EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Gateway and Web Client – interactive Questions and Answers session on the use of updated XML delivery files

Q&A Webinar

Presented by Kristiina Puusaari on 25 and 26 July 2016

Outline of Today's Q&A session

- eSubmission Gateway background and latest news
- Benefits of using XML delivery file
- eCTD EU M1
- Scope of the system
- Create delivery file screen DEMO
- Filenaming
- How to include delivery file in the submission
- Submission using the web client
- 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 now extending the use of XML delivery files for majority of procedure types following a successful pilot started in May 2016
- The XML delivery files are replacing filenaming conventions for eSubmission Gateway. Delivery files are used to provide submission 'metadata' to allow automated feedback to the applicant on the status of the technical validation, the upload to the EMAs review system and sharing the submissions with the network via the Common Repository and PSUR Repository
- The use of XML delivery files is now strongly recommended for all* submission types

*where available

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

- This updated version of the XML delivery file creation user interface complies with the updated eCTD EU Module 1 specification which introduces concept of 'submission type' and 'submission unit'
- The delivery files should be used for all submissions provided in eCTD following the new EU M1 specification from July 2016. **The delivery files** should also be used for all submissions provided in the previous version of **eCTD EU M1 specification (v2.0)**
- The use of XML delivery files will become **mandatory** for all **eCTD** submissions from 1 October 2016 in line with the mandatory use of the new EU M1 specification.
- 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.
- Mandatory use of eSubmission Gateway for all Paediatric submissions is planned and will be communicated in near future.

Benefits of using XML delivery files

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- Use of delivery files is implemented to improve and **harmonise** the submission process for all applicants;
  - There is **no need** use cumbersome **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 or from Art. 57 database depending on the procedure type
  - Simple, intuitive user interface
  - Reduces errors
  - Compliance with updated EU M1 specification

eCTD EU Module 1 v3.0 and v3.0.1

- Revised list of submission types and new submission unit list (EU M1)

Submission type	Submission unit	Sequence number
MAA	Initial	0000
MAA	Validation-response	0001
MAA	Additional-info	0002
MAA	Responses	0003
MAA	closing	0004

Scope of the system

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 filenaming conventions

- Ancillary medicinal products (medical devices)
- Pass 107q and 107n for nationally authorised products

Scope of the system

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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)

Currently out of scope - continued use the existing filenaming conventions

- Veterinary MRL submissions
- Veterinary PSURs

How to create a delivery file

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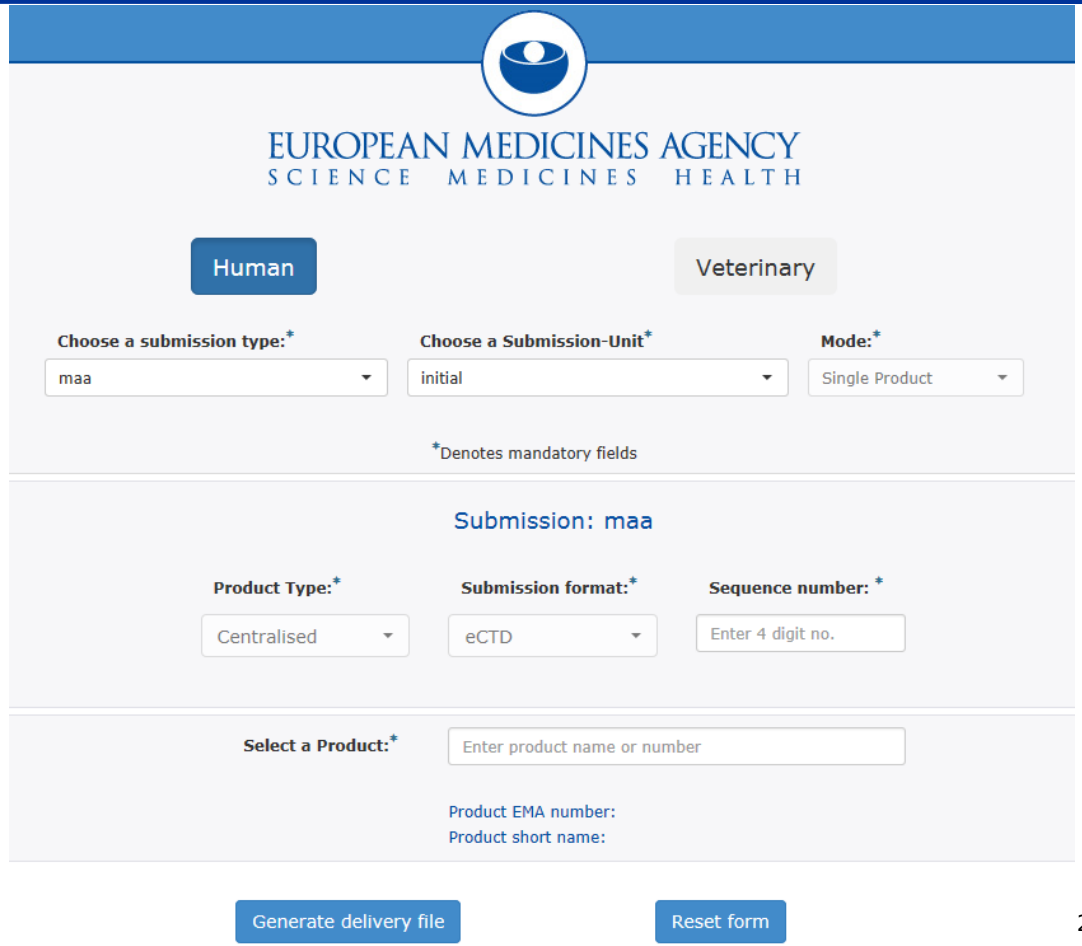
- The delivery file screen requires different information depending of the regulatory activity
- Each submission requires it's own delivery file and submission via the eSubmission Gateway – as previously using the filenaming conventions.
- It is not possible to group eCTD format Human submissions
- No 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 please review PSUR Repository guidance*

Create delivery file screen - example



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.

Filenaming

- 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:
  - HC000999_Wonderpill_0020.zip
  - HC000999 Wonderpill responses 0021.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 NeeS guidelines if relevant for your submission type.

How to include delivery file in the submission (1/2)

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- 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)

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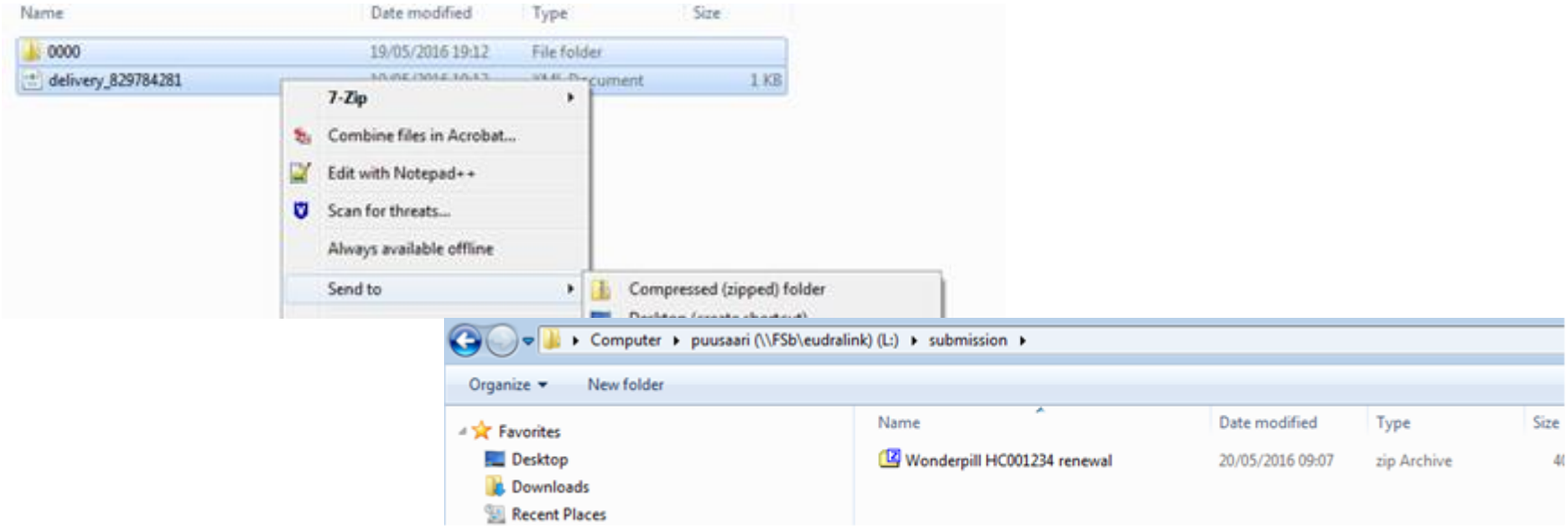
- Ensure that the xml delivery file is placed in the top level folder, in the same level as the submission folder. Both the submission folder and the xml delivery file must be in the top level folder – ensure that the folder structure is not superfluous as this will cause a rejection – if there are additional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

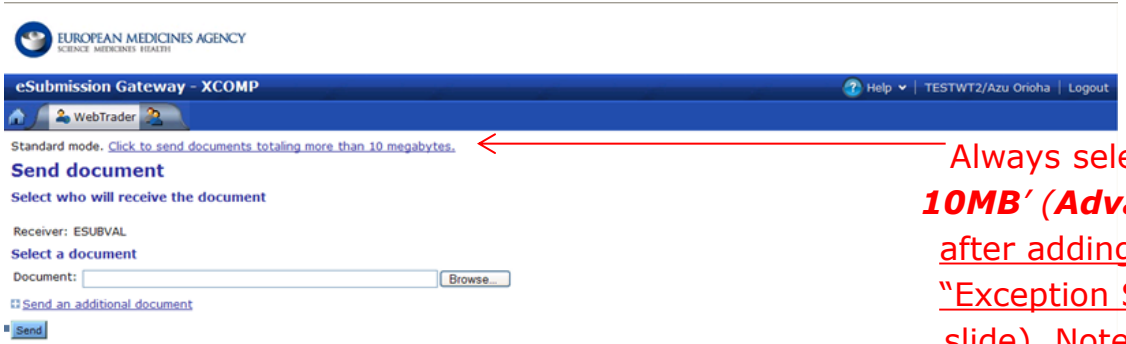


Submission using the Web Client (1/2)

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)

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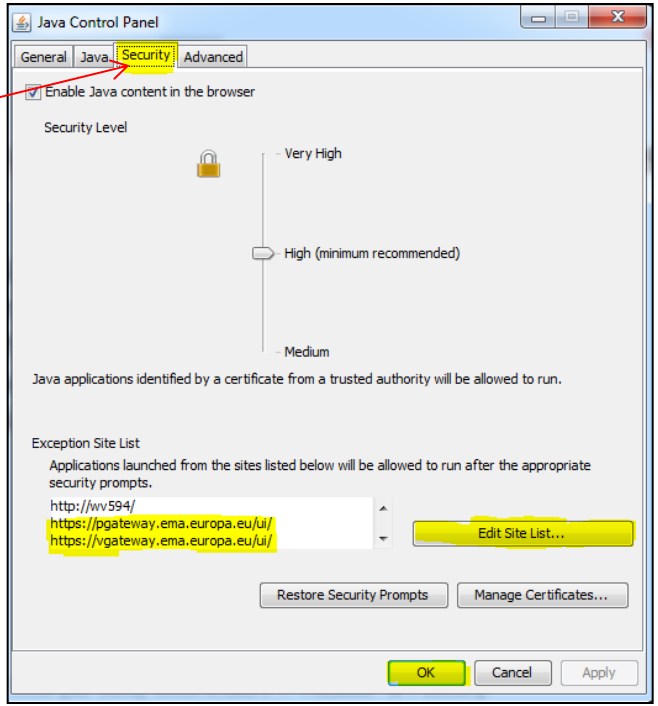
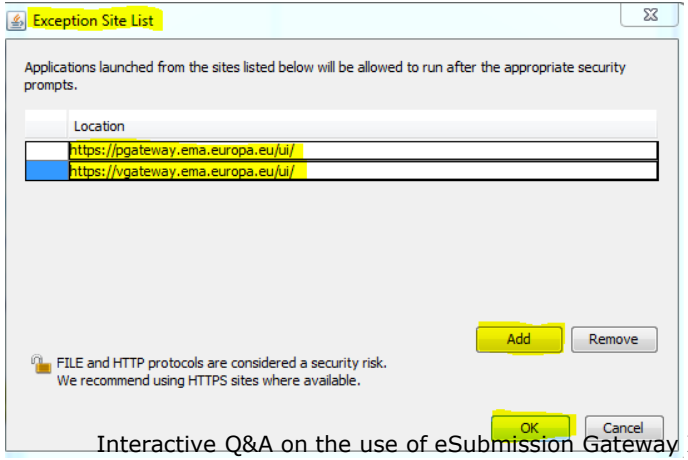
To use the Webclient, **Add eSubmission Gateway Sites in the Exception Site List in the Java Console**
To note that you'll need 'Local Administrator Rights' to configure those settings.

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/





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

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

Useful links

- ***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

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