EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository – MAH Training on new functionality

Webinar training on new functionality provided in release 1.07.00

Presented by Kristiina Puusaari on 25 July 2016

Outline of Today's training session

- PSUR Repository background and latest news
- Release v1.07.00
- Create delivery file screen
- Supplemental submissions
- Delivery file in the package
- Submission deadline
- Submission using the Web Client
- Issues with create delivery file screen
- How to avoid problems
- File naming
- Questions from the training session
- PSUR Repository support
- Contact information

PSUR Repository background and latest news

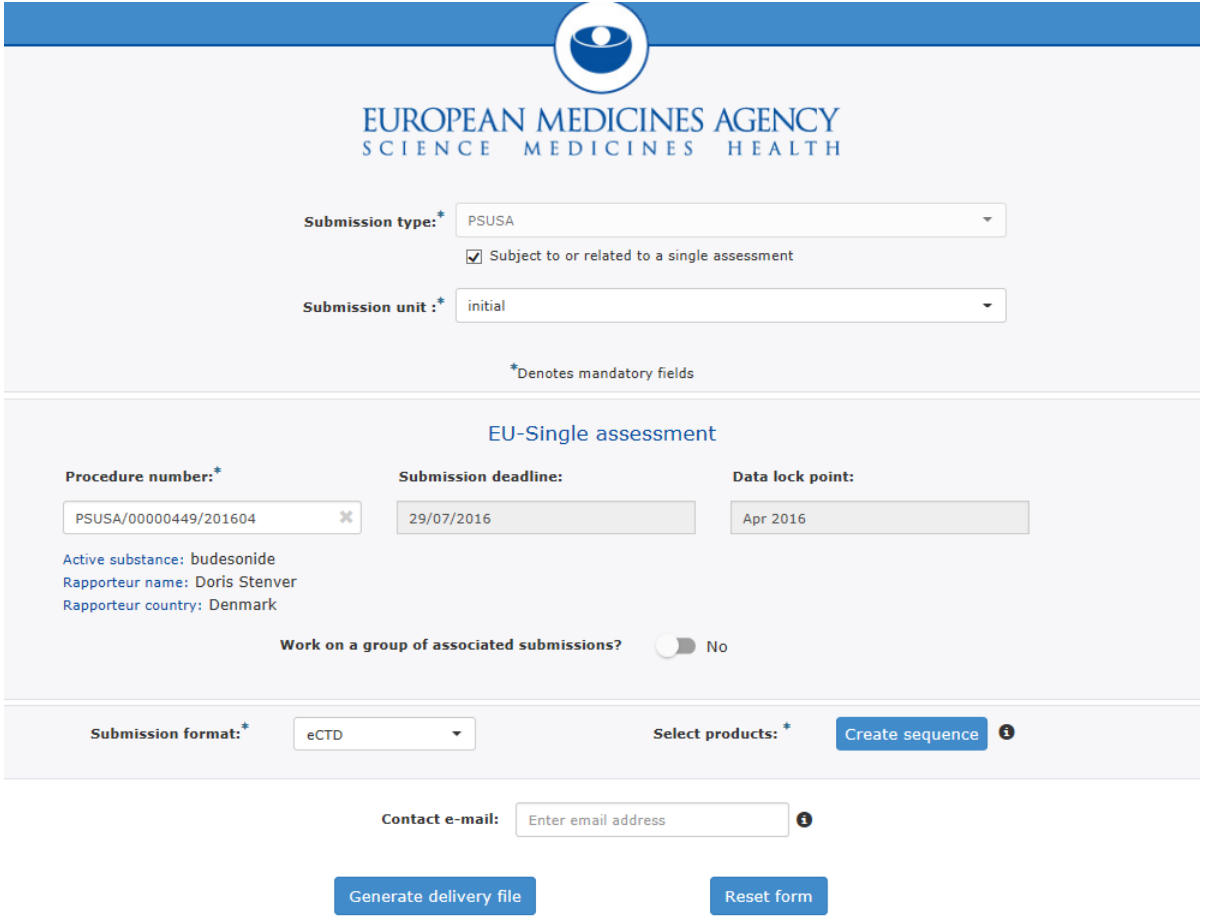
- As per the Article 107b paragraph 1 and Article 28(2) regulation 726/2004) all PSUR procedures shall be submitted **electronically**
- **xml delivery files must be used for all PSUR and PSUR supplemental submissions (e.g. responses).** It is **not possible** to use filenaming conventions to send PSURs and supplemental submission related to PSURs
- The use of the PSUR Repository is now **mandatory for all PSURs as of 13 June 2016.** All PSURs should be submitted to the PSUR repository via eSubmission Gateway/Web Client. PSUR should not be submitted directly to the National Competent Authorities after 13 June 2016.
- MAHs access to the PSUR Repository is limited to the access to create delivery file screen
- The updated **delivery files** should be used for all submissions, including those provided in NeeS format and those created using the previous version of **eCTD EU M1 specification (v2.0)**
- **Updated delivery files are required for all submissions from 25th July 2016 to align metadata with the changes in automated upload to the PSUR Repository**

Release v1.07.00

- Updated xml delivery file creation screen to introduce the concept of 'submission unit' as in eCTD EU Module 1 specification v3.0 and v3.0.1

Submission type	Submission unit	Sequence number
PSUR	Initial	0075
PSUR	Responses	0079
PSUR	closing	0082

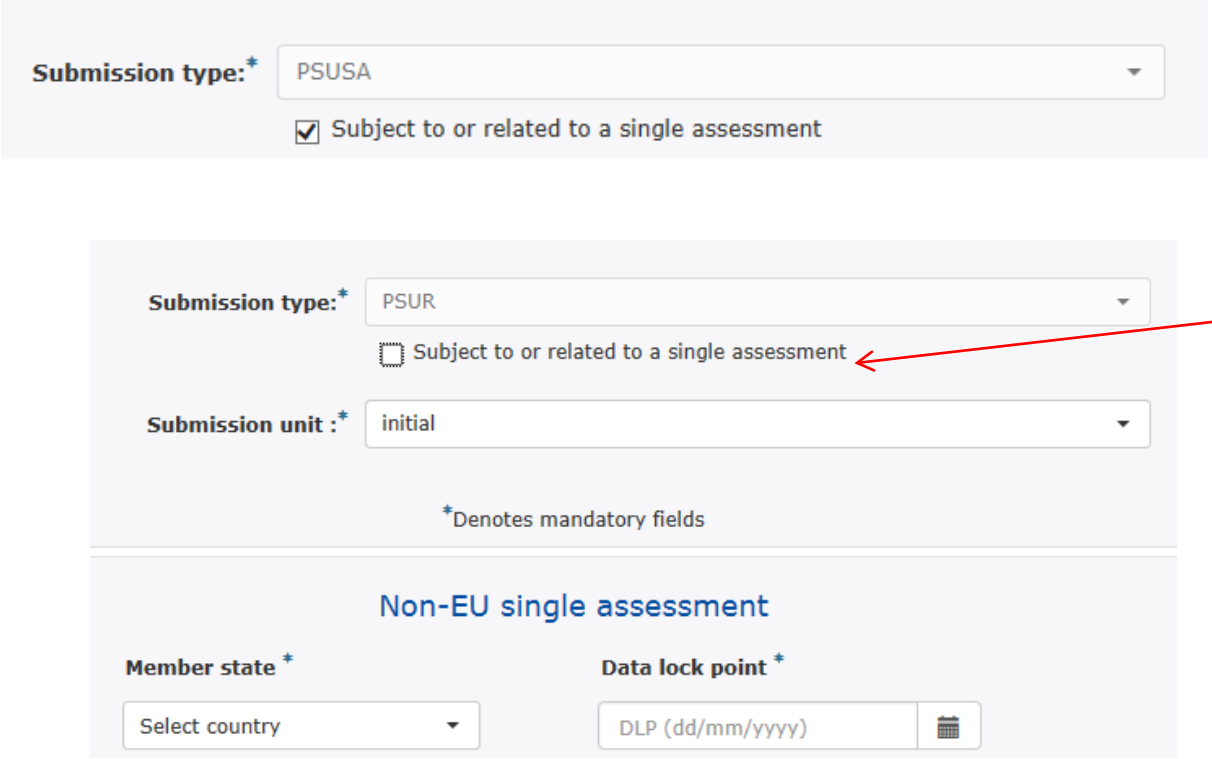
Create delivery file screen (1/14)



The screen is divided into different sections:
The user will be required to complete each field in each section.

- Regulatory activity and type of assessment
- Details of the assessment procedure
- Submission format and Product selection
- Contact email address

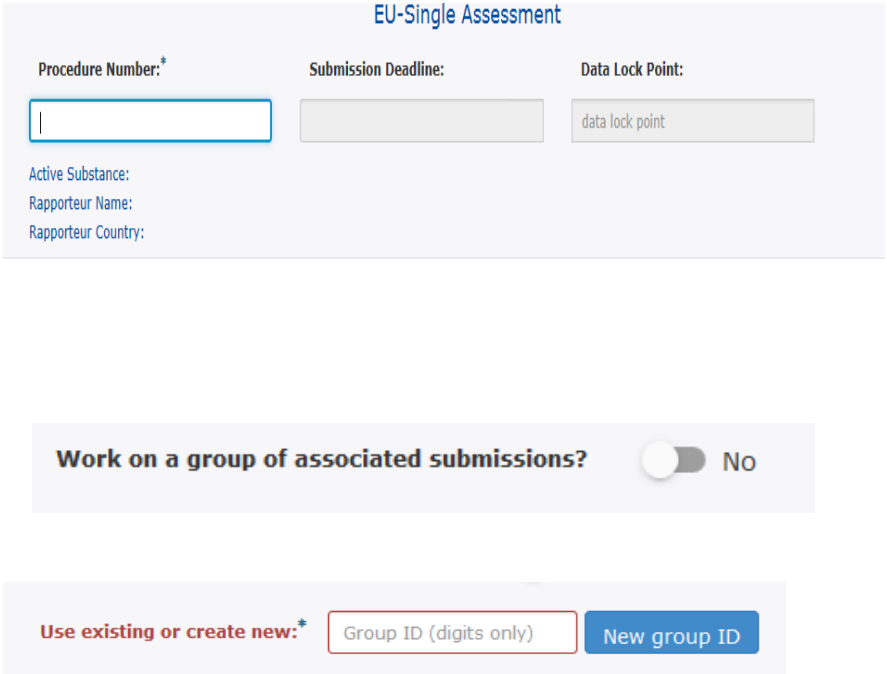
Create delivery file screen (2/14)



When sending a PSUR that is included in the PSUR Single Assessment Procedure the Submission type is always PSUSA. This is preselected as a default.
For submissions of non-EU single assessment, please untick the box and selection will change the submission type will automatically change to PSUR.

When checkbox is cleared the screen will change to allow the user to fill in the Member State and DLP for the National Competent Authority assessment

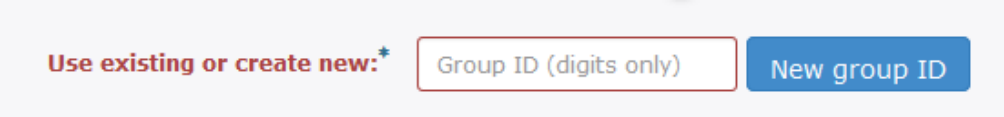
Create delivery file screen (3/14)



Type in minimum of 4 characters of the procedure number, the field will filter as you type. Select the correct procedure number. Submission deadline and DLP fields are automatically filled reflecting the EURD list information and are provided for visual confirmation only. It is **not** possible to create xml delivery file for initial **PSUR submission** prior to the DLP date. To create delivery file for procedure that has passed submission deadline obtain 'late submission id' from EMA. There is no deadline for delivery files for **Supplemental** submissions (e.g. responses) that should be used for all subsequence submissions after the initial PSUR.

Indicate if you wish to work on a group of associated submissions. The system is set to 'No' by default.
This function should be used for those products for which you have created **a single PSUR document** which is included in lifecycles of multiple different products, for example duplicate products. It can be used to link to together different products that have same or different submission format i.e. eCTD or mixed eCTD and NeeS. It can also be used to group together NeeS products but this should be avoided as single submission covering all different NeeS products can normally be made.

Create delivery file screen (4/14)




```
            <contact_email>test@test.com</contact_email>
            <group_id>1033634123</group_id>
        </EU_Periodic_Safety_Update_Report>
    </Regulatory_Activity>
</Submission_Metadata>
```

Once you select 'yes' the system asks you to create a 'New group ID' or to enter existing group ID.

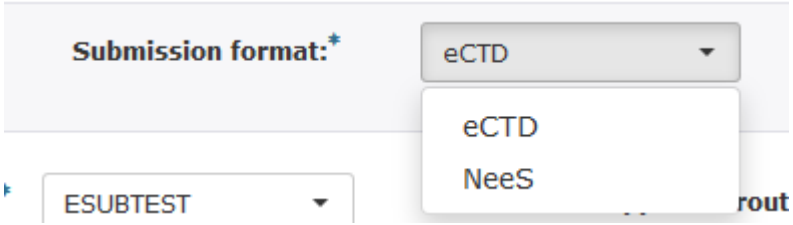
Press 'New group ID' to generate a group ID. A new ID should be initiated for new PSUR (or responses) submissions to link the different submissions containing the **same** PSUR document together. This is so that the NCAs can identify that a same PSUR cover multiple products without having to open the same document from different submissions.

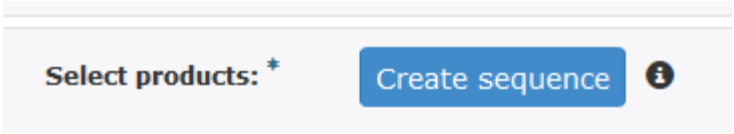
The grouping requires manual indication from MAH, the system is no able to recognize associated submissions or identify that same document is included in different submissions.

Note down the group ID in case you accidentally reset the delivery file screen. If you forget to note down the group ID, you can find it from the xml delivery file.

Existing group ID should **only** be used in case one of the associated submissions has **failed** and has to be **resubmitted**.

Create delivery file screen (5/14)





Please note that the advice note and PSUR Repository present the products with different granularity (advice note: pharmaceutical form vs. all presentations in PSUR Repository)

Select the correct submission format.

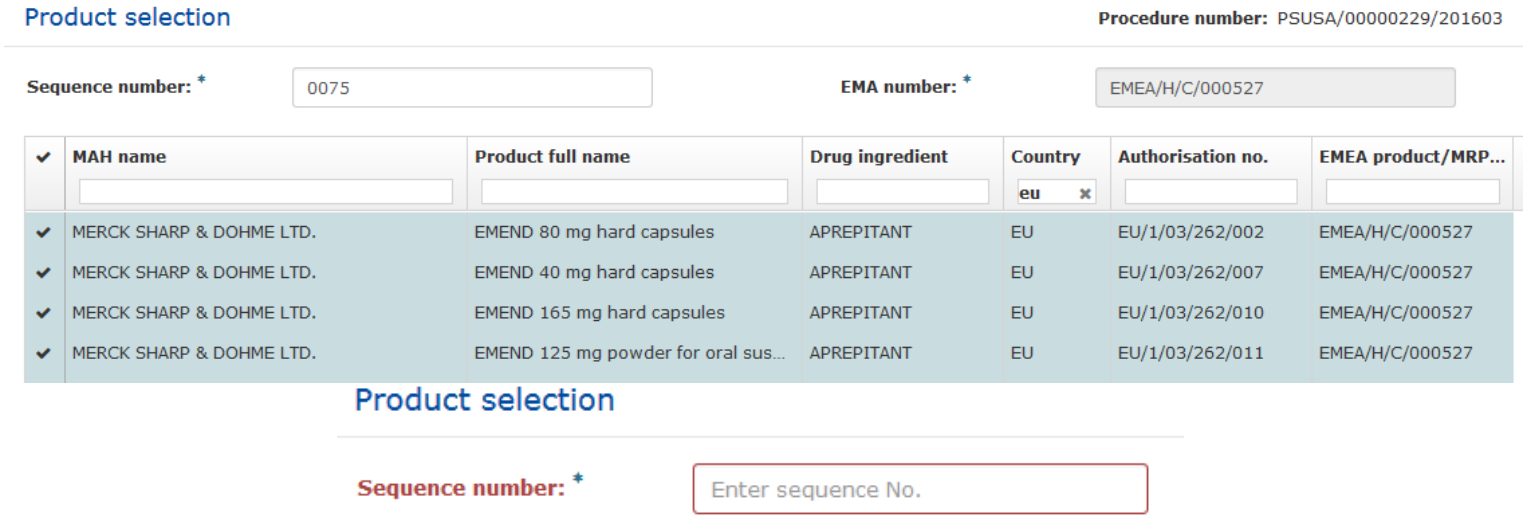
You cannot change the submission format after creating a sequence – to avoid wasting time, ensure the correct submission format has been selected before starting to work with product selection.

Select 'Create sequence' to enter the product selection functionality.

The product selection is based on the list of products containing the relevant active substance(s) as per the EURD list entry. The list is retrieved from XEVDMP, also called Art. 57 database.
If the product is missing or it has incorrect legal basis in Art. 57 database it will be missing from the PSUR Repository product listing. If any product details are incorrect this will also be reflected in the PSUR Repository interface.

Upon receipt of the 'Advice note' the MAH should check that the listing corresponds with the products indicated to the procedure in the PSUR Repository.

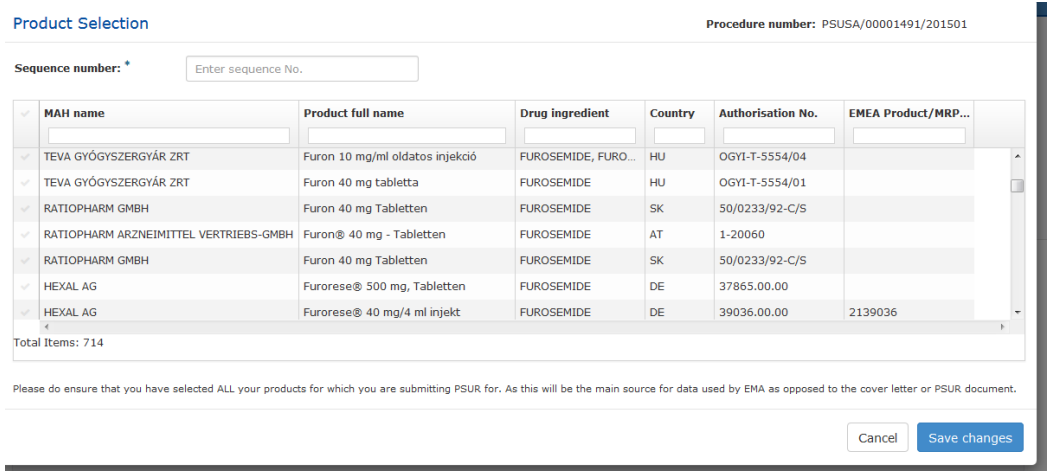
Create delivery file screen (6/14)

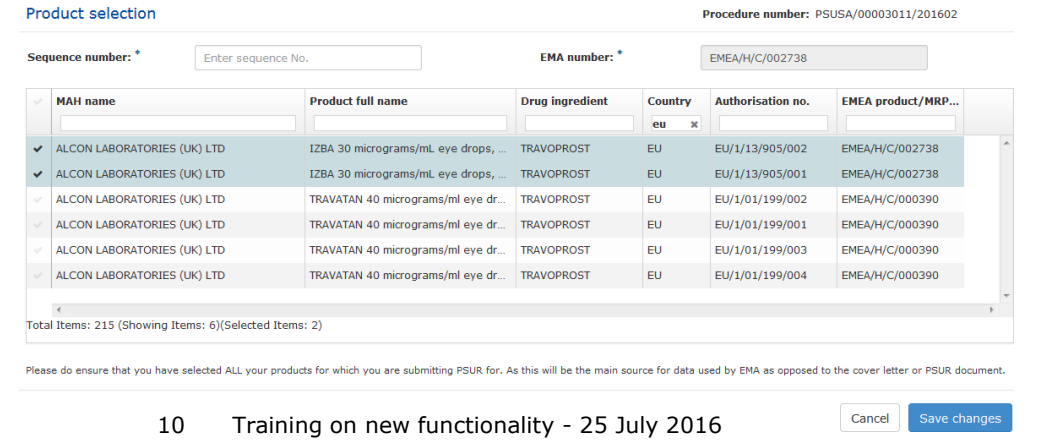


Enter the relevant sequence number. For eCTD products this is the next sequence number in the product lifecycle. There should be no standalone eCTD sequences grouping products together. For NeeS products; use the sequence number you would use for the next submission in the product lifecycle – this might be following sequential numbers or simply 0000. It is not possible to save the changes without entering sequence number.

EMEA product number is now automatically filled in using the EMA product database. It is no longer necessary to provide this manually.

Create delivery file screen (7/14)



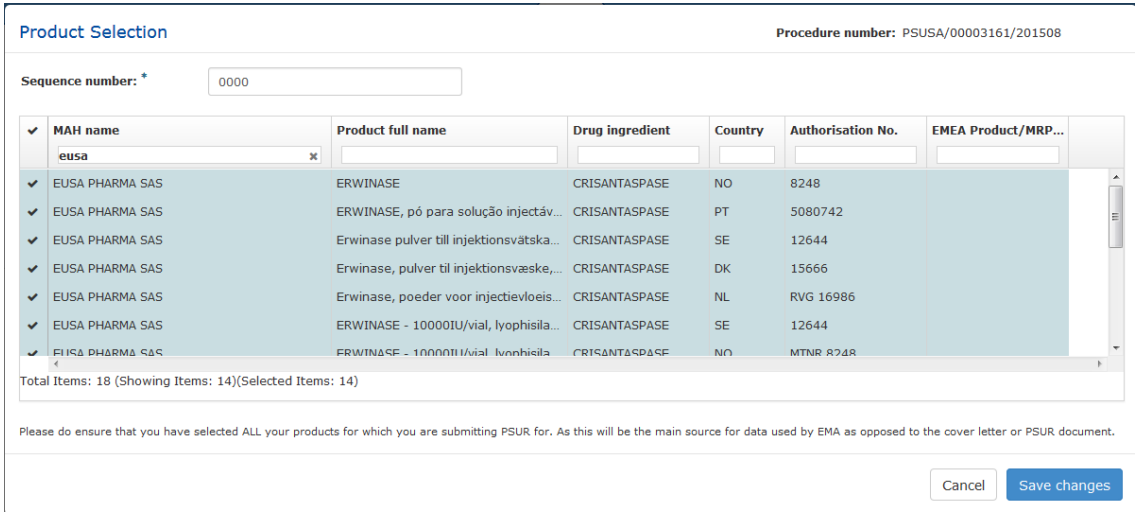


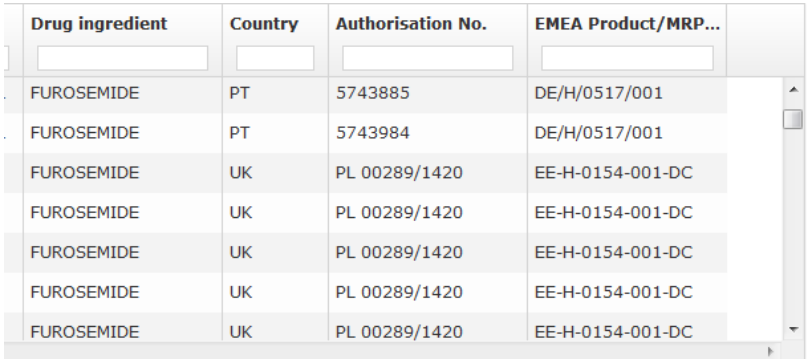
Select all products/presentations that are covered by the PSUR you are submitting. You can select all the products/presentations by clicking beside the MAH Name. Alternatively you can select individual products/strengths/presentations by clicking individual rows.

As the list contains all products with all presentations the list can be lengthy and in order to find your product you can filter the list with one or multiple filters. If the product names are similar it is helpful to use authorisation/product numbers.
For CAP eCTD submissions only one product – with all it's presentations - can be selected. It is important to select all presentations of the product to ensure complete listing to be included in the procedure.

All generic (if relevant for the given procedure) and all products with different alphabet are also included in the list and can be searched in the relevant language or filtered according to product numbers. If you cannot find your product from the list check the EURD list for submission requirements and ensure that the product has correct legal basis in Art. 57 database.

Create delivery file screen (8/14)



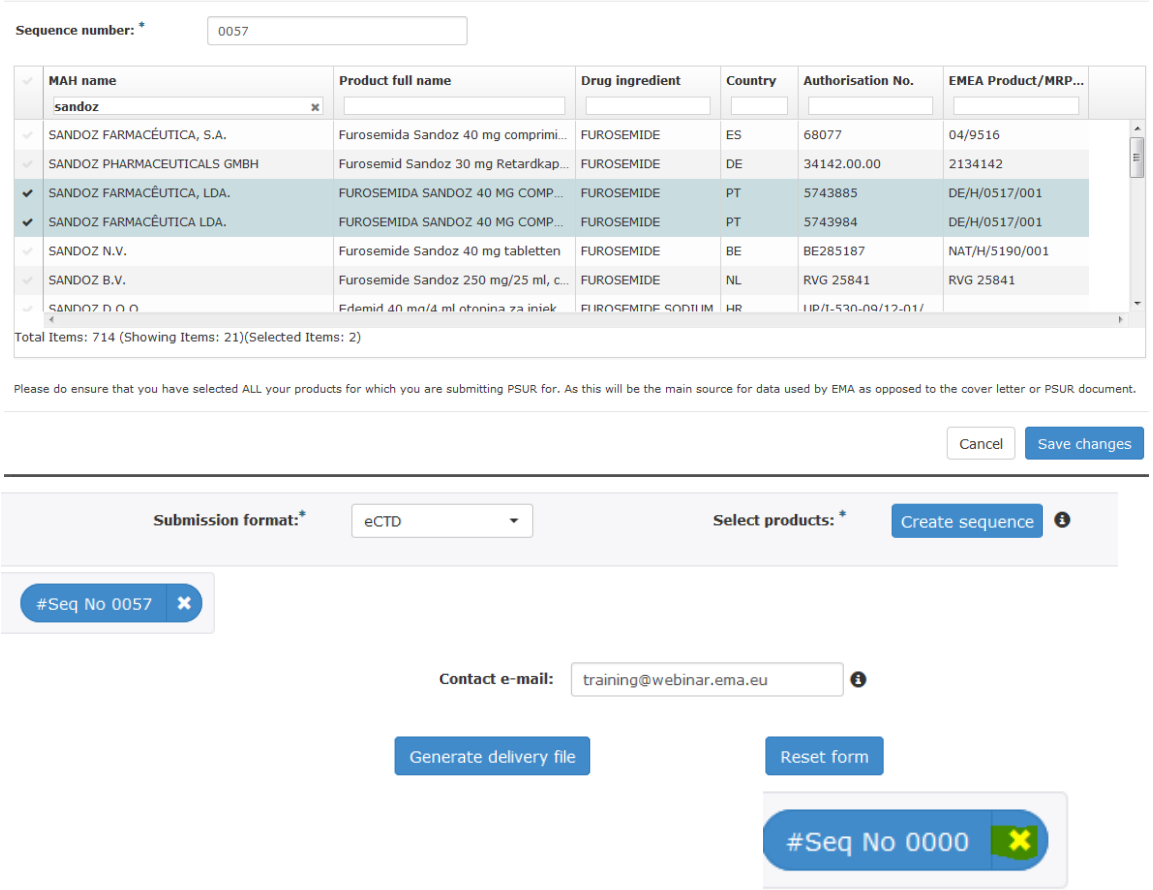


For MRP/DCP you can select multiple eCTD products from the list if the products have harmonised, comprehensive lifecycle across the member states. If MRP/DCP products do not have a harmonised eCTD lifecycle only one product (with all its presentations) should be selected.
Only one sequence number is provided on package level.

It is not possible to select more than one CAP from the list.

Select the correct products/presentations, a visual confirmation will be provided in the fields Authorisation number and MRP/DCP number if relevant.

Create delivery file screen (9/14)



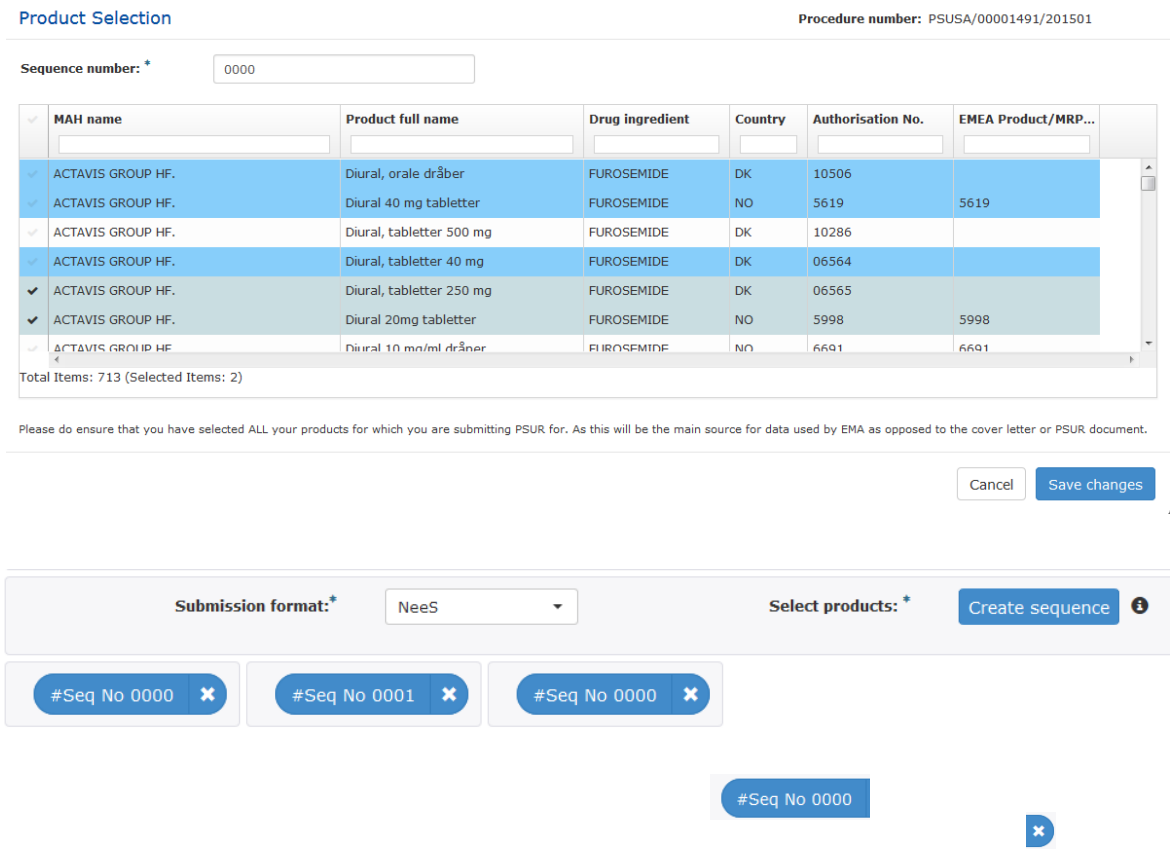
Once you have selected all relevant products/presentations ensure you have entered the correct sequence number and EMEA product number if relevant and proceed to 'save changes'

You are returned to the main screen and the sequence is shown with it's sequence number.

For eCTD products you can only add one 'sequence'.

Please note that you cannot change the submission format after product selection – if this is incorrect you will need to delete the previously created sequence by clicking the ✖ button next to the sequence number.

Create delivery file screen - NeeS (10/14)

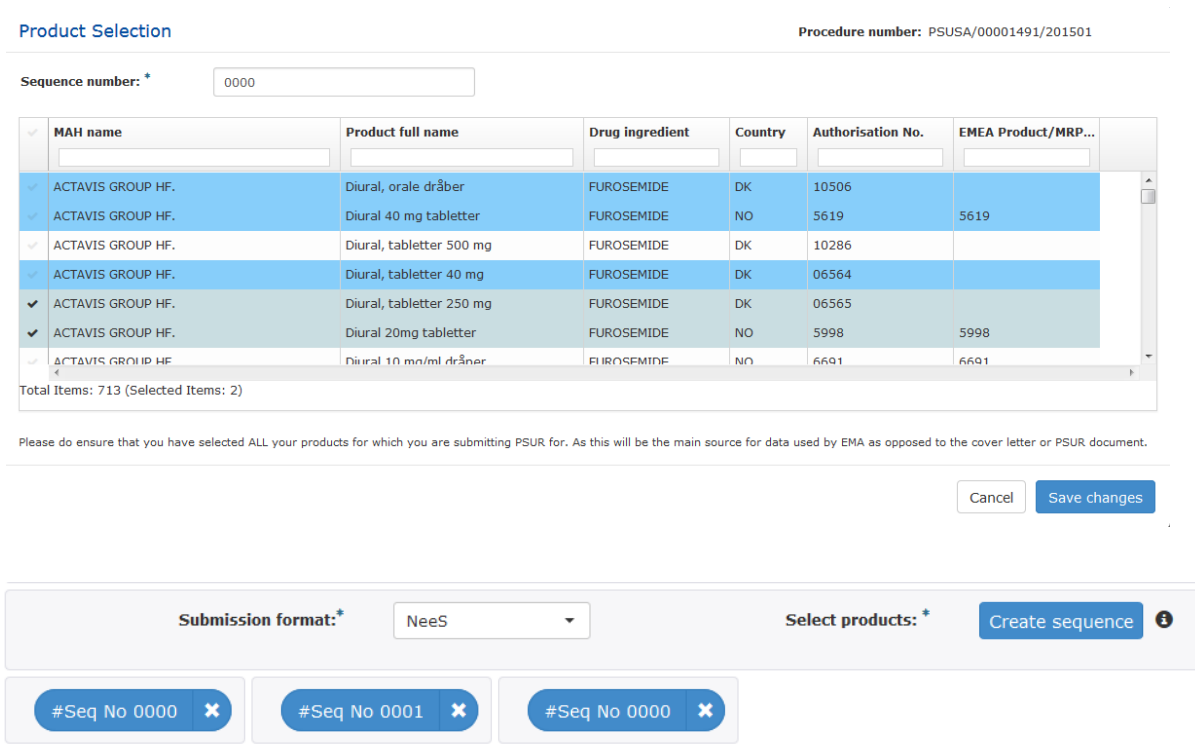


For NeeS submissions the sequence number is used as a 'virtual' reference to the relevant sequence number allowing the NCAs to follow the NeeS product lifecycle. For NeeS format submissions you can add multiple products per sequence and it is also possible to indicate different sequence number if necessary.

If you normally create and submit separate submission sequences for different NCAs for products in NeeS format you should continue to do so and you can instead of indicating the NeeS sequence numbers in the single delivery file 'group together the associated submissions' (not recommended for NeeS).

It is possible to send same NeeS sequence to multiple different NCAs with different NCA cover letters included within the single submission sequence - you can add new sequence from 'Create sequence' button.

Create delivery file screen - NeeS (11/14)

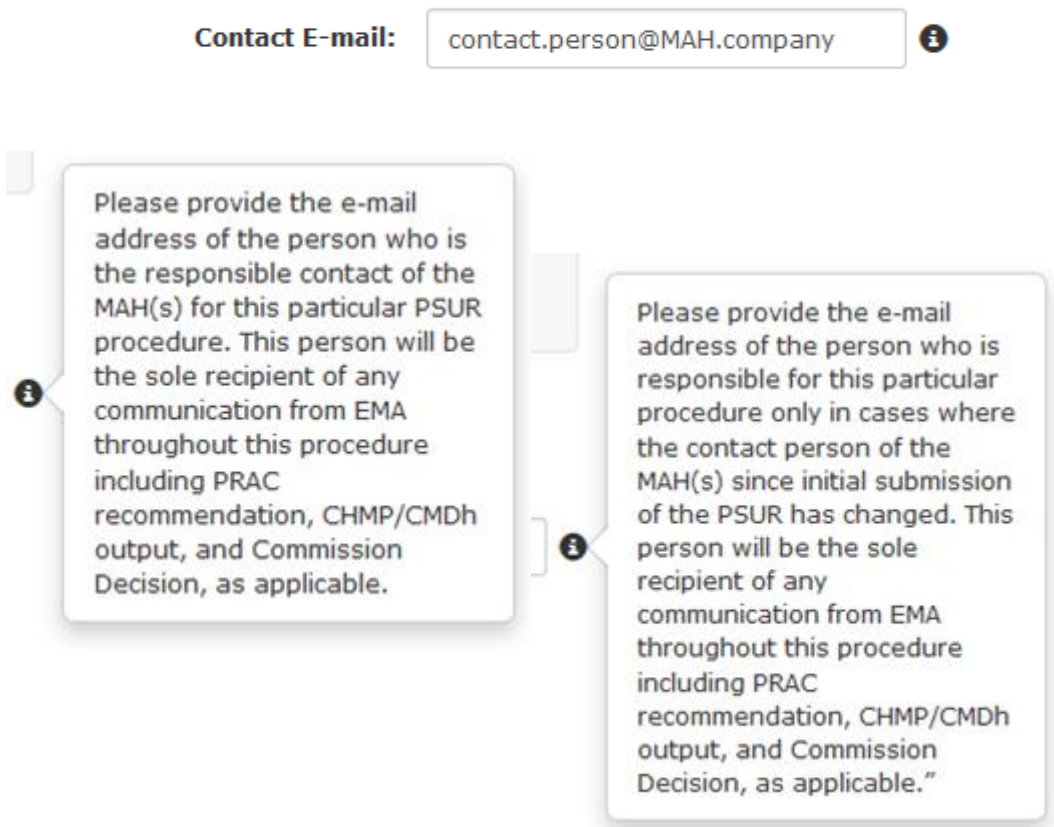


When adding additional sequences to NeeS submissions the full list of products will be opened and the products/presentations already selected in the previous sequence(s) are highlighted in blue.
Continue selecting products and indicating the relevant sequence number(s) until you have added all products/ presentations covered by your PSUR document.

All sequences are shown on the main screen with their sequence numbers. You can open and view the selected products within the sequences by clicking the #Seq No 0000 button. Do not click ✖ unless you wish to delete the sequence.

You can only include one NeeS submission per zip package with a single delivery file!

Create delivery file screen (12/14)



To finalise the delivery file enter an email address for the procedure contact person. Only one email address can be provided.
Mailbox email address can be used to ensure multiple users receive the messages if necessary.

The contact person email address will be used for **all communication from EMA throughout the procedure** – it is very important to include the correct contact email.

For supplementary information submissions only include the email address if the contact person has changed since the initial PSUR was submitted.

Any changes to the contact person can also be made at any time with an email to Procedure Assistant (PA).

Create delivery file screen (13/14)

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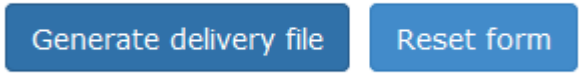
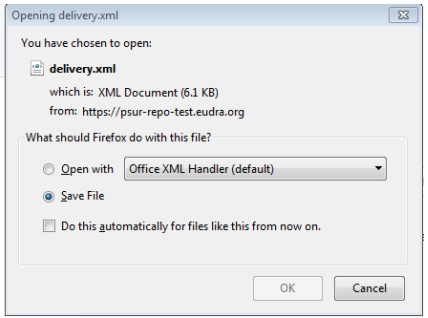
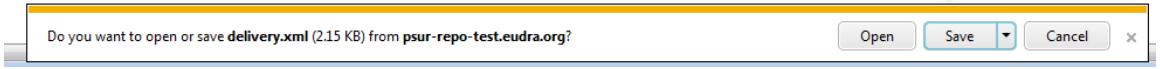




Save the xml delivery file in a named folder or a location where you can easily identify it especially if you are creating multiple delivery files for associated submissions.



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

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

If you wish to prepare another delivery file for associated product after generating the delivery file ensure you have created a folder where to save the associated delivery file, remove the sequences using ✖ and leave all other information intact – including the group ID. If you have accidentally reset the form re-enter the details as before including the same group ID as previously and proceed to product selection. You can find the group ID from the xml delivery file if needed.

Create delivery file screen (14/14)

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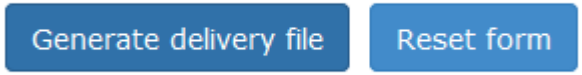
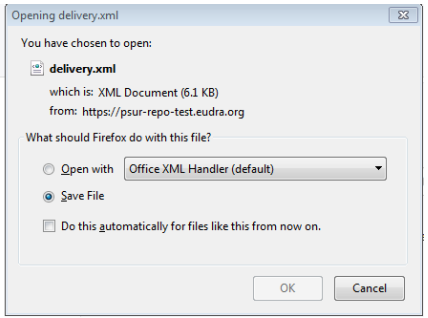
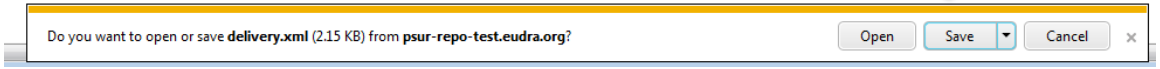




Save the xml delivery file in a named folder or a location where you can easily identify it especially if you are creating multiple delivery files for associated submissions.

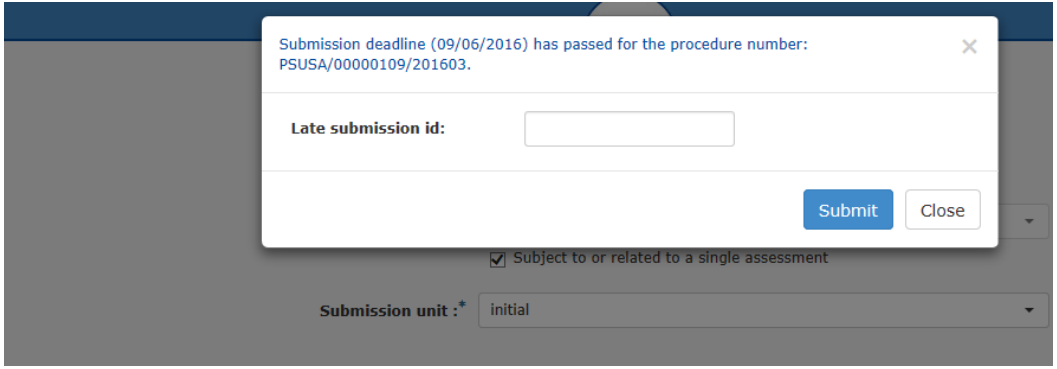


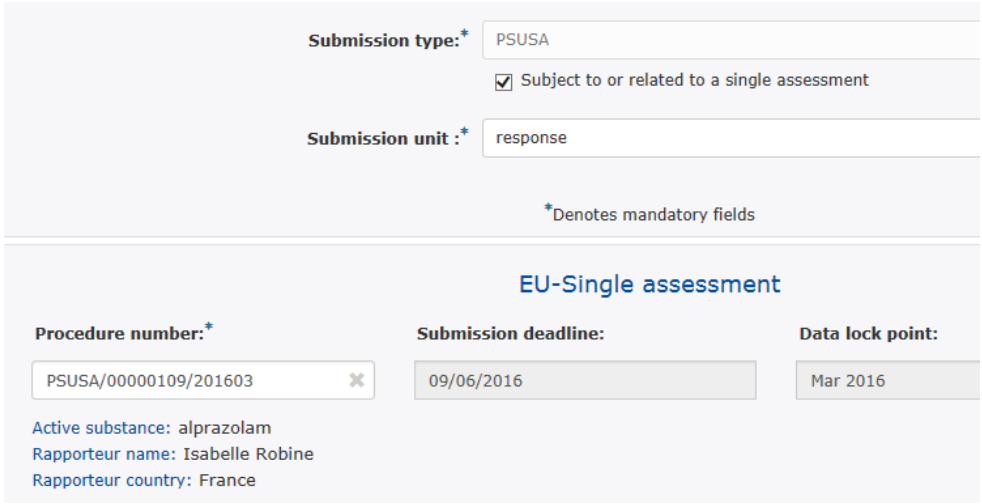
The saving of the delivery file is different depending which browser you use!

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

It is now 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.

Supplemental submissions (1/2)





Regulatory activity 'Supplementary Information' has now been replaced by the use of combination of 'submission type' and 'submission unit' as per the updated EU M1 Specification v3.0. After the submissions of the 'initial' PSUSA or PSUR submission for which a positive acknowledgement has been received the submission type remains PSUSA/PSUR and the relevant submission unit should be selected, for example responses, additional information etc.

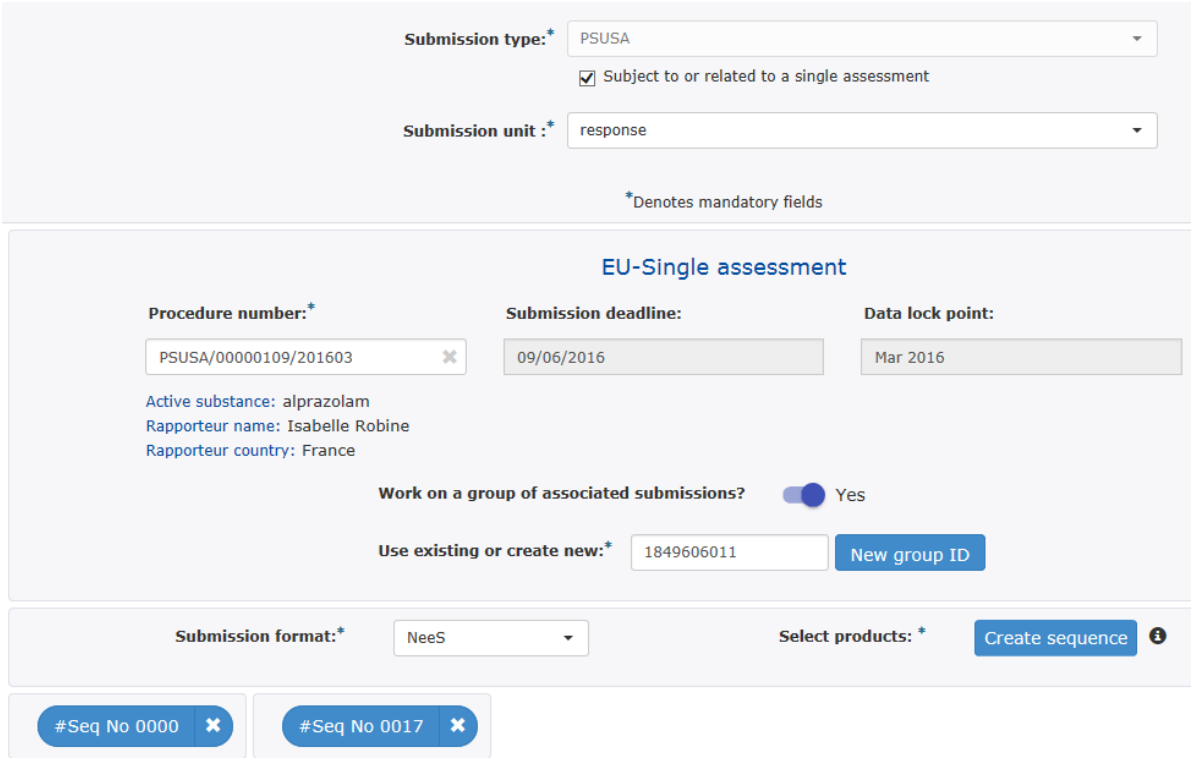
If responses have been submitted using supplementary information any future submissions should reflect the new attributes.

If you cannot find your procedure number contact https://servicedesk.ema.europa.eu as soon as possible.

Supplemental submissions **are not linked to a specific deadline** and it is possible to select procedure number, without late submission id, for procedure for which the submission deadline for initial PSUR submission has passed.

Non-EU single assessment submissions are **not linked** to EURD list **submission deadlines** however, same principal applies for subsequent submissions.

Supplemental submissions (2/2)



Functionality to group together associated (re)submissions, responses and MAH comments should be used similar way as for initial PSUR/PSUSA submissions. If you have prepared a single responses document or MAH comments document covering multiple products you should indicate that the document content is the same by grouping together associated submissions.

Do **not** use the same 'group ID' as you used for the initial PSUR submission as this is not the same document as the supplementary information – only ever associate same 'documents' to each other.

If you are not sure how to use this functionality review the user guide, contact https://servicedesk.ema.europa.eu

Delivery file in the package (1/2)

- 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 file according to Annex 3 filenaming examples if you wish to do so. The zip package filename is not checked by the system.

Delivery file in the package (2/2)

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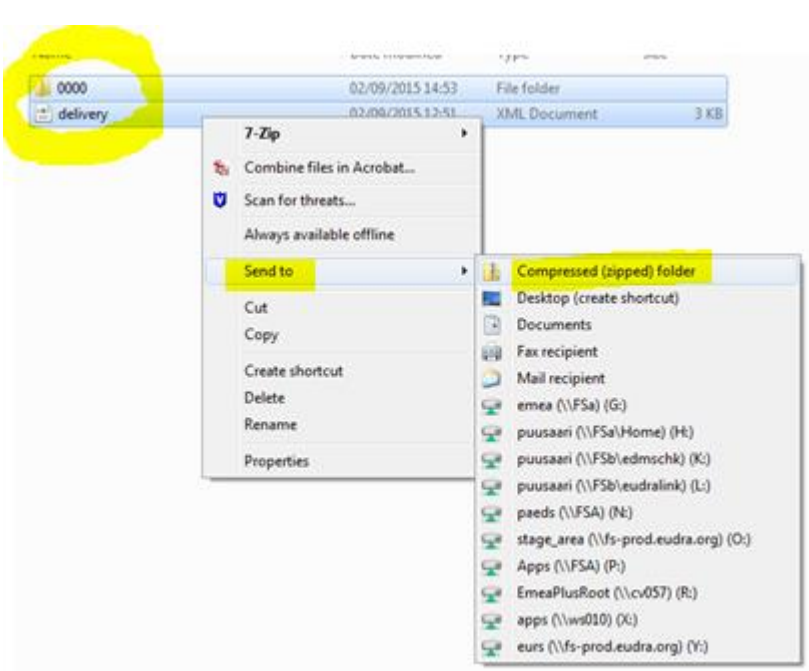
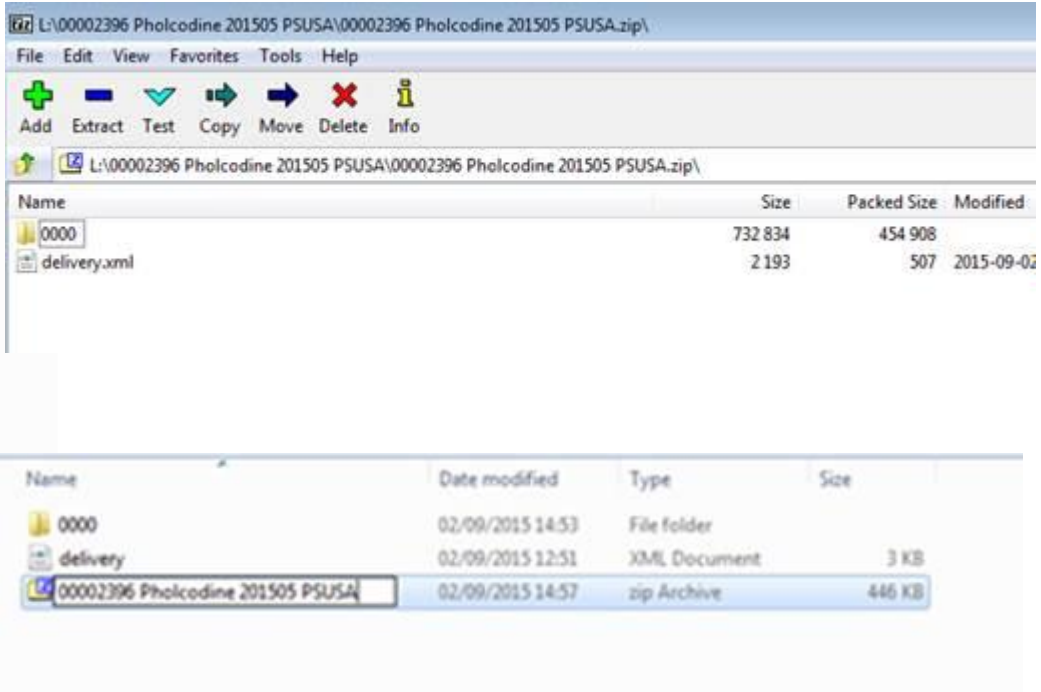
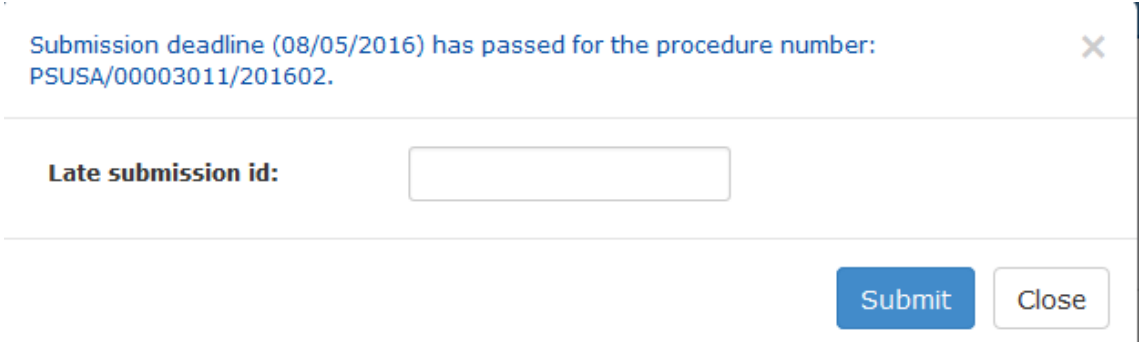
- Ensure that the xml delivery file is placed in the top level folder, in the same level as the submission folder. Both the submission folder and the xml delivery file must be in the root folder – ensure that the folder structure is not superfluous as this will cause a rejection – if there are additional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





Submission deadline



Submission date (According to the timelines defined in GVP Module VII, Section A)

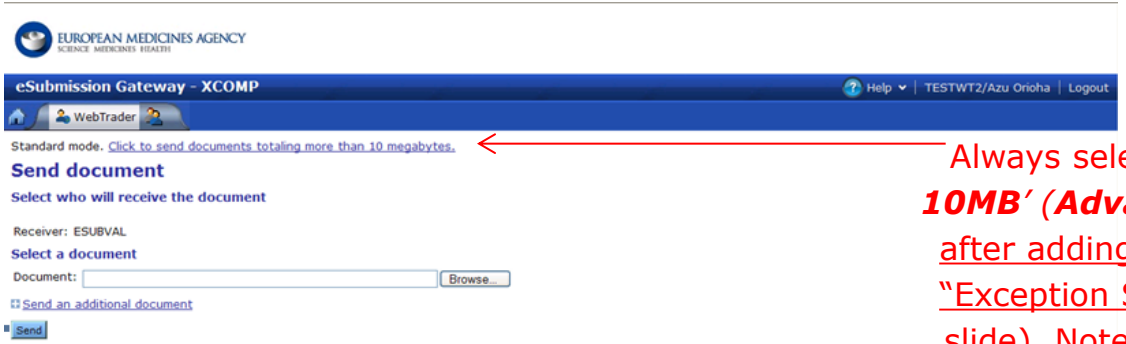
- Built in business rules prevent creation and use of previously created xml delivery file(s) after the submission deadline. This deadline is linked to the EURD list where the deadlines are published
- If you have missed the submission deadline contact the EMA (https://servicedesk.ema.europa.eu) as soon as possible to check if the product can still be included in the procedure. Please state **procedure number** and the **reason why the submission deadline** was missed.
- If it is still possible to include the submission in the procedure, EMA will provide you with a new '**late submission id**'. The late submission id will allow you to create an xml delivery file for your submission once you enter a valid late submission id in the pop up window and press submit. You can then proceed to fill in the delivery file and submit.
- Non-EU single assessment submissions are **not** linked to submission deadlines and hence do not require late submission id.

Submission using the Web Client

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.

Issues with create delivery file screen

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- After a new release you may experience issues due to cookies to the old version. It's 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 Art. 57 database is the official product database and the MAHs have the legal obligation to update their information in the database
- Following the linking of the procedure number and the products included in each PSUSA procedure majority of products will still be displayed through real-time view in to Art. 57 database (with **overnight** update for any changes in the Art. 57), however, certain procedures/products, due to the complexity, will be presented through a pre-generated list and if changes are introduced the list needs updating to reflect the changes in the PSUR Repository (ad hoc request by MAH to EMA – ensure that you have sufficient amount of time for this request to be reflected in the product list for your procedure).
- If you have missed the submission deadline, for any reason, and are unable to create the xml delivery file – contact the EMA (https://servicedesk.ema.europa.eu) as soon as possible to check if the product can still be included in the procedure and to obtain a 'late submission id'

How to avoid problems

- 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

Reminder on how to name the zip package

- 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 **PSUR repository** submissions via the Gateway
- Suggested file name examples (as per Annex 3):
  - **CAPs**: HC000999_Wonderpill_0020.zip, HC000999 Wonderpill responses 0021.zip
  - **NAPs included in PSUSA**: Companyname_00000000_YYYYMM_0020.zip
  - **Single, pure NAP**: MemberState_YYYYMM_ActiveSubstance_0020.zip
- There is no requirement for underscores or spaces.
- Additional information e.g. 'responses' can be included in the file name
- The 8 digit unique (PSUSA) number shown as 00000000 in the above examples and the -YYYYMM- format Data Lock Point, can be found in the published EURD list)
- Folders inside the zip containing submissions (e.g. Sequence 0001, 0002 etc.) should follow the eCTD or NeeS guidelines.

Support and guidance

PSUR Repository:
http://esubmission.ema.europa.eu/psur/psur_repository.html

eSubmission Gateway and Web Client:

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

- User documents
- Multimedia tutorials
- Training dates
- Who to contact

PSUR Repository Support

- PSUR Repository related queries: https://servicedesk.ema.europa.eu
- Procedure related queries: **contact the allocated procedure manager**
- Technical validation issues (e.g. missing or 'Failure' Acknowledgements): https://servicedesk.ema.europa.eu
- Use of the EMA **service portal** https://servicedesk.ema.europa.eu will be introduced for PSUR submission in future

Contact information and useful links

EUROPEAN MEDICINES AGENCY

- ***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
- ***EURD LIST:*** http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf
- ***Dossier Requirements for CAPs:*** http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500003980.pdf
- ***Guidance for NAPs:*** http://www.hma.eu/314.html
- ***Procedural guidance on PSURs:*** http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp&mid=WC0b01ac0580023e7d
- ***CMDh Best Practice Guide on the use of eCTD in the MRP/DCP:*** http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/eSubmissions/CMDh_084_2008_Rev.4_2015_06_clean.pdf

Thank you for your attention

Further information

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