



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Webinar training on v3.2 – updated system including new fields





Outline of Today's training session

- eSubmission Gateway and Web Client latest news
- Scope of the system
- 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
- Known issues in the current release
- Gateway website
- Gateway support
- Useful links



eSubmission Gateway and Web Client latest news

- The use of the XML delivery files is now mandatory for all Human and Veterinary submissions via the eSubmission Gateway and the Web Client (with exception of initial MAA applications for Ancillary medicinal substances in medical device – these submissions should be sent using filenaming convention. Subsequent sequences for Ancillary medicinal substances should be sent using the XML delivery files.
- This updated version introduces a number of new fields that have been added to the XML delivery files in anticipation that these fields may in future replace the use of the Formatted Table Template that is currently provided as a part of the submission cover letter.
- This release **does not** abolish or change the requirement to provide the Formatted Table Template as a part of the cover letter – further fields will need to be implemented in to the XML delivery file as well as change of the existing business processes will need to be taken into consideration before this can be done. Please continue to provide the cover letter as previously until otherwise announced.
- More information on the use of the Formatted Table Template is available [here](#).



Human (incl. Art. 58 WHO products)

- Annual Re-assessment
- Clinical data for publication – final version
- Clinical data for publication – redacted version
- Extension
- Lifting of suspension
- Marketing Authorisation Application (MAA)
- Notification Art. 61(3)
- Paediatric Art. 46
- Post-Authorisation Measure (pam-anx)
- Post-Authorisation Measure (pam-capa)
- Post-Authorisation Measure (pam-leg)
- Post-Authorisation Measure (pam-mea)
- Post-Authorisation Measure (pam-p46)
- Post-Authorisation Measure (pam-paes)
- Post-Authorisation Measure (pam-rec)
- Post-Authorisation Measure (pam-sda)
- Post-Authorisation Measure (pam-sob)
- Post-Auth. Safety Study protocol (Pass107q)
- Post-Auth. Safety Study report (Pass107n)
- Reformat of Dossier

- Renewal
- Risk Management Plan (RMP)
- Transfer of MA
- Urgent Safety Restriction (USR)
- Type IA variation (single and IG)
- Type IA_{IN} variation (single and IG)
- Type IB variation (single and WS)
- Type II variation (single and WS)
- Withdrawal
- Referrals
- Active Substance Master File (ASMF)
- Plasma Master File (PMF)
- PSUR for Art. 58 (WHO) products
- PSUR/PSUSA
- Paediatric submissions
- Signal detection

Currently out of scope – continued use the existing file naming conventions

- Ancillary medicinal products (medical devices) – initial maa submissions only. All subsequent sequences should be submitted using the delivery file

Veterinary

- Annual Re-assessment
- Article-45
- Extension
- Lifting of suspension
- Marketing Authorisation Application (MAA)
- Post-Authorisation Measure (pam-anx)
- Post-Authorisation Measure (pam-leg)
- Post-Authorisation Measure (pam-mea)
- Post-Authorisation Measure (pam-rec)
- Post-Authorisation Measure (pam-sda)
- Post-Authorisation Measure (pam-sob)
- Post-Authorisation Safety Study (pass)
- Reformat of dossier
- Renewal
- Risk Management Plan (RMP)
- Transfer of MA
- Type IA variation (single and IG)
- Type IA_{IN} variation (single and IG)
- Type IB variation (single and WS)
- Type II variation (single and WS)
- Withdrawal
- Referrals
- Active Substance Master File (ASMF)
- Veterinary MRL submissions
- Veterinary PSURs

Mandatory use of XML
from 1st April 2017

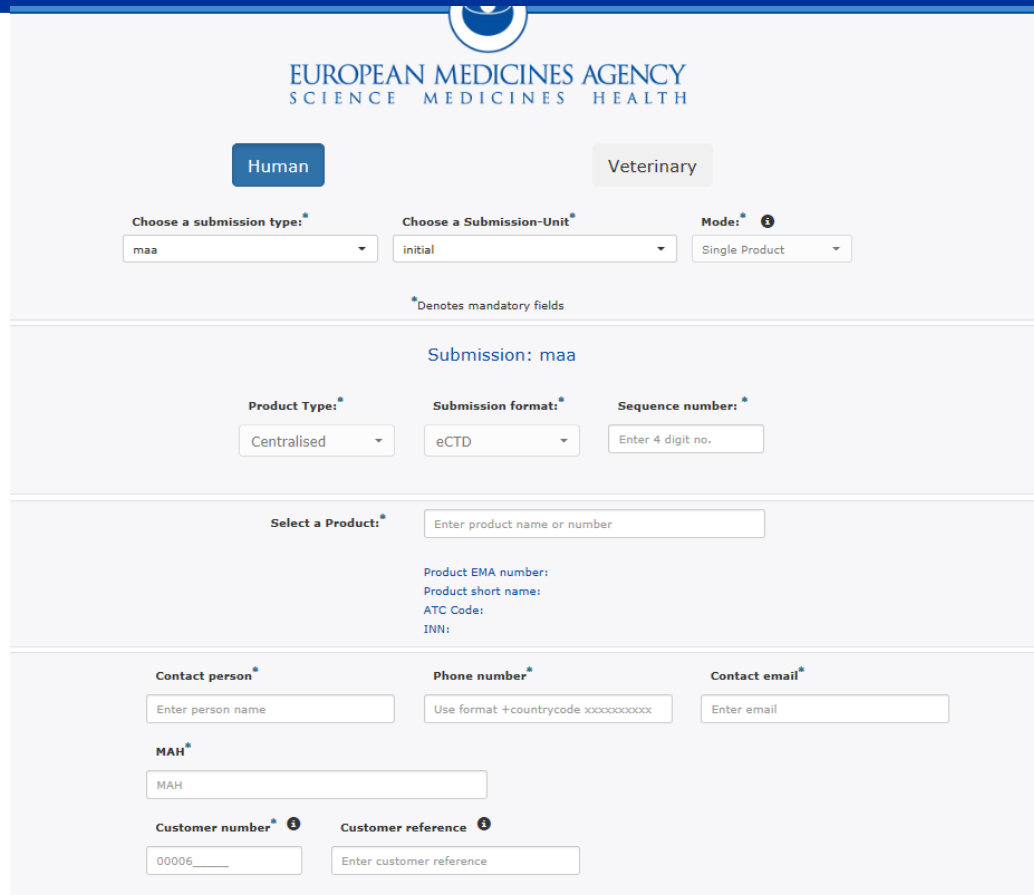


How to create a delivery file

- Each submission requires its own delivery file and submission via the eSubmission Gateway – as previously using the filenaming conventions (exceptions apply for veterinary submissions only)
- It is not possible to group eCTD format Human submissions
- No change for the submission rules
- Grouping (IG), worksharing (WS) and Referral submissions are 'linked' together using the relevant IG, WS and referral numbers – individual submissions are required for each product with individual eCTD lifecycle.

Note: for details on PSUR/PSUSA submissions for any other product but those authorised under Art. 58 (WHO) please review [PSUR Repository guidance](#)

Create delivery file screen (1/24)



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Human (selected) | Veterinary

Choose a submission type: *
maa

Choose a Submission-Unit*
initial

Mode: * ⓘ
Single Product

*Denotes mandatory fields

Submission: maa

Product Type: *
Centralised

Submission format: *
eCTD

Sequence number: *
Enter 4 digit no.

Select a Product: *
Enter product name or number

Product EMA number:
Product short name:
ATC Code:
INN:

Contact person *
Enter person name

Phone number *
Use format +countrycode xxxxxxxxxxx

Contact email *
Enter email

MAH *
MAH

Customer number * ⓘ
00006

Customer reference ⓘ
Enter customer reference

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:*

maa

var

CAP

var-type1a

var-type1ain

var-type1b

var-type2

Centralised

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

Depending on the selected **Submission type** available 'units' may be differ for different types of applications.

Choose a Submission-Unit*

initial ▼

No selection

initial

validation-response

response

additional-info

closing

consolidating

corrigendum

reformat

Select the **submission unit** from the **dropdown** list

The submission unit is used in conjunction with the submission type. Sequential submissions, e.g. RSI, LoQ, LoOI are sent using the **same submission type** as the initial submission with a relevant submission unit, for example validation-responses or responses.

Depending on the selected **Submission type** available 'units' may differ for different types of applications.

More information on the eCTD EU M1 specification is available on the [eSubmission website](#).

Choose a Submission description*

No selection ▼

No selection

Responses to RSI

Responses to Day 120

Responses to Day 150

Responses to Day 180

It is planned that in a future release the submission description 'Responses to RSI' will be automatically filled or filled at the back-end and not visible in the UI

Select the **submission description** from the **dropdown** list

The submission description is a new field which is used in conjunction with the submission unit **responses**. It provides further granularity on the type of the responses provided e.g. RSI, Day 120 LoQ or 180 LoOI.

Depending on the selected **Submission type** available 'descriptions' differ for different types of applications.

Responses to RSI should be used for post-authorisation activities and the Responses to Day 120, 150 or 180 should be used for **maa** and **extension** applications.

Choose a submission type:^{*} Choose a Submission-Unit^{*}

var-type2 response

Mode:^{*}

Single Product

Single Product

IG(grouping of variations)

WS

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

For majority of centralised procedure submissions submission mode is defaulted to 'single'

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

Product Type:*

Centralised ▾

Centralised

National

Submission format:*

eCTD ▾

eCTD

Nees

Other

Sequence number:*

0016

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.

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 ensure that the submission will pass the automated technical validation upon receipt to EMA.

Where relevant, please provide the submission sequence number.

For eCTD submissions this is always the next number in the product lifecycle.

For Nees submissions, depending on the product, this may be the next number in the product lifecycle or value 0000.

For submission format 'other' you may enter 0000.

Create delivery file screen (7/24)



Select a Product:*

- Zavesca-EMA/H/C/000435
- Zavicefta-EMA/H/C/004027

Select a Product:*

- Aluvia-EMA/H/W/000764
- Pyramax-EMA/H/W/002319
- Hexaxim-EMA/H/W/002495
- Hemoprostol-EMA/H/W/002652
- Tritanrix HB-EMA/H/W/003838

Generate delivery file

Select a Product:*

- Porcilis Porcoli Diluvac Forte-EMA/V/C/000024
- Fevaxyn Pentofel-EMA/V/C/000030
- Quadrisol-EMA/V/C/000032
- Metacam-EMA/V/C/000033
- Neocolipor-EMA/V/C/000035
- Nobilis IB4-91-EMA/V/C/000036
- Suvaxyn Aujeszky 783 + O/W-EMA/V/C/000038

Generate delivery file

Product selection is linked to the **product type** (centralised or national) and depending on the product 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 human and veterinary CAPs are retrieved. Products authorised as ancillary medical devices and under Art. 58 (WHO) are also available through the selection for 'Centralised'.

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

For **initial MAA application** you should search for the number in format H0001234 or V0001234. For any subsequent submissions for that same procedure or for any other post-authorisation activity the product number is in format H/C and H/W or V/C for Veterinary products.

The EMA product number is available on the Eligibility confirmation letter as 'Product Reference'. The Eligibility Confirmation Letter indicates Product number e.g. H0002271 or V0001234.

This Product Number (or Product Reference) remains the same throughout the product lifecycle and it should be used regardless what type of submission is being transmitted.



Product EMA number:
Product short name:
ATC Code:
INN:

When a CAP product is selected from the list, the EMA product number, product name, ATC code and the INN are shown for visual confirmation. The ATC code and INN are currently not displayed for 'maa-initial' submission, this will be added to the delivery file in a future release.

Create delivery file screen (9/24)

Select a Product:*

Select a Product:*

t worksharing number:*

- ASCORBIC ACID-**PARACETAMOL** RATIOPHARM
- ASPIRIN/**PARACETAMOL**/CAFFEINE WOCKHARDT UK LTD
- BEST-IN **PARACETAMOL** EXTRA PAIN RELIEF WRAFTON LABORATORIES
- RUSCOWAL PLUS **PARACETAMOL**

Select a Product:*

✕ ASPIRIN

Procedures for **human** worksharing (WS) variations, signal detection and referrals containing **Nationally Authorised Products** are connected to XEVDMP also known as Art. 57 database.

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

The product short name is the name the MAH has given for the product in Art. 57 database field 'product short name'.

When the product is selected it is added to a list under the search field.

Click anywhere on the field with the product name to extend the view to select individual products or presentations.

You can remove the product by clicking the **X** to the left of the product name.

Create delivery file screen (10/24)

Select a Product:*

✕ ASPIRIN

✕ ASPIRIN

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...
BAYER SRL	ASPIRIN 500 mg drajeun	RO	6006/2013/05	FR/H/0482/001
BAYER VITAL GMBH	Aspirin 500 mg überzogene Tabletten	DE	86750.00.00	FR/H/0482/001
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/01	FR/H/0482/001
M&A PHARMACHEM LTD	Dispersible Aspirin Tablets 75mg BP	UK	04077 / 0182	
CLONMEL HEALTHCARE LTD.	Aspirin 75 mg Gastro-resistant Tablets	MT	AA1045/02801	
ACTAVIS UK LTD.	Aspirin 75 mg Dispersible Tablets	IE	PA 176/15/3	
BAYER DOO	Aspirin 500 mg tablete	HR	HR-H-460897624-01	

total Items: 61

For nationally authorised products you are able to repeat the step and add more than single entry, however, only one **'product'** should be added. Each product with a different eCTD/NeeS lifecycle requires a separate delivery file and separate submission.

Depending on the way how the MAH has entered the product in Art. 57 it may be necessary to select more than a single product short name to capture all presentations of a single product.

It is possible to sort and filter the list of products/presentations by clicking the name of the columns and by typing in the field.

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/03	FR/H/0482/001
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/02	FR/H/0482/001
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/04	FR/H/0482/001
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/05	FR/H/0482/001
BAYER SRL	ASPIRIN 500 mg drajeuri	RO	6006/2013/01	FR/H/0482/001

Select the products by ticking the relevant row on the left of the screen. You can select all products by clicking the tick mark next to the MAH name field.

Create delivery file screen (11/24)

✕ ASPIRIN COMPLEX HEISSGETRÄNK >

✕ ASPIRIN COMPLEX HEIßGETRÄNK >

✕ ASPIRIN COMPLEX HEISSGETRÄNK

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	87846.00.00	DE/H/3635/001
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	78357.00.00	
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	78356.00.00	

←

Total Items: 3 (Selected Items: 3)

✕ ASPIRIN COMPLEX HEIßGETRÄNK

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	87846.00.00	DE/H/3635/001
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	78357.00.00	
✓ BAYER VITAL GMBH	ASPIRIN COMPLEX HEISSGETRÄNK 5...	DE	78356.00.00	

Repeat the step as many times as necessary and once you have selected all relevant products/presentations, close the selection by clicking anywhere in the field with the product short name.

Select a Procedure Number:*

EMEA/H/C/000581/II/0032/G

Grouping(more than one scope):

When variation procedure number is selected for variation that contains more than 1 scope 'Grouping (more than one scope)' is automatically ticked.

In future releases it will be possible to indicate grouping of multiple scopes also for initial variation submissions.

Select worksharing number:*

Nothing selected

ws/00

WS/0009

WS/0025

WS/0046

Select worksharing number:*

ws/0877

Generate delivery file

WS/0877

WS/0889

WS/0872

In order to facilitate the planning of a worksharing procedure, MAHs are advised to inform the Agency at least two 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 pa-bus@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: PA-BUS@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

Contact person*	Phone number*	Contact email*
<input type="text" value="Enter person name"/>	<input type="text" value="Use format +countrycode xxxxxxxxxxx"/>	<input type="text" value="Enter email"/>
MAH*		
<input type="text" value="MAH"/>		

When Centrally Authorised Product (CAP) is selected, the product contact person name, contact person contact details and the MAH name are automatically filled in on the delivery file.

These details should not be modified in the delivery file for CAP submissions.

In case of Referral submission the contact details may be updated if necessary.

Following concerns being raised regarding the privacy of the contact person name/contact details these details may be removed from the user interface in future.



Choose a submission type:* Choose a Submission-Unit*

maa initial

In case of **initial** submission of a **maa** or **Type IB** or **Type II worksharing variation** fields called **Customer number** and **Customer reference** are displayed.

Choose a submission type:* Choose a Submission-Unit* Mode:* ⓘ

var-type2 initial WS

Customer number* ⓘ **Customer reference** ⓘ

00006_____ Enter customer reference

In case of initial maa application, the customer number is not filled in automatically.

For WS variations, the SAP customer number will be prefilled when the CAP product is selected.

Referrals Article*

Nothing selected

- Article5(3)
- Article13
- Article16C1C
- Article16C4
- Article20
- Article29(4)
- Article30
- Article31
- Article107i
- Article29PAED

Referrals:

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

The **product type**, **submission format** and **sequence number** depend on the type of referral selected.

Select the EMA referral number by typing any part of the referral number, product name or substance name in the EMA referral no. or name field.

Select a Referral:*

Enter EMA Referral no. or name

Select a Referral:*

007

EMEA/H/C/000644/A20/0072-Tygapil - CETERO_A20/0072

EMEA/H/C/001064/A20/0007-Ribavirin Teva Pharma BV -

CETERO_A20/0007

Select a Product(CAPs):*

Product EMA number:

Product short name:

Select a Product(NAPs):*

Non- authorised product(s)/Herbal product(s)

Enter additional products, excluding the lead product. Lead product and applicant name should be provided in 500 characters remaining.

Product name:*

Applicant name:*

Referrals:

Select the CAP or NAP product as described previously.

If the procedure contains non- authorised products or herbal products you should indicate Product name and Applicant name in the fields provided. Additional products/applicants/MAHs may be indicated in the free text field.

When at least one NAP product is selected from the product database the product name and applicant name fields will be come optional selected

Contact person*	Phone number*	Contact email*
<input type="text" value="Enter person name"/>	<input type="text" value="Use format +countrycode xxxxxxxxxxx"/>	<input type="text" value="Enter email"/>
MAH*		
<input type="text" value="MAH"/>		

Referrals:

When CAP product is selected, product contact person name and contact details and the company name are auto-filled from the EMA product database. The details can be edited to provide the contact details for the relevant procedure.

For NAPs these should be manually entered

<input checked="" type="checkbox"/> Is this fee related ?	Customer number* ⓘ <input type="text" value="00006_____"/>	Customer reference ⓘ <input type="text" value="Enter customer reference"/>
---	--	--

When referral is fee related, please tick the 'is this fee related' box and enter the customer number and customer reference if relevant

Create delivery file screen - ASMF (21/24)

Choose a submission type:^{*}

Choose a Submission-Unit:^{*}

Mode:^{*}

*Denotes mandatory fields

Submission: **asmf**

Select ASMF:^{*}

ASMF number:

Substance name:

Select a Product:^{*}

Product EMA number:

Product short name:

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

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 or product name in the search field. All ASMF submissions must be related to a CAP. If the submission relates to multiple CAPs, select a CAP as the lead product.

If you are **unable** to find your ASMF procedure number or the product please contact EMA via the [service portal](#) and for urgent submissions use filenaming convention to submit.

Select a PMF Holder:*

Pmf holder ref. number:

Pmf holder name:

For PMF enter the PMF number by typing in the search field any part of the PMF number.

The more you type the more the list is filtered.

For Paediatric Investigation Plan, waiver or modification enter the 6 digit PIP number in the free text field.

Choose a submission type:* **Mode:***

paediatric submissions Single Product

*Denotes mandatory fields

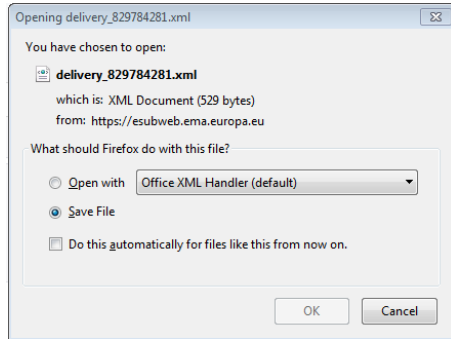
Submission: paediatric submissions

Pip number: *

Enter Pip no.

Generate delivery file

Reset form



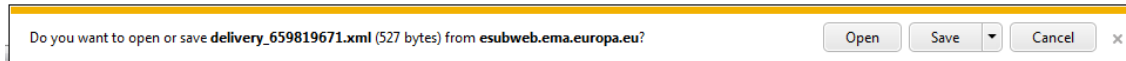
Save the xml delivery file in a named folder or a location where you can easily identify it especially if you are creating multiple delivery files for associated submissions.

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!

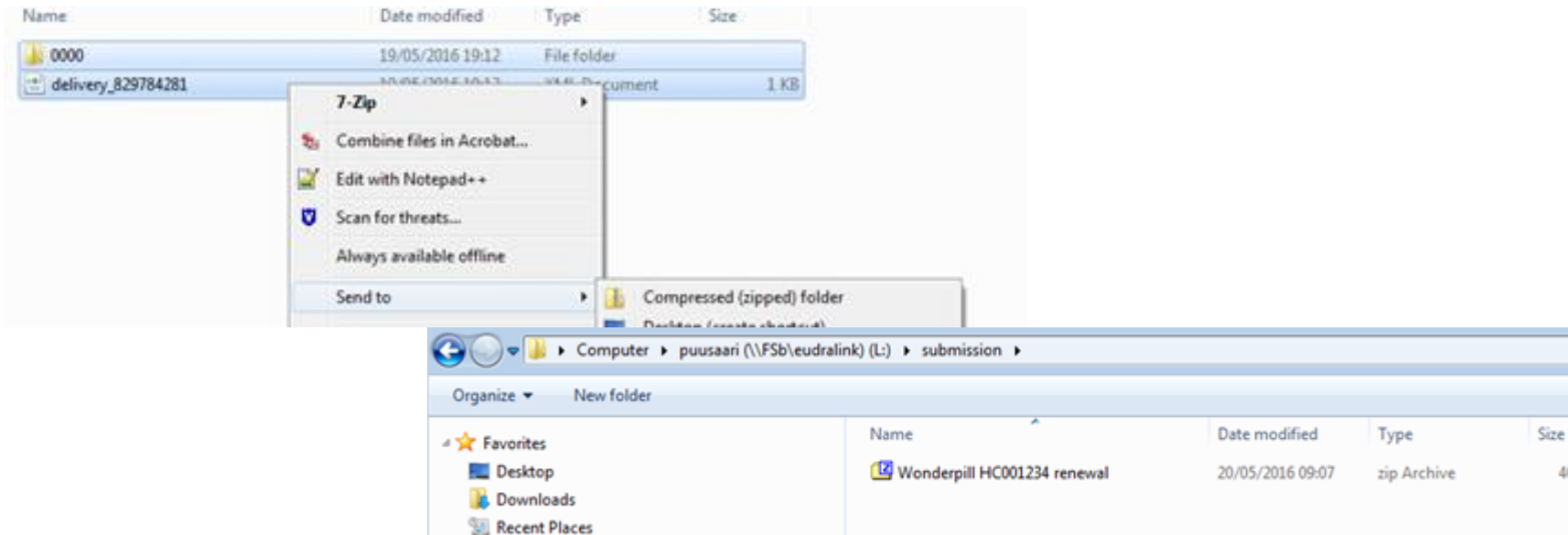


- Submission **metadata is provided via XML delivery file**, however package should ideally have a **meaningful** name (for submission support and archiving purposes)
- File names **will not be validated** for submissions via the Gateway
- File name examples:
 - **CAPs**: HC000999_Wonderpill_0020.zip, HC000999 Wonderpill responses 0021.zip
 - **NAPs included in WS**: Wonderpill_WS0000_ 0020.zip
 - **NAPs included in referral**: Companyname_0000_0020.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. Sequence 0001, 0002 etc.) should follow the eCTD or NeesS guidelines if relevant for your submission type.

- 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. 0017), possible word version working documents folder and the xml delivery file in a folder -> create the zip
- Check that the zip file only contains the submission folder, possible working documents 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.

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

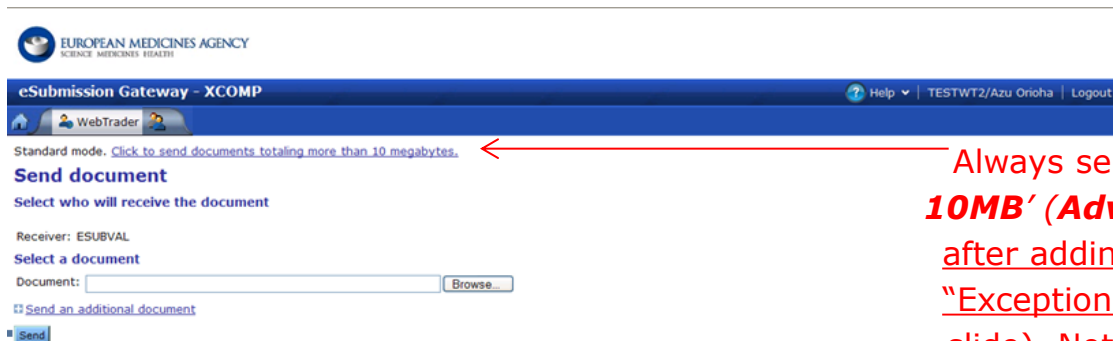
- Ensure that the xml delivery file is placed in the top level folder, in the same level as the submission folder. Both the submission folder and the xml delivery file must be in the top level folder – ensure that the folder structure is not superfluous as this will cause a rejection – if there are additional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



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.

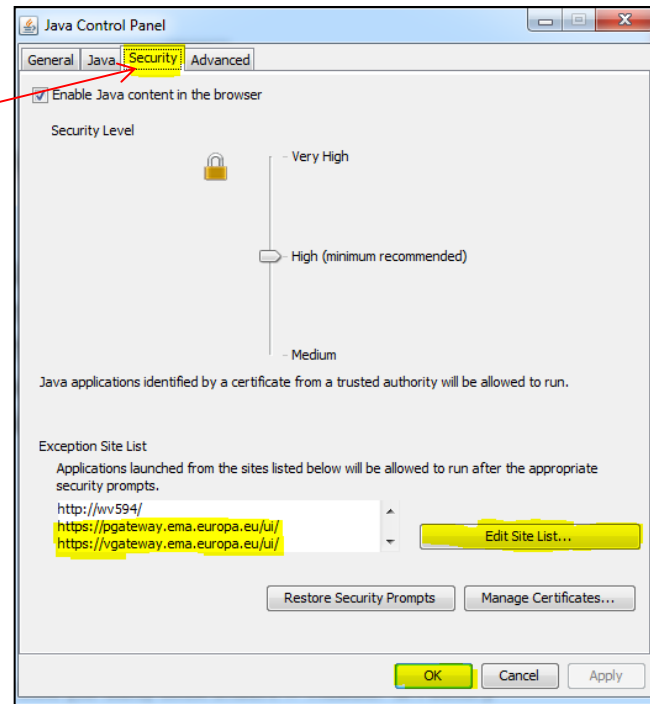
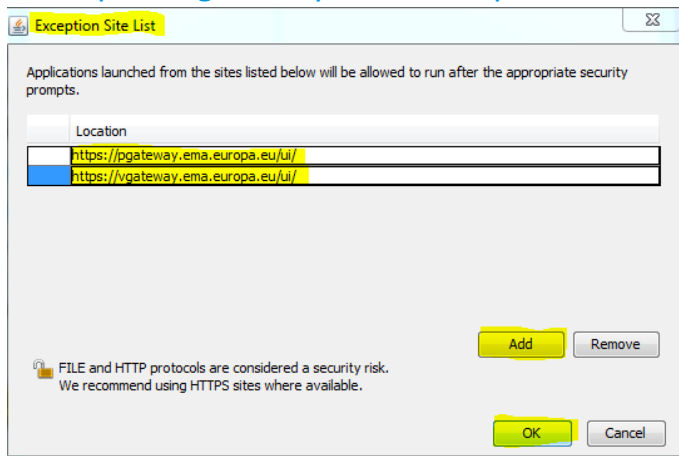
Submission using the Web Client (2/2)

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/>



You may experience issues with the latest release of Mozilla Firefox – potential need to downgrade the version used for sending submissions via Web Client



- Only one package and delivery file should be included per zip file
- Do not add NeeS submissions inside eCTD zip file or on the same delivery file
- Do not add eCTD submission inside NeeS zip file or on the same delivery 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
- The eSubmission Gateway **does not replace CESP** (except for PSURs)– NAPs should be submitted via the Gateway only if they are included in EMA coordinated Worksharing, Signal detection, PASS 107 or Referral procedures. Note all PSUR must be submitted to the PSUR Repository via the eSubmission Gateway
- Changes to Art. 57 database are reflected in the delivery file creation UI within 24 hours



- Follow-up measures are called PAMs and should be submitted using relevant submission type 'pam-xxx'
- 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 – each submission type requires its own delivery file and submission – there is no change to this in comparison to using filenames conventions



- It is not possible to create XML delivery files for initial maa submissions for ancillary medicinal products at the moment – pls use filenaming convention (initial submission of the ancillary medicinal product in medical device only)
- Submission-Unit 'Reformat' should only be available with submission type 'none' shown as reformat/baseline in the xml delivery file UI. Reformat must not be combined with any other submission type.
- Submission description 'Responses to RSI' should be automatically selected on the background – it should not be necessary for user to manually select this in the UI
- In future releases it will be possible to indicate grouping of multiple scopes also for initial variation submissions.
- Referral Article and the Referral procedure fields should be linked so that only procedures relevant to the selected article can be selected
- PAMs should not normally have 'response' submissions – the submission description for PAM responses will be removed
- Available submission units for each submission type will be amended in future to only allow relevant selection



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
- Who to contact



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 eCTD & Nees:** <http://esubmission.ema.europa.eu/tiges/cmbdocumentation.html>
- **Dossier Requirements for CAPs:**
http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf



Thank you for your attention

Further information

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

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

Send a question via our website www.ema.europa.eu/contact

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