PSUR Repository – MAH Training on new functionality

Webinar training on new functionality provided in release 1.04.00

Presented by Kristiina Puusaari on 14 October 2015

Outline of Today's training session

- PSUR Repository background and latest news
- Release v1.04.00 – main changes
- Release v1.05.00 – sneak preview
- How to create a delivery file
- Create delivery file screen
- Supplementary information
- Delivery file in the package
- Submission deadline
- Issues with create delivery file screen

- To whom to submit
- How to avoid problems
- Filenaming
- 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 supplementary information submissions from 1 September 2015**, it is no longer possible to use filenaming conventions to send PSURs and supplementary information sequences related to PSURs

- During transitional period it is strongly recommended to submit to the PSUR repository to ensure that all MAHs are familiar with the system

- Phased implementation allowing both MAHs and NCAs get used to the system – simulated mandatory use anticipated from 2016 for EU Single Assessment procedures

- The use of the PSUR Repository will become **mandatory for all PSURs from June 2016** after which the PSURs should only be submitted to the repository via eSubmission Gateway/Web Client

- MAHs access to the PSUR Repository is limited to the access to create delivery file screen

Release v1.04.00 – summary of main changes

- Major change to the product selection functionality – only products containing the relevant active substance(s) are displayed in the product selection window

  - Limits the available products to those in scope

  - No more 'product short name' search for EU PSUR Single Assessment

  - Removing limitations for Generic products

  - Removing limitations for product search due to language differences

- Ability to indicate 'associated' submissions – i.e. to be used when one single PSUR covers multiple products with individual eCTD lifecycles. This functionality allows 'deduplication' of submissions for NCA reviewers

- Addition of MAH contact email address (new mandatory field)

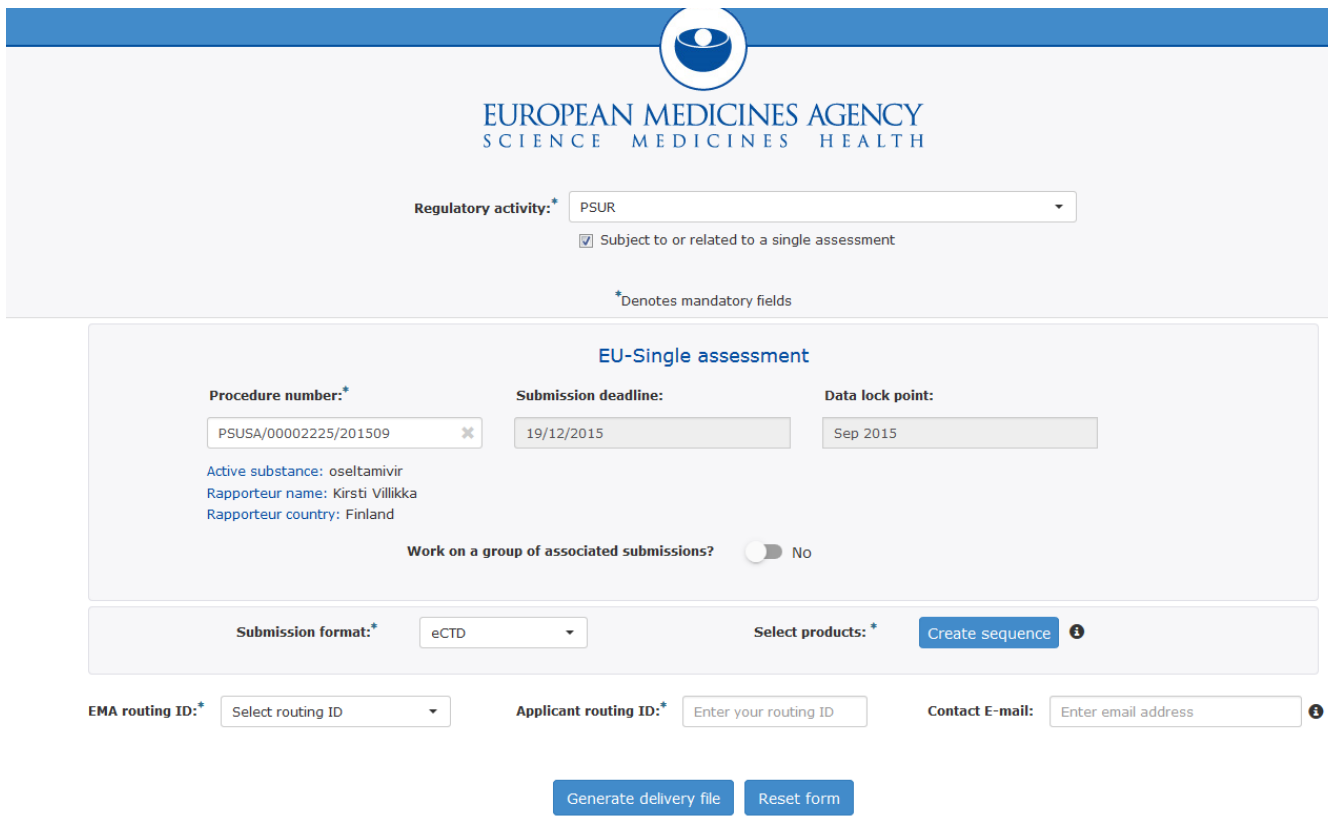# Release v1.05.00 – sneak preview to main changes

- API – allows automated retrieval of PSURs from the Repository by the NCAs

- Improved notifications and workflow support – post-audit functionalities (for NCAs)

- Other functionality TBC

Examples:

- If a PSUR covers **more than one product** and these are managed in **eCTD** format, then a new **delivery file** and a separate submission is required for each product – these different submissions should be grouped together using the new 'group of associated submissions' functionality

- MRP/DCP products with harmonised lifecycle can be included in one single xml delivery file with a single submission

- Example 1: the PSUR relates to Product A and Product B both managed using an eCTD product lifecycle. A **separate** submission is required for each product and **different** delivery file needs to be attached for each submission. The submissions should be indicated as associated submissions

- Example 2: the PSUR relates to multiple products authorised via MRP/DCP with harmonised eCTD lifecycle – **single** xml delivery file and submission should be sent

- Example 3: the PSUR relates to Product C and Product D. The product C is managed using eCTD and product D is maintained using NeeS lifecycle. It is not possible to combine the submission for these products and each will need to be submitted with the relevant delivery file. The submissions should be indicated as associated submissions

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SCIENCE MEDICINES HEALTH

Regulatory activity: * PSUR

☑ Subject to or related to a single assessment

*Denotes mandatory fields

EU-Single assessment

Procedure number: *   **Submission deadline:**   **Data lock point:**

PSUSA/00002225/201509 ✕   19/12/2015   Sep 2015

Active substance: oseltamivir
Rapporteur name: Kirsti Villikka
Rapporteur country: Finland

Work on a group of associated submissions?   No

Submission format: * eCTD   **Select products:** *   Create sequence ℹ

EMA routing ID: * Select routing ID   **Applicant routing ID:** * Enter your routing ID   **Contact E-mail:** Enter email address ℹ

Generate delivery file   Reset form

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

- Routing information and contact email address

Select the correct Regulatory activity (PSUR or Supplementary information). Supplementary information is to be used for resubmissions after successful initial PSUR submission, MAH comments and responses.

Confirm the type of assessment; when checkbox is cleared the screen will change to allow the user to fill in the Member State and DLP for the local country's assessment

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EU-Single Assessment

Procedure Number: *

Submission Deadline:

Data Lock Point:

data lock point

Active Substance:
Rapporteur Name:
Rapporteur Country:

Work on a group of associated submissions?   No

Use existing or create new: *   Group ID (digits only)   New group ID

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 **PSUR** for procedure that has passed submission deadline, or prior to the DLP date. There is no deadline for delivery files for **Supplementary information** submissions 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 multiple different products lifecycles, 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.
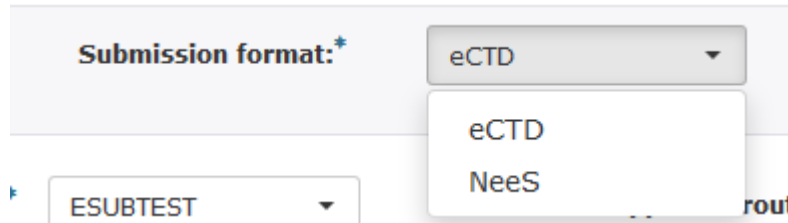
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Once you select 'yes' the system asks you to create a 'New group ID' or to enter existing group ID.

Press the button called 'New group ID' to generate a new group ID. A new ID should be initiated for new PSUR (or supplementary information) 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.
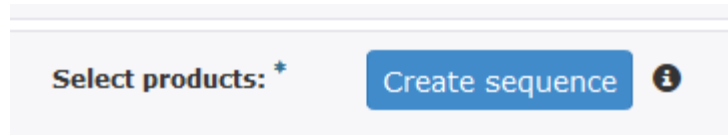
Existing group ID should **only** be used in case one of the associated submissions has **failed** and has to be **resubmitted**.

Use existing or create new:*   Group ID (digits only)   New group ID

Use existing or create new:*   1033634123   New group ID

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

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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 now based on the list of products containing the relevant active substance(s) as per the EURD list entry.
If the product is missing or 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.

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Product Selection

Procedure number: PSUSA/00002653/201509

Sequence number: * 0078

EMA number: * EMEA/H/C/000944

✔	MAH name	Product full name	Drug ingredient	Country	Authorisation No.	EMEA Product/MRP...
✔	BAYER PHARMA AG	Xarelto 10 mg film-coated tablets	RIVAROXABAN	EU	EU/1/08/472/003	EMEA/H/C/944
✔	BAYER PHARMA AG	Xarelto 10 mg film-coated tablets	RIVAROXABAN	EU	EU/1/08/472/004	EMEA/H/C/944
✔	BAYER PHARMA AG	Xarelto 15 mg film-coated tablets	RIVAROXABAN	EU	EU/1/08/472/012	EMEA/H/C/944

Product Selection

Procedure number: PSUSA/00002653/201509

Sequence number: * Enter sequence No.

EMA number: * EMEA/H/C/_____

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 and the EMEA number for CAPs.

For all CAPs you must enter the EMEA product number in the correct, 6 digit format. The number is normally visible in the field called EMEA/MRP/DCP number if it has been entered in Art. 57. If the format is not correct or the number is missing the MAHs are encouraged to update Art. 57 database when convenient – missing EMEA number does not prevent submission to the PSUR repository but improves data quality in Art. 57 and allows future automation.

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Product Selection   Procedure number: PSUSA/00001491/201501

Sequence number: * [Enter sequence No.]

	MAH name	Product full name	Drug ingredient	Country	Authorisation No.	EMEA Product/MRP...
	TEVA GYÓGYSZERGYÁR ZRT	Furon 10 mg/ml oldatos injekció	FUROSEMIDE, FURO...	HU	OGYI-T-5554/04	
	TEVA GYÓGYSZERGYÁR ZRT	Furon 40 mg tabletta	FUROSEMIDE	HU	OGYI-T-5554/01	
	RATIOPHARM GMBH	Furon 40 mg Tabletten	FUROSEMIDE	SK	50/0233/92-C/S	
	RATIOPHARM ARZNEIMITTEL VERTRIEBS-GMBH	Furon® 40 mg - Tabletten	FUROSEMIDE	AT	1-20060	
	RATIOPHARM GMBH	Furon 40 mg Tabletten	FUROSEMIDE	SK	50/0233/92-C/S	
	HEXAL AG	Furorese® 500 mg, Tabletten	FUROSEMIDE	DE	37865.00.00	
	HEXAL AG	Furorese® 40 mg/4 ml injekt	FUROSEMIDE	DE	39036.00.00	2139036

Total Items: 714

Please do ensure that you have selected ALL your products for which you are submitting PSUR for. As this will be the main source for data used by EMA as opposed to the cover letter or PSUR document.

[Cancel] [Save changes]

Product Selection   Procedure number: PSUSA/0000222S/201509

Sequence number: * [Enter sequence No.]   EMA number: * [EMEA/H/C/_____]

✓	MAH name	Product full name	Drug ingredient	Country	Authorisation No.	EMEA Product/MRP...
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 30 mg hard capsule	OSELTAMIVIR	EU	EU/1/02/222/003	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 12 mg/ml powder for oral su...	OSELTAMIVIR	LI	EU/1/02/222/002	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 12 mg/ml powder for oral su...	OSELTAMIVIR	EU	EU/1/02/222/002	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 6 mg/ml powder for oral sus...	OSELTAMIVIR	EU	EU/1/02/222/005	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 75 mg hard capsule	OSELTAMIVIR	EU	EU/1/02/222/001	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 75 mg hart hylki	OSELTAMIVIR	IS	EU/1/02/222/001	EMEA-H-C-000402
✓	ROCHE REGISTRATION LTD, U.K.	Tamiflu 12 mg/ml pulver til mikstur, s	OSELTAMIVIR	NO	EU/1/02/222/002	EMEA-H-C-000402

Total Items: 20 (Selected Items: 20)

Please do ensure that you have selected ALL your products for which you are submitting PSUR for. As this will be the main source for data used by EMA as opposed to the cover letter or PSUR document.

[Cancel] [Save changes]

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 now 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.

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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.

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.

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 rather than a mandatory requirement as for eCTD. For NeeS format submissions you can add multiple products per sequence and it is also possible to indicate different sequence number if necessary as in the previous version of the system.

If you normally create and submit separate submission sequences for different NCAs for NeeS format products 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 could be 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.

EMA Routing ID: *

Any Routing ID ▼

Any Routing ID

ESUBPROD

Applicant routing ID: * Enter your routing ID

Technical Details

	TESTING	PRODUCTION
Account Status	ENABLED	ENABLED
Routing ID	ESUBTEMAPSUR	ESUBPEMAPSUR

Details for eSubmissions web client

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

After confirming you have selected the correct products proceed to select the EMA routing ID from dropdown list and enter the senders 'Applicant routing ID'.
It is very important to add the correct routing ID in correct format. If the routing ID is incorrect the sender will not receive an acknowledgement and hence does not know if the submission has been successfully received by EMA and if it has been made available via the repository.

Do not confuse the 'User ID' with your 'Routing ID'. The user ID is used to log in to the Web Client and has '-admin'. The Routing ID can be found under section 'Technical details' in the registration form.

The same Gateway account and user ID can be used for PSUR submissions and all other eSubmissions to EMA – there is no need to create new account for PSURs.

Contact E-mail: contact.person@MAH.company ℹ️

Please provide the e-mail address of the person who is the responsible contact of the MAH(s) for this particular PSUR procedure. This person will be the sole recipient of any communication from EMA throughout this procedure including PRAC recommendation, CHMP/CMDh output, and Commission Decision, as applicable.

Please provide the e-mail address of the person who is responsible for this particular procedure only in cases where the contact person of the MAH(s) since initial submission of the PSUR has changed. This person will be the sole recipient of any communication from EMA throughout this procedure including PRAC recommendation, CHMP/CMDh output, and Commission Decision, as applicable."

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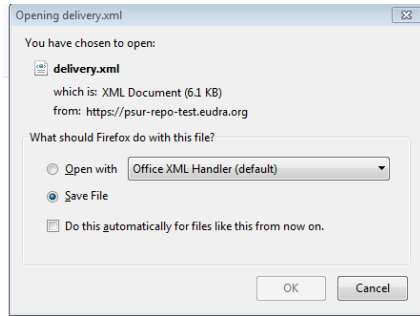
Any changes to the contact person can also be made at any time with an email to Procedure Assistant (PA).

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Generate delivery file   Reset form

Opening delivery.xml

You have chosen to open:

📄 delivery.xml

which is: XML Document (6.1 KB)
from: https://psur-repo-test.eudra.org

What should Firefox do with this file?

○ Open with   Office XML Handler (default)
● Save File
☐ Do this automatically for files like this from now on.

OK   Cancel

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.

Do you want to open or save **delivery.xml** (2.15 KB) from **psur-repo-test.eudra.org**?   Open   Save ▼   Cancel   ✕

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 – supplementary information

Regulatory activity 'Supplementary Information' should be used for **all subsequent submissions** following the 'initial' PSUR submission for which a positive acknowledgement has been received, this consists of any need for (re)submission, responses, MAH comments etc.

It is possible to submit supplementary information sequences for products for which PSUR was previously submitted using filenaming convention but not for those procedures for which the PSUR was not submitted to the EMA at all – if you cannot find your procedure number contact PSURRepository@ema.europa.eu as soon as possible.

Supplementary information submissions **are not linked to a specific deadline** and it is possible to select procedure number for which the submission deadline has passed.

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

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Regulatory activity:* Supplementary information

☑ Subject to or related to a single assessment

*Denotes mandatory fields

EU-Single assessment

Procedure number:* PSUSA/00001491/201501

Submission deadline: 30/10/2015

Data lock point: Jan 2015

Active substance: furosemide
Rapporteur name: Margarida Guimarães
Rapporteur country: Portugal

Work on a group of associated submissions? ⬤ Yes

Use existing or create new:* 1165766167   New group ID

Submission format:* NeeS   **Select products:*** Create sequence ⓘ

#Seq No 0000 ✖   #Seq No 0001 ✖   #Seq No 0000 ✖

Functionality to group together associated (re)submissions, responses and MAH comments should be used similar way as for initial PSUR 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 PSURrepository@ema.europa.eu or do not use it at all! The use of 'group ID' is not mandatory.

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Create delivery file screen – delivery file in the package

- 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.

- Do not rename the delivery file

- 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

- 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.
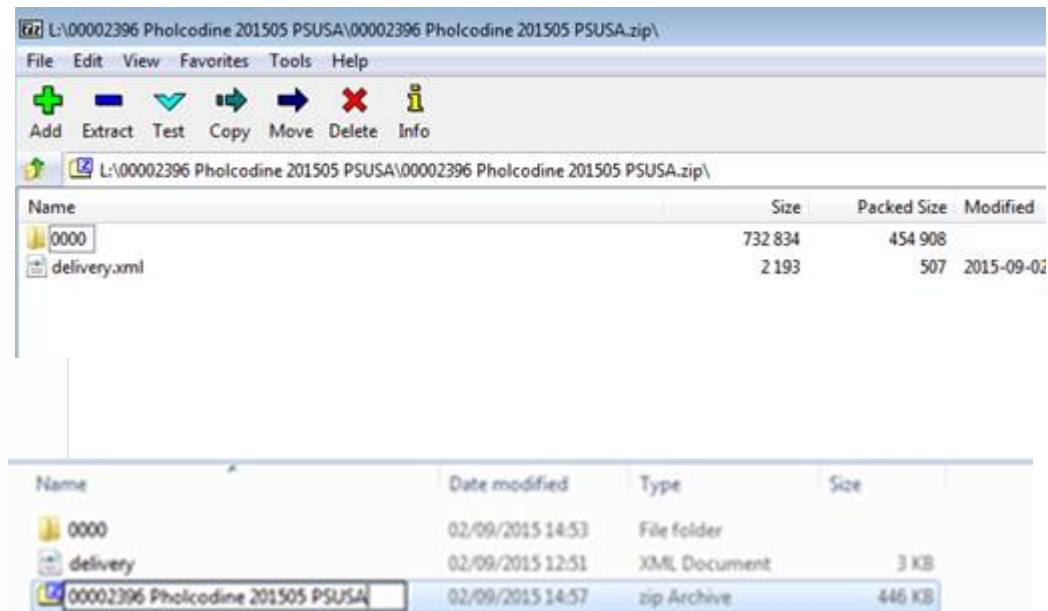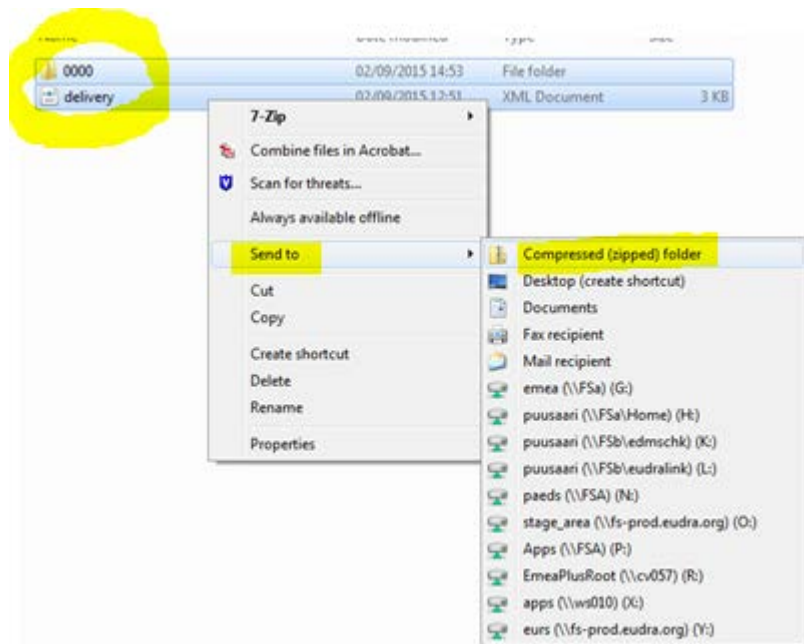
Create delivery file screen – submission deadline

- 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 and are unable to create the xml delivery file – contact the EMA (PSURRepository@ema.europa.eu) as soon as possible to check if the product can still be included in the procedure. Please state the reason why the submission deadline was missed.

- In order for EMA to create the xml delivery file for you, please provide:

  - The procedure number (e.g. PSUSA/00001234/201509)

  - Submission format (eCTD or NeeS)

  - The list of products/presentations/strengths the PSUR covers – i.e. the Annex I

  - Sequence number(s)

  - Applicant (senders) Routing ID

  - Contact email address

- EMA will prepare the delivery file and will provide it to you via email to enable you to make the submission

- Particularly after a new release has been deployed you might 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 had the legal obligation to update their information in the database by end of 2014

- 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 (PSURRepository@ema.europa.eu) as soon as possible to check if the product can still be included in the procedure

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To whom I need to submit my PSUR - before mandatory use

<u>CAPs</u>:

- To the European Medicines Agency – **mandatory** submission through eSubmission Gateway/ Web Client including XML delivery file created in the <u>PSUR Repository user interface</u>

<u>NAPs:</u>

<u>Mixed CAP/NAP and NAP/NAP PSUSA procedure (as per EURD list)</u>:

- To all Member States in which the medicinal product has been authorised

- CAP/NAP: To the PRAC Rapporteur as per the <u>submission requirements for PSURs</u> (i.e. via CESP or CD/DVD)

- NAP/NAP: To the Lead Member State appointed for the procedure (even if the product is not authorised in that Member State) as per the <u>submission requirements for PSURs</u> - No need to submit to PRAC rapporteur even though the name is mentioned in the EURD list

- Additionally to the European Medicines Agency – submission through eSubmission Gateway/ Web Client including XML delivery file created in the <u>PSUR Repository user interface</u>. Optional, but strongly recommended prior to the mandatory use

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

- Do not rename the delivery file

- Always use the "Advanced Mode" for **all** transmissions via the Web Client, also for submissions smaller than 10MB to receive the Acknowledgements from the eSubmission Gateway / Web Client

- Submission **metadata is provided via XML delivery file**, however package should 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: **PSURRepository@ema.europa.eu**

- Procedure related queries (prior to Procedure Manager allocation): **PSURquery@ema.europa.eu**

- Technical validation issues (e.g. missing or 'Failure' Acknowledgements): **ectd@ema.europa.eu**

Contact information and useful links

- **Gateway Registration Documentation** (contact info, forms, guidance documents): http://esubmission.ema.europa.eu/esubmission.html

- **Gateway Registration team:** esubregistration@ema.europa.eu

- **Technical issues during webclient set-up:** gatewaysupport@ema.europa.eu

- **Technical validation issues** (e.g. 'Failure' Acknowledgements): ectd@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

- **Dossier Requirements 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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