EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository – MAH Training on new functionality

Webinar training on new functionality provided in release 1.03.00

Presented by Kristiina Puusaari on 12 August 2015.

Outline of Today's Webinar

- PSUR Repository background
- To whom I need to submit my PSUR
- Release v1.03.00
- Reminder on how to name the zip package
- How to create a delivery file
- Create delivery file screen
- Issues with create delivery file screen
- Common issues
- How to avoid problems
- Support and Guidance
- Future releases
- Regular bulletins
- PSUR Repository support
- Contact information and useful links

PSUR Repository background

- *Article 25a of Reg. (EC) 726/2004* requires the Agency (in collaboration with the EC and Member States) to set up and maintain a repository for PSURs and corresponding assessment reports.
- 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 PSUR submissions from 1 September 2015**, after this date it will not be possible to use filenaming conventions to send PSURs and supplementary information sequences related to PSURs.
- Phased implementation allowing both MAHs and NCAs get used to the system – simulated mandatory use anticipated from early 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 will only be submitted to the repository only via eSubmission Gateway/Web Client. During transitional period it is strongly recommended to submit to the PSUR repository even before this deadline to ensure that all MAHs are familiar with the system.

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

CAPs:

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

NAPs:

Mixed CAP/NAP and NAP/NAP PSUSA procedure:

- To all Member States in which the medicinal product has been authorised
- CAP/NAP: To the PRAC Rapporteur as per the submission requirements for NAPs (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 submission requirements for NAPs - 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 PSUR Repository user interface. Optional, but strongly recommended prior to the mandatory use

Release v1.03.00 – summary of main changes

- It is now possible to select multiple eCTD products on a single xml delivery file for products with harmonised eCTD lifecycle (MRP/DCP)
- It is now possible to submit multiple PSURs for different products contained in the same PSUR Single Assessment (PSUSA) procedure using xml delivery files without failure (issue related to EMA receiving systems corrected)
- It is now possible to submit non-sequential submissions of PSURs for the same PSUSA procedure (issue related to EMA receiving systems corrected)
- It will no longer be possible to use **filenaming conventions** for any PSUR and Supplementary information submissions via eSubmission Gateway / Web Client from **1 September 2015**. The xml delivery file must be used for all such submissions.

Reminder on how to name the zip package

- 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.

How to create a delivery file

Examples:

- If a submission contains **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 with the exception of MRP/DCP products with harmonised lifecycle.

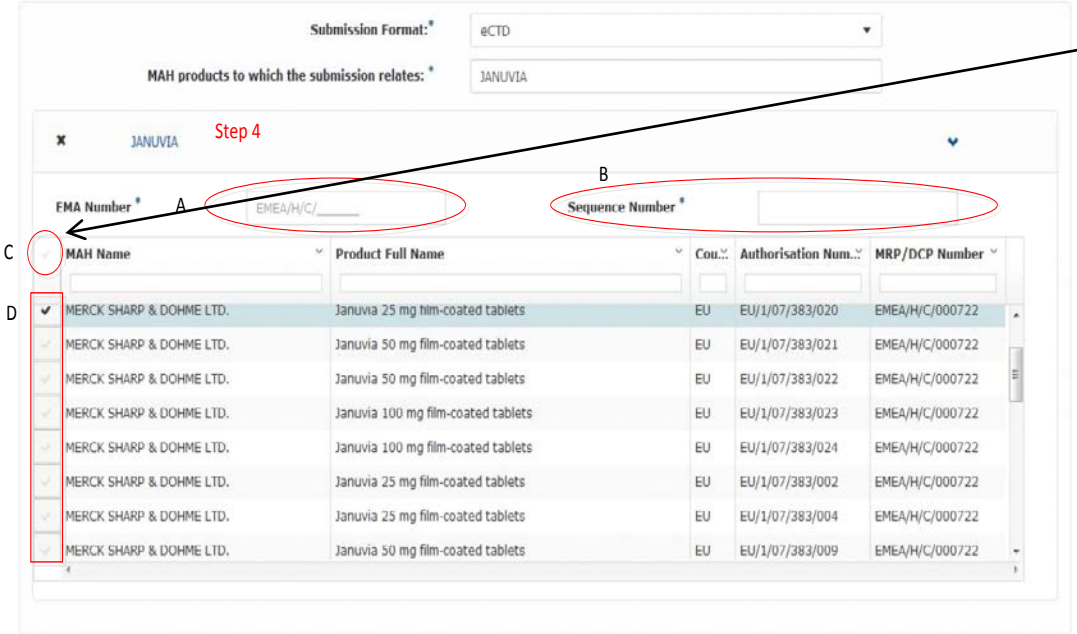
- Example 1: the PSUR relates to Product A and Product B both managed using an eCTD product lifecycle. A **separate** submission is required for each product and **different** delivery file needs to be attached for each submission.

- 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.

Delivery file can be created multiple times for same products and the UI can be used for testing the product search however, test submissions should not be sent with an xml delivery file created in the production environment.

Create delivery file screen



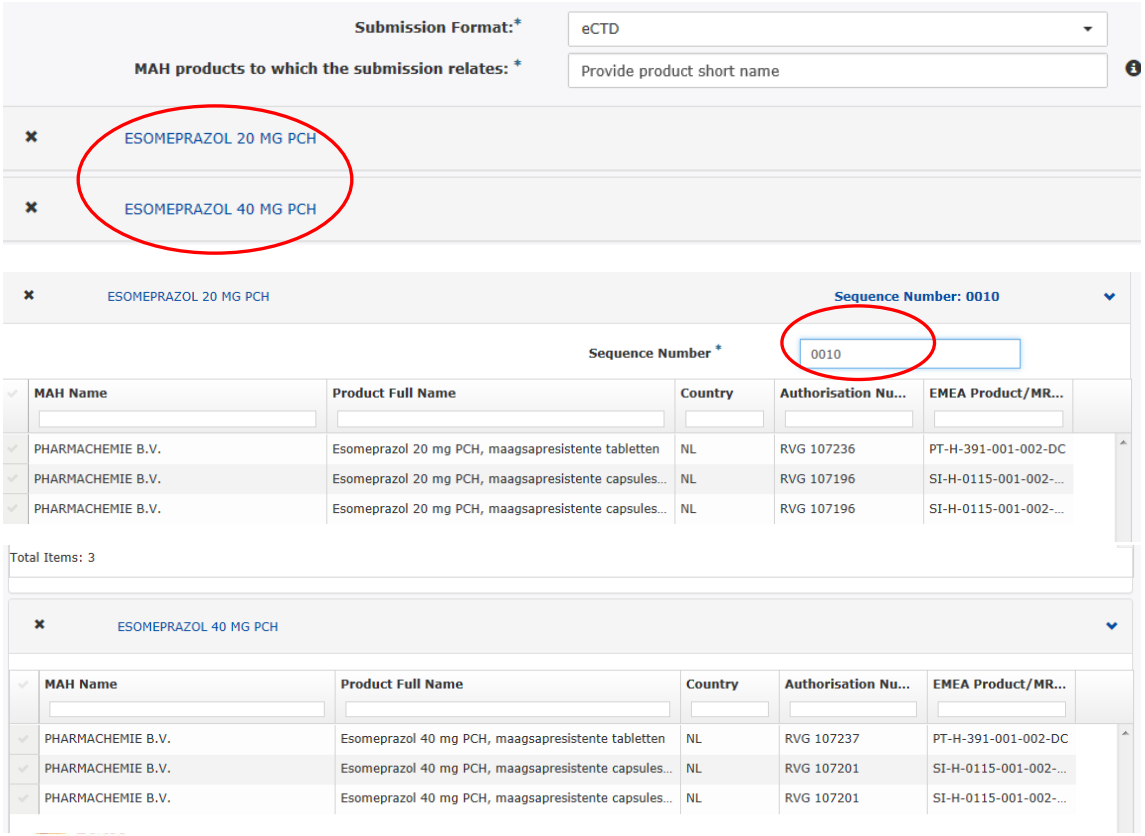
Select one or more of the products/presentations that are listed in the PSUR document being submitted. The user can select all the products/presentations by clicking beside the MAH Name (indicated by label “C” in the picture below) or they can select individual products/strengths/presentations by clicking individual rows (indicated by label “D” in the picture below).

For CAP eCTD submissions only one product - in the product short name level - can be selected.

For MRP/DCP products with harmonised eCTD lifecycle multiple products can be submitted as single package with single xml delivery file

It is not possible to add NeeS submissions for eCTD delivery file. Separate delivery file and separate submission must be prepared. Bundling/grouping of eCTD and NeeS submissions is not allowed.

Create delivery file screen

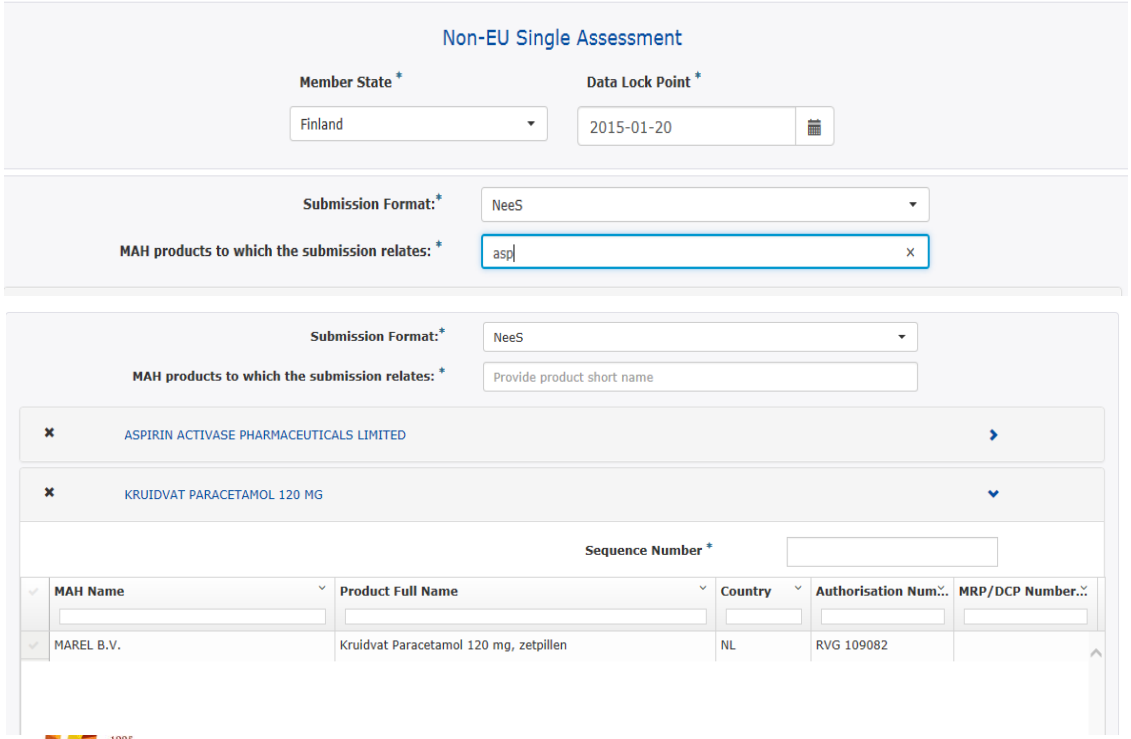


If submission type is eCTD, you are now able to repeat the step to add multiple products on the product short name level for those products that have harmonised, comprehensive lifecycle across the member states. Only one sequence number is provided on package level.

Click on the product name shown to show the list of full product names at the presentation level. The list can be hidden by clicking the name of the product again.

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

Create delivery file screen

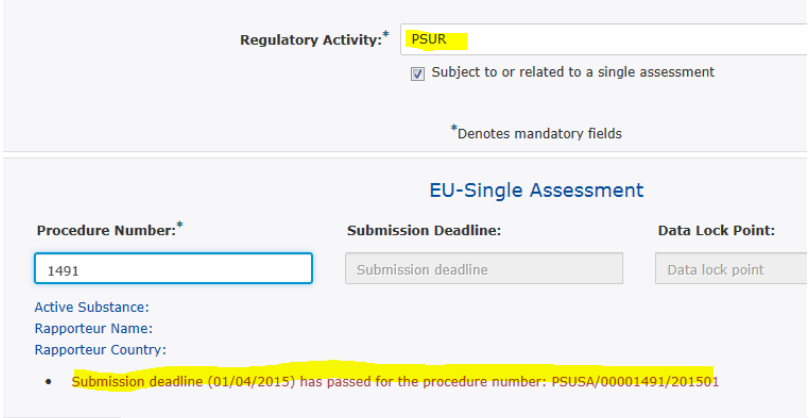


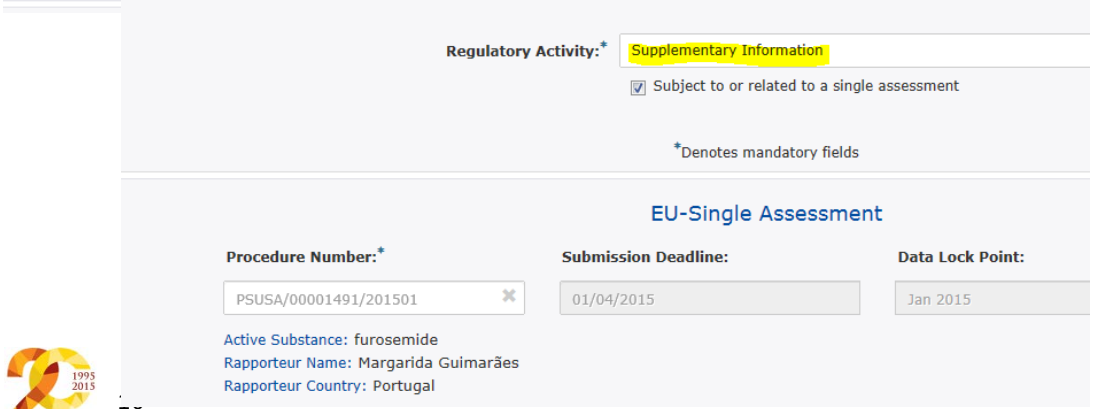
If the PSUR submission is for a product which is authorised in one Member State only, select the correct MS from the list and enter the correct data lock point manually.

In case of NeeS submissions, you can repeat the step to add multiple products if these have the same DLP.
For eCTD multiple products can now be selected but this be only done if they have the same submission sequence number.

If you have made a mistake, click the cross on the left hand side and the product is removed.

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 etc.

It is possible to submit supplementary information sequences for products for which PSUR was previously submitted using filenaming convention or not submitted to the EMA at all.

When supplementary information is selected 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.

Issues with create delivery file screen

- 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
- If you cannot find your product from the dropdown menu, check the entry in Art. 57 database and add/edit Art. 57 database
- If you see errors in the product information/name/numbers/legal basis log in to Art. 57 to make changes/updates
- 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

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 double check that you have entered the correct EMEA/H/C number in 6 digit format for all CAP products. This is normally visible in the field called ‘EMEA Product/MRP/DCP number’ field. If the number is missing, please add it in Art. 57
- Do not rename the delivery file (unless you accidentally saved it twice and it’s called e.g. delivery(2).xml), only rename to delivery.xml
- 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

Future releases and change requests

- Future releases have been scheduled and will be delivered within the next coming months
  - Usability improvements and bug fixes as per existing and new change requests
  - Improvements to the product selection are planned in the future (limiting the product selection to those products that contain the active substance of the selected PSUSA procedure only)
  - This should also resolve issues related to the product selection for Generic products and products for which the names are in Cyrillic letters

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

User Documents

Slides and the Q&A from 21 May webinar	Slides and Q&A's
PSUR Repository user registration form for NCA users	Repository user registration
MAH PSUR Repository User Guidance document	MAH user guide (06/08/2015)
NCA PSUR Repository User Guidance document	NCA user guide (06/08/2015)
PSUR Repository FAQ document	Questions and answers
Examples of simplified filenames for PSUR submissions	Annex 3
How to submit to PSUR Repository - existing Gateway users	Presentation
How to submit to PSUR Repository – New Gateway users	Presentation
Release Notes	Release notes (06/08/2015)
NAP eCTD submissions workaround solution	Presentation
PSUR Submission requirements during the transitional period	Presentation
Multimedia Tutorials	
Pilot training for NCA users	Multimedia webinar
How to submit PSURs training for existing Gateway users	Multimedia webinar
How to submit PSURs training for new Gateway users	Multimedia webinar
How to submit to PSUR Repository – pilot training for MAH	Multimedia webinar
Technical Documents	
Draft specifications of the PSUR Repository API	Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs
Supplementary Specification	Additional email notifications specification
Who to contact	
MAH Gateway user registration	GatewaySupport@ema.europa.eu
NCA User registration	ITservicedesk@ema.europa.eu
Gateway submission related technical issues	eSubmission@ema.europa.eu
PSUR Repository training, user guide or Q&A document related question or any other query related to the PSUR Repository or the pilot	PSURrepository@ema.europa.eu
PSUR procedural questions for the EU Single Assessment coordinated by the Agency. 1	PSUR procedural guidance Q&A

Regular bulletins

- Network
- Industry (summary)

PSUR Repository Bulletin

Week commencing 3 August 2015

- Release 1.03.00 of the PSUR Repository is made available for both MAHs and NCAs on 6 August delivering improved functionality and defect fixes which have been identified during the pilot phase. The updated system release notes and MAH and NCA user guides can be found under User documents on this page.
- The scope for release v.1.04.00 is being agreed with the advisory group and the release is planned for October 2015. The user acceptance testing (UAT) for the release is planned for September 2015. Call for interest for this UAT will be sent out early September.

Action items and reminders

- Training session for MAHs and other industry users concentrating on the new features of the PSUR repository v1.03.00 will be held on Wednesday 12 August 2015 at 1pm UK time. This session will be recorded and the recording made available on this page. Book your place by emailing PSURRepository@ema.europa.eu. It is recommended to review previous training material prior to attending this session as it will only cover the new functionality delivered in the new release.
- A follow-on interactive Q&A session on the use of PSUR Repository for MAHs and other industry users will be held on Thursday 10 September 2015 at 1pm UK time. This session will be recorded and the recording made available on the PSUR Repository webpage. Book your place by emailing PSURRepository@ema.europa.eu. It is strongly recommended to review available training material prior attending this interactive session where we will answer your questions on the new functionality. This Q&A session will not cover procedural aspects.
- Users should continue to report any issues they have with the system through the PSUR Repository mailbox PSURRepository@ema.europa.eu.
- List of available procedures for the August pilot on the basis of the submissions in the system has been distributed to the network. MAHs will be informed of the procedures taking part in the August pilot.

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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