PSUR Repository – Interactive Q&A

Interactive Q&A session with MAHs on the new functionality provided in release 1.03.00

Presented by Kristiina Puusaari on 10 September 2015

Outline of Today's Q&A session

- PSUR Repository background and latest news
- Release v1.03.00 – main changes
- Release v1.04.00 – sneak preview
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- To whom I need to submit my PSUR
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- Standalone eCTD sequence vs eCTD lifecycle

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- Support and Guidance
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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 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 should only be submitted to the repository via eSubmission Gateway/Web Client.

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 addressed)

- It is now possible to submit non-sequential submissions of PSURs for the same PSUSA procedure (issue related to EMA receiving systems corrected)

Release v1.04.00 – sneak preview to main changes

- Major change to the product selection functionality – once the procedure number is entered a list of products containing the relevant active substance(s) included in the procedure are displayed

  - Limits the available products to those in scope

  - 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)

Does mandatory use of xml delivery file mean mandatory use of the PSUR Repository? (1/2)

Not at all – There are 2 different aspects;

- Transmission support: xml delivery file vs filenaming convention; and

- To whom to submit: NAPs submitted to member states as per current practice during the transitional period vs after mandatory use only to the PSUR Repository.

Previously it was possible to submit **CAP** and **NAP** PSURs contained in PSUR Single Assessment to EMA using [filenaming conventions](#), from 1 September the filenaming conventions were switched off for all PSURs and related supplementary information submissions. The filenaming conventions for all other procedure types remain in force.

This means in practice that **it will continue to be mandatory to submit CAP PSURs** to EMA via eSubmission Gateway/Web Client. The only change is that they must be submitted using the xml delivery file and not with a filenaming convention

Does mandatory use of xml delivery file mean mandatory use of the PSUR Repository? (2/2)

What about PSURs for products authorised via MRP/DCP/NP?

NAP (MRP/DCP/NP) PSUR submissions to EMA and to the PSUS Repository **remain optional**, but **strongly recommended until June 2016** - Mandatory use of the PSUR repository

If NAP (MRP/DCP/NP incl. pure single NAPs) PSUR is submitted to EMA, it must be submitted to the PSUR Repository – i.e. the xml delivery file must be used (Mandatory use of the xml delivery file)

As the network will be moving to a 'simulated mandatory use' possibly in early 2016 meaning that the repository will be fully used for the assessment purposes, it is strongly recommended that the submissions are already provided to the repository even though the use is not yet mandatory. This gives all parties an opportunity to experience the use of the repository prior to the mandatory use and also gives an opportunity to detect any technical/business process issues that can be rectified in time before the mandatory use.

To whom I need to submit my PSUR – prior to mandatory use (1/3)

- There is **no change** to the existing submission rules for submissions to NCAs during the transitional period – both, pure single NAPs and products included in the EU PSUR Single Assessment (PSUSA) procedure

- Submission to PSUR Repository is strongly recommended for all PSURs and supplementary information, responses etc.

CAPs:

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

- Submissions with filenaming conventions only are no longer accepted for CAPs

To whom I need to submit my PSUR – prior to mandatory use (2/3)

NAPs:

Mixed CAP/NAP PSUSA procedure:

- To all Member States in which the medicinal product has been authorised submission requirements for PSURs (i.e. via CESP or CD/DVD)

- **CAP/NAP**: To the PRAC Rapporteur i.e. the person named in the EURD list. The submissions should be sent as per the submission requirements for PSURs (i.e. via CESP or CD/DVD)

- 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** before the mandatory use

To whom I need to submit my PSUR – prior to mandatory use (3/3)

NAPs:

NAP/NAP PSUSA procedure:

- To all Member States in which the medicinal product has been authorised [submission requirements for PSURs](#) (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) [submission requirements for PSURs](#) (i.e. via CESP or CD/DVD). There is no need to submit to the 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** before the mandatory use

Does delivery XML replace use of filenames?

- Submission **metadata is provided via XML delivery file**, however package should still have a **meaningful** name for technical support and archiving purposes

- File names are **not validated** for **PSUR repository** submissions via the GW/Web Client

- 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.

Product selection functionality in the XML file creation interface – link to Art. 57 / XEVMPD (1/2)

- The product listing and the product information is read **directly** from Art. 57 database (real-time view to Art. 57) and hence, if the product is missing, the name/legal basis/other information is incorrect/missing it will be reflected in the PSUR Repository User Interface exactly as it is in Art. 57 and the data needs to be corrected by the MAH before the product selection

- After any update to the XEVMPD / Art. 57 database, the database needs to synchronise with the PSUR Repository – this is done every night – please ensure that you have enough time to create xml delivery file and make the submission before the submission deadline

- When the new release (v1.04.00) is introduced later this autumn majority of products will still be displayed through real-time view to Art. 57 (with overnight update for any changes in the Art. 57), however, certain 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)

Product selection functionality in the XML file creation interface – link to Art. 57 / XEVMPD (2/2)

- The improved product selection in release (v1.04.00) will only display those products that contain the relevant active substance(s)

- The 'product short name' filter will be removed and the list of products will display all presentations and strengths

- The filtering in the product selection will be improved and it will possible to use a 'shopping trolley' type functionality where you can use 'select all' of filtered, displayed products/presentations, remove the filter and select another filter and select more products using 'select all' function

- UAT is coming up soon to test this new functionality!

Product selection functionality in the XML file creation interface and link to fees

Q. If the interface displays multiple different versions of a licence for multiple languages in a market such as Belgium (e.g. licence BE143744) as part of the NeeS XML submission, would that mean a duplication of the fee each time? Or would your internal systems apply only one licence fee charge

A. The fees system is not directly linked to the product selection in the PSUR Repository and hence it does not generate a duplicate fee if all the versions are selected.

B. It is important to select all relevant products/presentations/strengths to reflect the correct scope of the procedure. It is very important that the Annex/listing of products provided as a part of the cover letter matches the product selection in the xml delivery file

Product selection functionality in the XML file creation interface – supplementary information/responses

- The original xml delivery file created for the purpose of sending the 'initial' PSUR submission cannot be reused as it is with regulatory activity 'PSUR' for the submission of the 'supplementary information' sequences as the system looks at the regulatory activity type and the original submission deadline and will automatically reject any submission that has arrived after the deadline

- To avoid potentially complex product selection for responses/suppl. info submission, the original xml delivery file can be repurposed by manually editing the xml so that the regulatory activity is changed from PSUR to supplementary information

  - Note the list of products must not have changed

  - Spelling of the 'supplementary information' must be exactly as if it was selected from the dropdown

  - This should not be automated and must be manually checked as changes to xml structure might be introduced in future releases of the system

What is the applicant (senders) routing ID and why I need to enter it in the xml delivery file

- If you think of the eSubmission Gateway / Web Client as a mailing system, the senders routing ID is like the senders 'email address'.

- Currently due to the way the system has been implemented this information is required – I have raised this with my technical colleagues and we are hoping to introduce an improvement to this in one of the future versions of the eSubmission Gateway/Web Client.

- For the time being it is very important to enter the correct senders routing ID in the xml delivery file in order to receive the receipts and acknowledgements from the system.

- If the Applicant (senders) routing ID is incorrect/missing you will not receive an acknowlegement

I have missed the submission deadline and now I am unable to create an xml delivery file, what can I do?

- Built in business rules prevent the creation of xml delivery file after the submission deadline. This deadline is linked to the EURD list where the deadlines are published

- 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

- 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 product names/presentations/strengths to be included
  - Sequence number(s)
  - Applicant (senders) Routing ID

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

- We are looking at the possible improvements to this functionality with the technical team

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

Where should the xml delivery file be 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

Where should the xml delivery file be in the package?
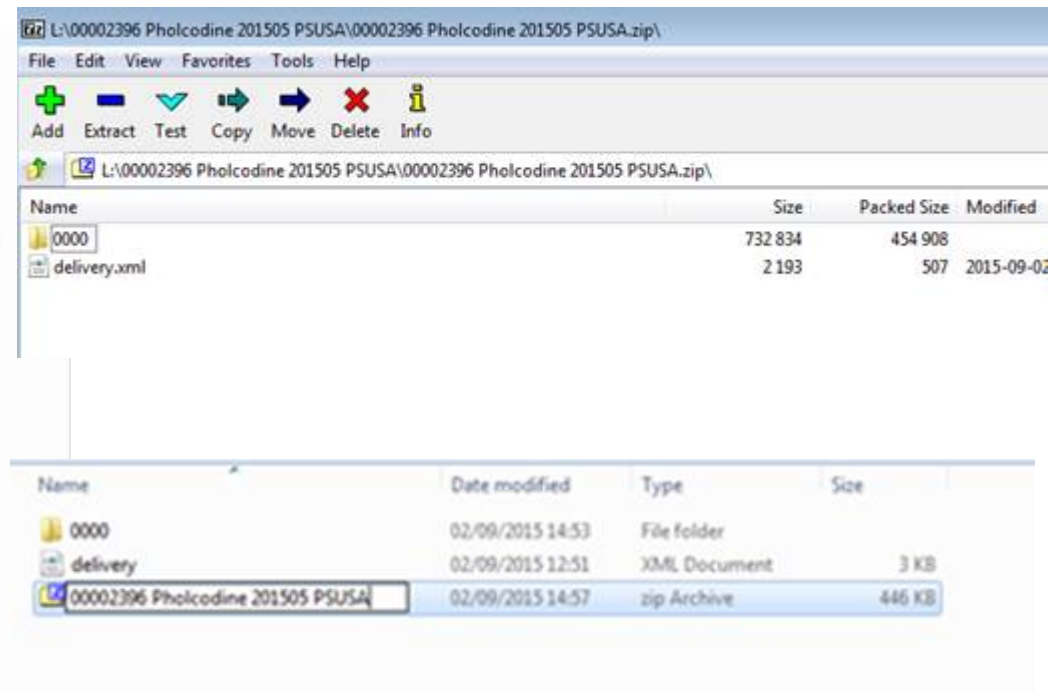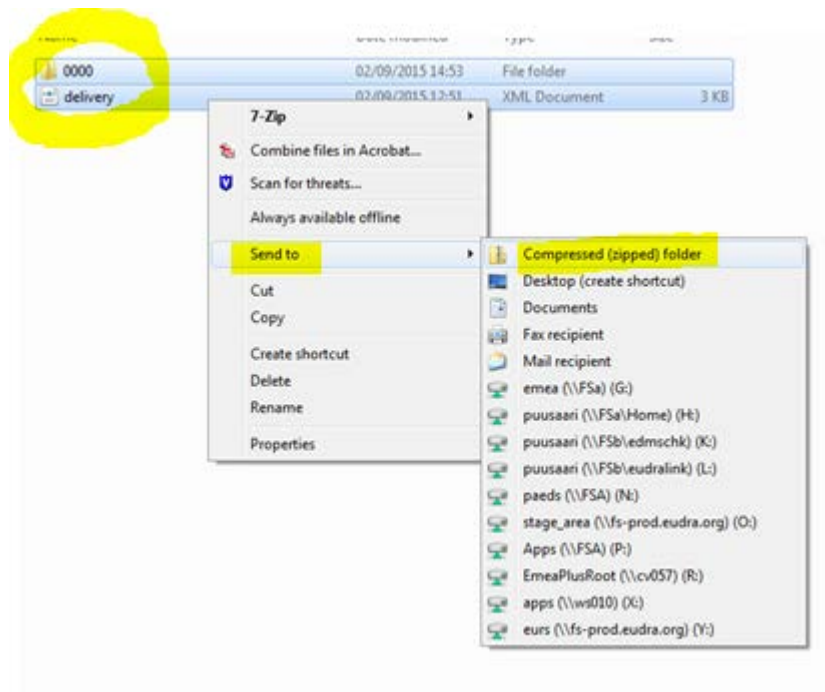
Can I create a standalone eCTD sequence grouping different products with same active substance?

- The PSUR should always be the next sequence in the product lifecycle. A separate, standalone eCTD sequence can break the product lifecycle in the receiving agencies

- It can also cause issues for those products that currently have NeeS lifecycle but will be transferred to eCTD format in future

- A single PSUR can be submitted for multiple MRP/DCP products with harmonised, comprehensive lifecycle

- If the product currently has NeeS lifecycle the PSUR should be submitted in NeeS format – there is no need to create a specific eCTD sequence for NAP PSURs

- If the MAH wishes to move the product from NeeS to eCTD instructions in the EU Harmonised technical eCTD guidance should be followed

Can I submit to the PSUR Repository on behalf of my local representatives?

- Many companies/MAHs like to centralise the sending of submissions, including PSURs – the eSubmission Gateway / Web Client and the PSUR Repository allow submissions on behalf of other MAHs/local representatives

- There are no restrictions in place on the submissions on behalf of another MAH or submissions by a consultancy or CRO

- Supplementary information submissions/submissions of responses can be made directly by the local offices even if the 'initial' PSUR was submitted by a 3rd party

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

- Always double check that you have entered the correct EMEA/H/C number in 6 digit format for all CAP products. This number visible in the field called 'EMEA Product/MRP/DCP number' field. If the number is missing or in incorrect format, please add/amend it in Art. 57

Q. Can the 'Generate Delivery File' button be moved further away from 'Reset Form' button

A. We have added this as a new CR and hopefully this can be implemented in a future version

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

  - A new version of the eSubmission Web Client will be available later this autumn – this new version will introduce improvements, for example 'default' selection of large file applet

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

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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