there are 'Generate delivery file' and 'Reset form' buttons.

EUROPEAN MEDICINES AGENCY
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Human Veterinary

Choose a submission type:*
vet-psur

Choose a Submission-Unit*
validation-response

Mode*
Single Product

*Denotes mandatory fields

Submission: vet-psur

Product Type*
Centralised

Submission format*
Other

Select a Product*
Metacam-EMA/V/C/000033

Product EMA number: EMEA/V/C/000033
Product short name: Metacam

Select Period covered*
1 May 2013 - 30 April 2016

Contact e-mail: Enter email address ⓘ

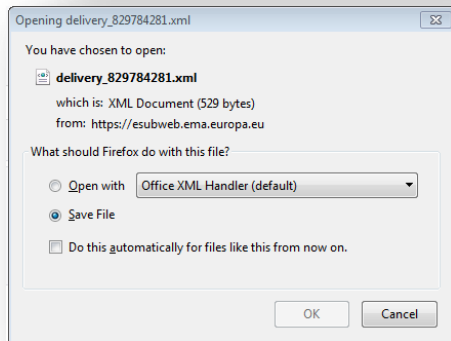
Generate delivery file Reset form

DEMO 2: Generating XML delivery file for a vet PSUR submission

Create delivery file screen

Generate delivery file

Reset form

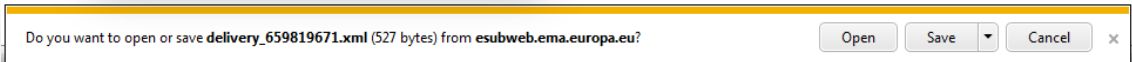


Save the xml delivery file in a named folder or a location where you can easily identify it especially if you are creating multiple delivery files for associated submissions.

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.



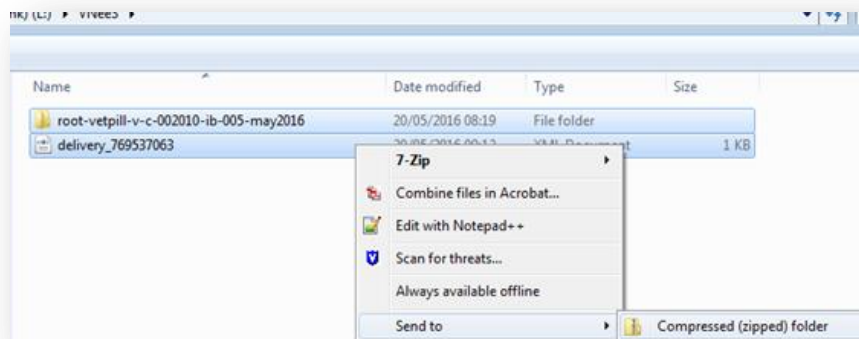
Do you want to open or save delivery_659819671.xml (527 bytes) from esubweb.ema.europa.eu?

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

- 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

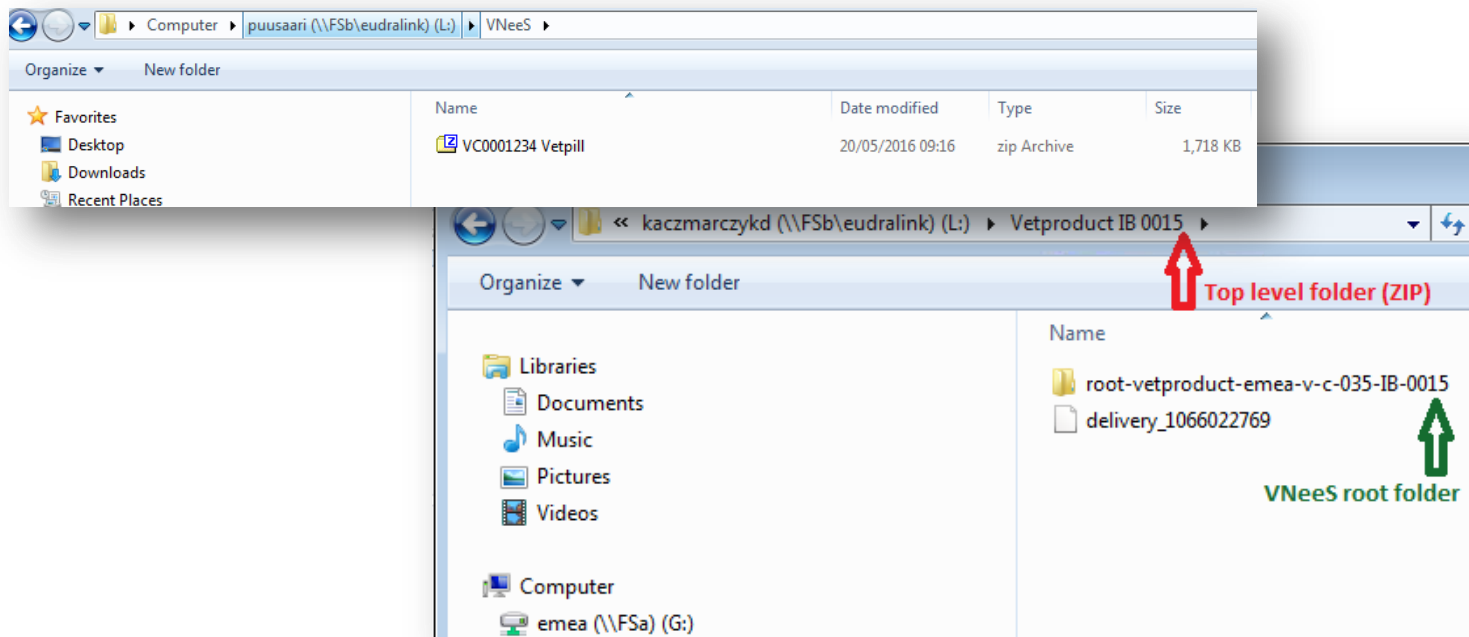


- Check that the zip file only contains the submission folder and the delivery file and that the zip is not placed inside another folder
- You can rename the zip to give it a simple, meaningful name. The zip package filename is not checked by the system but may help identifying the submission in case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

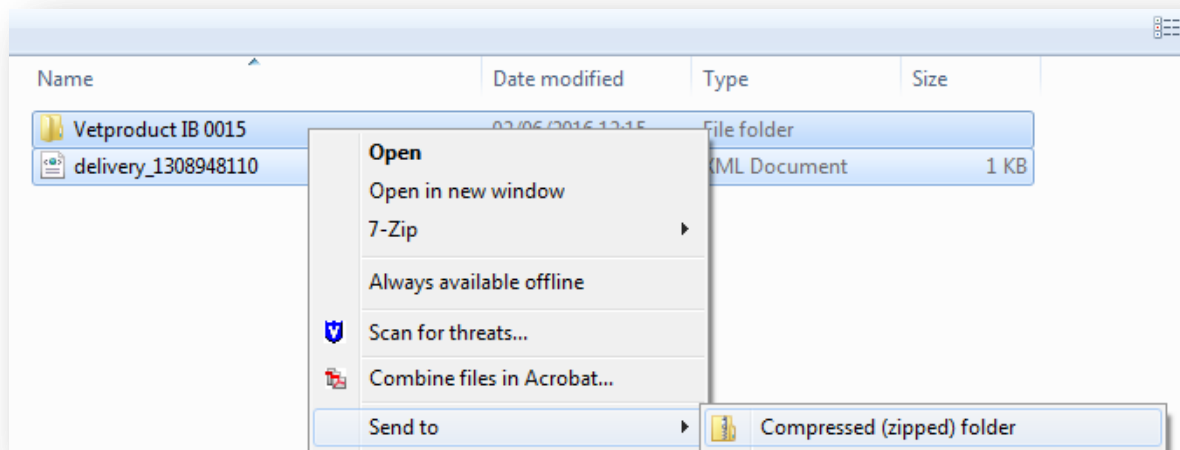
How to include delivery file in the submission



- 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.



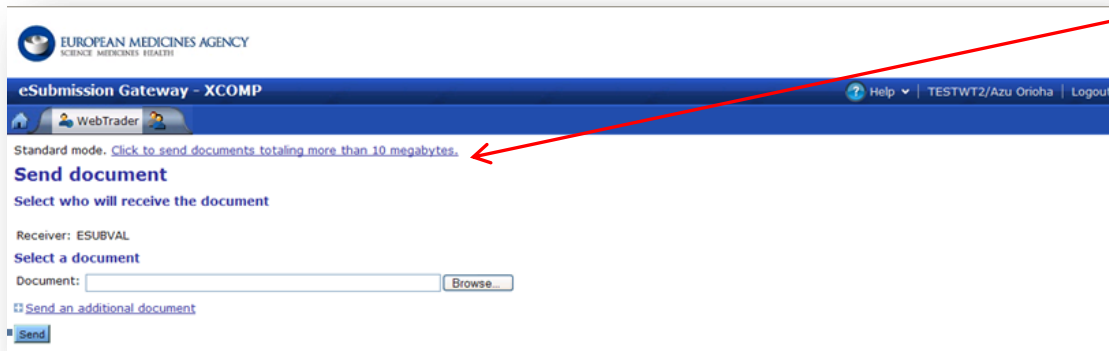
- For some small veterinary submissions to the Agency, it is possible for the whole submission to be provided as a **single PDF file** or an **unstructured collection of files**. In this case, place the file(s) in a folder with a meaningful name (no restrictions). When creating the zip, ensure that you 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:



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.

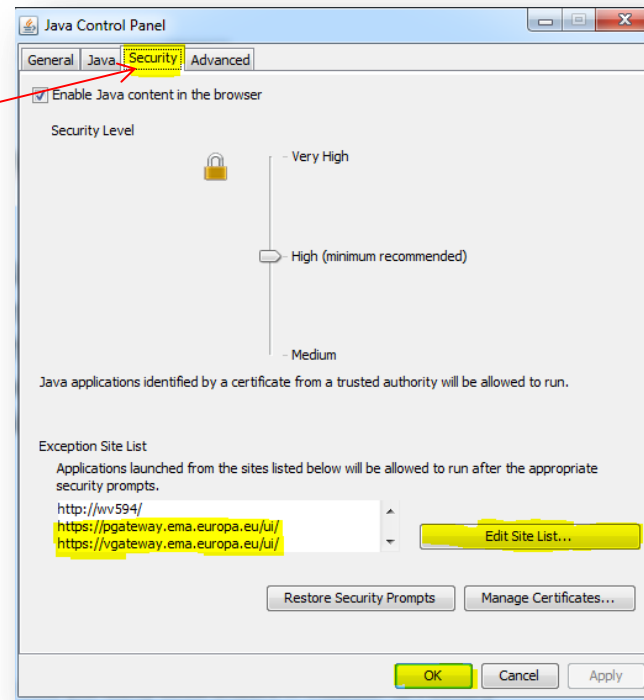
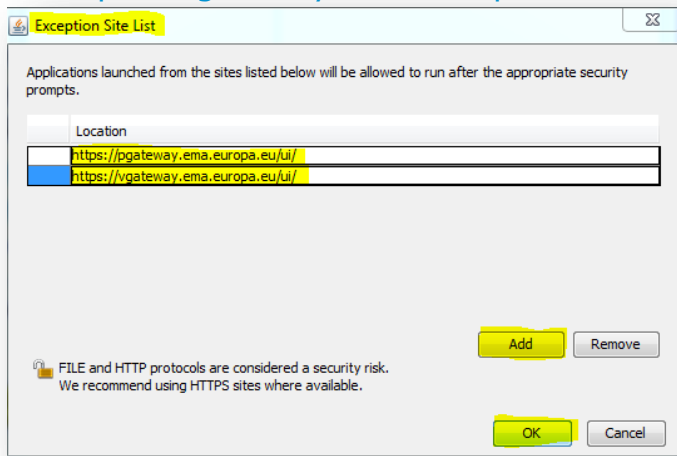
Submission using the Web Client

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/>





Avoiding problems



- 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>
- VNeedS **validation** should be done **prior** to the zipping the submission folder and the delivery file together. The delivery file should not be validated.

Use of different browsers:

- After a new release you may experience issues due to cookies (clear the cache) to the old version
- It is good to **clear the cookies** and refresh the screen if any unusual behaviour is detected. For persistent issues: try 'InPrivate' or incognito browsing – open new instance Ctrl+shift+P in IE and Mozilla Firefox or Ctrl+shift+N in Google Chrome
- The functionality for XML file generation screen may not be optimal with all browsers



- 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
- We are aware of a known issue with some ASMF submissions where the ASMF number may not be available – in those cases please use filenaming conventions

- 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
- Once logged in to the system, the Web Client website indicates a safety certificate problem - there is unfortunately no solution to this issue at present; for the time being users are asked to ignore the certificate issue and proceed to the website despite the warning

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

All veterinary-relevant information is also linked to the Veterinary eSubmissions website: <http://esubmission.ema.europa.eu/tiges/vetesub.htm>

Support for all eSubmission Gateway issues:

- Technical validation issues (e.g. missing or 'Failure' Acknowledgements)
- Gateway registration queries
- 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 (includes MRLs, excludes PSURs):**
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/11/WC500014483.pdf
- **Contact details of national competent authorities (NCAs) for PSUR submission:**
http://www.ema.europa.eu/docs/en_GB/document_library/Standard_Operating_Procedure_-_SOP/2009/09/WC500003101.pdf



Thank you for your attention

Further information

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

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