



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository – Interactive Q&A

Interactive Q&A session with MAHs on the new functionality provided in release 1.06.00





Outline of Today's Q&A session

- PSUR Repository background and latest news
- Release v1.06.00 – main changes
- Release v1.07.00 – sneak preview
- Q&A
- Support and Guidance
- Contact information and useful links



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.** It is **not possible** to use filenaming conventions to send PSURs and supplementary information sequences related to PSURs
- It is strongly recommended to submit to the PSUR repository to ensure that all MAHs are familiar with the system
- The use of the PSUR Repository will become **mandatory for all PSURs from 13 June 2016** after which the PSURs should only be submitted to the repository via eSubmission Gateway/Web Client. PSUR should not be submitted directly to the National Competent Authorities on or after 13 June 2016.
- MAHs access to the PSUR Repository is limited to the access to create delivery file screen



Release v1.06.00 – summary of main changes

- Ability for MAH to create xml delivery file and submit after submission deadline using a 'late submission id' **provided by the EMA upon request**
- No need to manually enter the sender and receiver routing IDs in the delivery file
- No need to manually enter the EMA product number for CAPs in the delivery file
- Unique name for each of the XML delivery file and ability to rename delivery files
- Make user aware of errors that are not visible on the screen due to size of form

Next release – sneak preview to main changes

- Amendment of Submission Type to align with the updated EU M1 (submission type and submission unit) – release around 1st of July 2016

| Submission type | Submission unit | Sequence number |
|------------------------|------------------------|------------------------|
| PSUR | Initial | 0075 |
| PSUR | Responses | 0079 |
| PSUR | Responses | 0082 |

- Other functionality and defect fixes TBC

If the product is not in the EURD list and not in the worksharing list: can you confirm that submission is due to the EMA only and not to NCA?

- Once the use of the PSUR Repository becomes mandatory on 13 June 2016, all PSUR should be submitted to the PSUR Repository only using the eSubmission Gateway. There should be no further submissions directly to the NCAs via CESP or CD/DVD for any PSURs (PSUR Single Assessment or non-EU single assessment).
- Prior to 13 June submissions should be made to the NCAs and additionally to the PSUR repository to gain experience on the use of the repository before the mandatory use.

We faced issue that a new authorised product procedure number was available in EURD list but not in the PSUR repository. May I know what the timeline to sync databases? And to whom we can contact in case of such issues?

Our product is on the EURD list with deadline submission coming up very soon, but the procedure number is not recognized by the PSUR portal. PSURrepository@ema.europa.eu has been contacted but no answer until now. How would you suggest to proceed?

Procedure Number is available in the dropdown of EMA PSUR Repository site, whereas while clicking on "CREATE SEQUENCE" button to select the product(s) – a message is shown 'no products are currently associated'. Whom should we contact and what would be the duration to get this resolved?

- If the Data Lock Point (DLP) for the procedure has passed and you have not received an Advice Note and the procedure is not available in repository, you should contact EMA immediately via the dedicated [fees query form](#).
- If you have received the Advice note however the product is not available in the PSUR Repository product selection, check the **legal basis of the product in Art. 57** to confirm it is correct and compare with EURD list to see if PSURs should be sent for products authorised under articles **Articles 10(1), 10a, 14, 16a** of Directive 2001/83/EC as amended.
- If submissions are required and you have updated Art. 57 database, received acknowledgement and waited 24 hours and the products are still not available contact EMA via the [EMA service portal](#).



What happens if one or more of the products are missing from the PSUR Repository interface and I can create a delivery file with only some of the products

- It is important to select all products included in the PSUR, from the PSUR Repository interface. Please ensure that Art. 57 database is up to date at all times (especially important when the DLP is approaching) and check the available products well in advance before the submission deadline so you have sufficient time to contact EMA and if necessary update Art. 57 if your products are missing/incorrect in Art. 57.

What if the procedures are mixed (Centrally authorised and NAPs).. shall we submit only eCTD?

- The CAPs must always be submitted in eCDT format as a part of the CAP product lifecycle.
- NAPs should be submitted in the format that the product lifecycle is in at the relevant member state. If submissions are normally made in NeeS format to NCAs that should be continued, if the product has eCTD lifecycle the PSUR must be submitted in eCTD format – the PSUR is always submitted as a part of the product lifecycle in the same format as the product lifecycle is held in the relevant member state. If the product has paper lifecycle you must convert to eCTD or NeeS to submit the PSUR.
- If the procedure contains both CAPs and NAPs you must create 2 delivery files as you can never mix CAP and NAP and eCTD and NeeS submissions, they must be submitted separately with their own xml delivery files and submission sequences.
- You should associate these submissions together using the '**Group ID**' if both submissions contain the same PSUR document.



If we have the same PSUR to be submitted for different products with different NeeS sequence, how can we manage the submission?

- As NeeS format is more flexible than eCTD it is possible to create a single submission sequence that contains a combined cover letter or separate cover letters and create a single delivery file that indicates the different sequence numbers for the different products but use the same submission sequence as the sequence 0000 for NCA 1 and sequence 0010 for NCA 2.
- It's important to remember that the submission zip file should only ever contain a single submission sequence. The MAHs might wish to indicate different 'sequences' for different products authorised in different member states. If you are including multiple, country specific cover letters in the package you might wish to indicate the different sequences for different NCAs.



In case of submission in NeeS format with multiple submission sequences, how should we name the submission package? With which sequence number?

- In these cases we recommend to name the submission for example 0000 and indicate the sequence number for the particular products in the delivery file. Alternatively, you can name the submission package using one of the actual sequence numbers.



Where a market has withdrawn a license and/or the license has not yet been approved for use and the NCA requires us to submit the PSUR, as we are not able to select the relevant Article 57 information via Single Assessment, would it be acceptable to use the non-Single Assessment option to ensure submission is made to the NCA?

- If the date of withdrawal is prior to the submission date, before or after the DLP, there is no requirement for submission unless requested by the NCA. At the time of withdrawal the MAH should liaise with the Agency to advise on this point. For a NAPs only procedure the withdrawn product would be excluded for the procedure which would be initiated for those products with a valid marketing authorisation.
- If required by the NCA you maybe advised to submit using the functionality for non-Single Assessment.

Regarding molecule for which all MAs in Europe have been abrogated before the DLP indicated in the EURD list, could you confirm that no PSUR submission is required anymore for the MAH to the EMA and to the NCA? There will not be "closure PSUR" anymore?

- If the date of withdrawal is prior to the submission date, before or after the DLP, there is no requirement for submission unless requested by the NCA. At the time of withdrawal the MAH should liaise with the Agency to advise on this point. For a NAPs only procedure the withdrawn product would be excluded for the procedure which would be initiated for those products with a valid marketing authorisation.

We notice that sometimes withdrawn products appear in the drop list whereas information in Art 57 database was updated correctly. Is there an obligation to select them?

- No there is no obligation to select the withdrawn products.

What is the late submission id and when can I use it?

- 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. Late submission id is used by the MAH to enable creation of delivery file and sending of submission after the submission deadline

What information should be sent in order to receive late submission ID and to whom?

- 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 '**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 are then able proceed to fill in the delivery file and submit.



When should I use late submission id?

- If you have missed the submission deadline for your PSUSA procedure
- Using late submission id should be an exception, always make sure you have enough time to submit on time before the deadline!
- Supplementary information submissions do not require late submission id and can be prepared at any time
- Non-EU Single Assessment submissions do not require late submission id and can also be prepared at any time

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

After 13 June 2016, for NAP products under Non-EURD list with different submission deadline in the same year, is it possible to harmonise them in a single submission?

- For advise on the non-EU Single Assessment Submissions please contact the relevant National Competent Authority to ensure that submission deadlines are not missed. The EMA is not involved in the Non-EU single assessment.

Is it possible to make a NAP late submission of a product not present in the EURD list prior to June 13th?

- The non-EU single assessment functionality does not have built in submission deadlines and late submissions can be made at any time.
- For advise on the non-EU Single Assessment Submissions please contact the relevant National Competent Authority to ensure that submission deadlines are not missed. The EMA is not involved in the Non-EU single assessment.

What about the same PSUR submission for more products in eCTD? Are the rules the same as for Nees submission?

- If a single PSUR document has been prepared by the MAH covering multiple products that have their own eCTD or mixed eCTD and Nees lifecycles, different xml delivery files and multiple different packages will need to be submitted. The MAH can indicate in the delivery file that submissions have same content using the 'grouping of associated submissions' functionality.
- Multiple eCTD products cannot be included in the same delivery file and a separate submission is required for each product to keep the product lifecycle.

If a PSUR was sent without a group ID then is it possible to send supplementary information with group ID?

- Yes, grouping of associated submissions can be used for supplementary information submissions even if the initial PSUR was not submitted using the group id.

What is a new group id? How it is assigned?

- When preparing grouped submissions the MAHs are able to generate a new group id. The **same group id** should be used for **all submissions that are associated together**. If you have created a group id and one of the submissions using this id fails, you should use the same group id.
- If you wish to send subsequent submissions containing new or different documents you must create a new group id.



When we are creating a "group of associated submissions" can we mix different formats before creating a sequence (i.e. eCTD or NeeS)?

- You can associate submissions in different formats (eCTD and NeeS) to each other but both have to be sent as individual, separate submissions. You must not include eCTD and NeeS submissions within the same submission sequence.

Is it possible to submit 2 different sequences with different lifecycles containing the same PSUR in a single submission if both of them are maintained using NeeS format? Can they be grouped in an only XML delivery file?

- NeeS format submissions can normally cover multiple different products in the same sequence – it is possible to simply create one single xml delivery file covering all different NeeS products and indicate the sequence number for each different NCA (if needed) in the delivery file. The single delivery file can then be submitted with a single submission sequence. Multiple sequences/packages inside single zip file are not accepted.
- You must only include one actual submission sequence in to the package. Alternative approach is to submit multiple separate NeeS submissions.

For NeeS non-harmonised NAPs that are registered through DCP/MRP can all the markets (RMS + CMS) submit individual PSURs if they wish to or should only one submission be made as they are MRP registrations?

- You should always submit to the PSUR Repository exactly the same sequences as you submit to the NCAs – in future you will no longer submit directly to the NCAs but only to the PSUR repository however the NCAs will still need to keep their own product lifecycles and hence require the same submissions to be available through the repository as would have been sent directly to them previously.

Any guidance /information/FAQs are planned to release for MAH before mandatory use of PSUR repository?

- A training session is planned for the 13th of June to go through details and changes related to the mandatory use.
- User guides and EMA guidance will be updated to reflect the mandatory use

When can we expect to have the updated guidance for PSUR after 13th of June available on e-submission website

- The updated guidance is planned to be available by 13th of June 2016 at the latest.

The submission deadline for the PSUSA procedure is on 14th of June 2016. Do we need to submit to the NCAs or is it sufficient to submit just to the PSUR Repository even if we submit prior to the 13 June 2016?

- As the submission deadline is after the mandatory use, there is no need to submit the PSUR directly to the NCAs even if the submission is made prior to the submission deadline. If the MAH wishes to send the submission to the NCAs directly and the submission is made prior to 13 June this is acceptable – PSUR submissions should not be sent to the NCAs on or after 13 June.

Is there a plan to also add DSUR submissions to the repository? What about other reports like 6-monthly updates or line listings or ASR etc, is it possible to submit these via the repository?

- DSUR submissions are out of the scope of the Repository as are other updates, line listings and ASRs.
- These should be submitted separately as a part of the product lifecycle to the relevant NCAs or to EMA for CAPs.

Is there a max number of users per MAH that can register to use the repository?

- There is no registration is required to create delivery files.
- It is recommended that a single eSubmission Gateway account is used per MAH for submissions.

How many people per MAH can be registered to submit via the gateway?

- No registration is required to create delivery files.
- It is recommended that a single

If we share a password for the gateway, can two people be logged in at the same time on the same account?

- Yes, the system allows multiple people to be logged on at the same time using the same user credentials.

The way our company is structured and our rules regarding sharing of accounts and passwords would mean we do need more than one user to be registered for the gateway. Is there absolutely no way for this to happen? We would need a min of about 15 registered users?

- It is recommended that a single eSubmission Gateway account is used per MAH for submissions.
- If the affiliated companies are located in a different country/region it is possible to have more than one account, however, we strongly recommend sharing an account to be able to see all the sent submissions and ACKs in the single account.

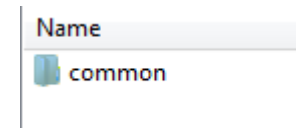
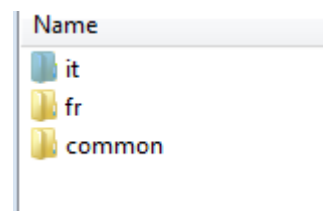
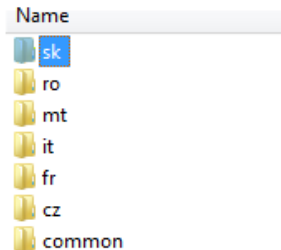
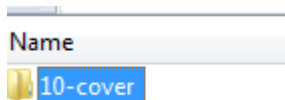
Can we change the registered user details for the gateway?

- Please contact the Gateway support via the EMA service portal to make changes to the registered users/passwords/settings

Do we need to include any specific national cover letters or letters of representatives for individual affiliates/countries for the initial PSUR submission subject to PSUSA after 13 June 2016?

It is not clear the cover letter submission after the 13 June. Do we still need to submit a different cover letter for the PSUSA rapporteur?

- It is possible to include **a single common cover letter covering all licences** in the submission – there is no need to circulate the cover letters separately. During the transitional period, when submissions are made directly to the NCAs and to the repository, a single cover letter or multiple cover letters can be used in the submissions.
- Some MAHs prefer to include both, the local cover letters and common cover letter in the submission – this is also fine and acceptable – however a discussion is currently ongoing with the network to agree on the use of a single cover letter only covering all NCAs.



The sequence number that we create in the PSUR repository portal is the same number of the related eCTD sequence number of the life cycle of the product?

- The sequence number indicated in the PSUR repository delivery file must always correspond to the sequence number of the submission and it must be the next sequential number in the product lifecycle.

Can we maintain a NeeS sequence number for PSUR submission independent from other regulatory variations in NeeS format too

- All submissions, regardless if they are in NeeS or eCTD format should always be submitted as a part of the product lifecycle. Standalone sequences should not be created as these may cause lifecycle issues later.



During the training it was listed that under the new rules a PSUR may have a closing sequence. Does this only relate to PSURs that result in labelling changes that need to be closed out, or will this be an extra submission that we'll have to submit for every PSUR?

- This was a simple example of potential lifecycle in future. There is currently no requirement to submit closing sequence for all PSUR submissions. Closing sequence is recommended for PSURs that result in labelling changes.



Is there a way to know whether there is a queue when submitting via Gateway in order to be in time for PSUR repository acknowledgment of receipt? Sometimes it takes some time to receive AKC.

- The eSubmission Gateway Filehandler processes the submissions as soon as they arrive. Normally if there is a delay with receiving the ACK this is due to issues in the submission that need to be solved with manual intervention and around submission deadlines there might be slight delay in handling the manual queue.

Yesterday, we tried to submit NeeS and eCTD PSUR. Two delivery files were created – one for eCTD, one for NeeS sequence. For the eCTD submission we received SUCCESS, but for the NeeS submission we received FAILURE - error number 31 (submission has an unknown structure). Do you have any idea what could go wrong if both ZIP files were prepared identically?

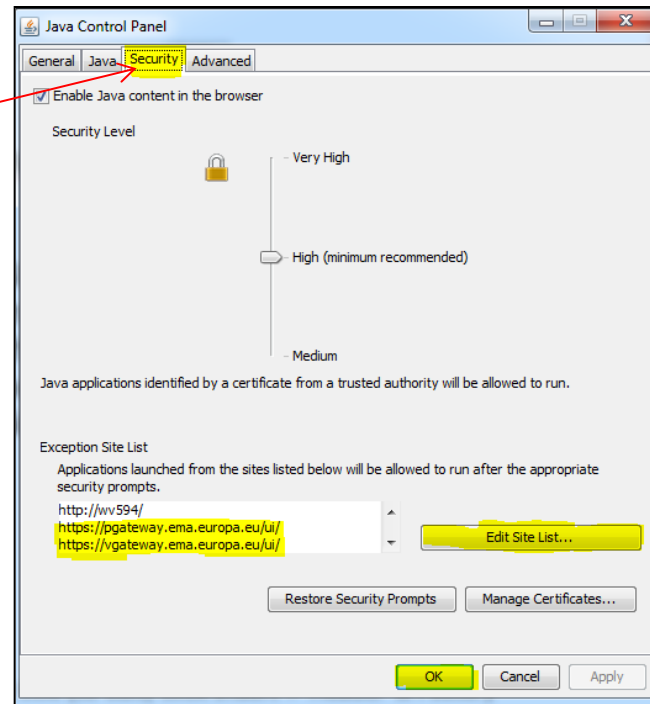
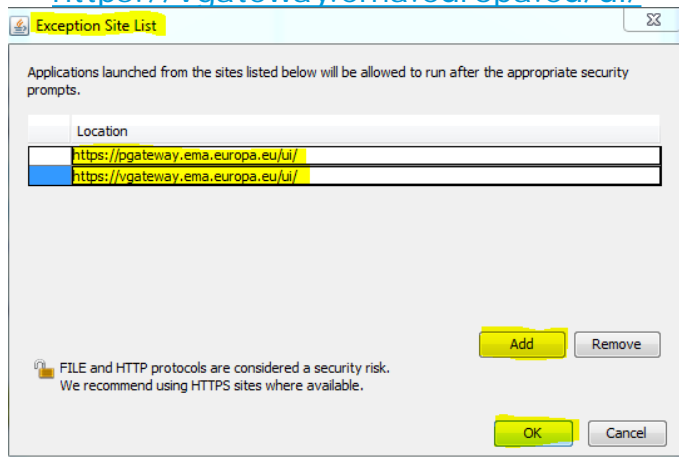
- Error 31 indicates that there was an issue with the NeeS structure of the submission. I would recommend to check that the NeeS package has been created correctly and that the delivery file is in the correct location.

To use the Webclient, **Add eSubmission Gateway Sites in the Exception Site List in the Java Console**

To note that you'll need 'Local Administrator Rights' to configure those settings.

1. Go to **Start Menu** and click on **Control Panel**
2. Click on **Java**
3. Go to the **Security tab**
4. Click the '**Edit Site List...**' button
5. Add following 2 URLs in the "**Exception Site List**":

- <https://pgateway.ema.europa.eu/ui/>
- <https://vgateway.ema.europa.eu/ui/>





Do rapporteurs have access to PSUR repository? Is there any specific action that MAH need to take towards them?

- All rapporteurs have access to the PSUR Repository. There are no specific requirements to submit directly to the Rapporteur. If a Rapporteur has contacted you directly and requested the submission directly to the NCA it is recommended to report this to EMA using the PSURrepository@ema.europa.eu mailbox.

We tried to submit a Package to the PSUR Repository (version 1.05). The zip file was created by WinZip and in a second trial by the zip manager of Windows 7. In both cases we got the message „Failure 55 Wrong sequence format:null“. We also produced the ZipFile with 7-Zip File Manager, and with this zip file the submission succeeded. Why is it not possible to use the common zip managers?

- This has been raised to the technical development team who have confirmed that both WinZip and the zip manager of windows 7 are compatible with the PSUR repository. If the issue persists please send details of the submission package and your local setup details, via the [EMA service portal](#). When reporting the issue, please provide as much details and screen shots as possible.



Do we need to still include a validation report in the package? Is there any specific file naming conventions (other than that explained for the delivery file) required in the package?

- There is no need to include validation report in the submissions.
- There are no required filenaming conventions when submitting using the XML delivery files. It is recommended that the package is given a meaningful name. The submission folders within the submission must follow the eCTD and NeeS specifications.



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 (prior to Procedure Manager allocation):
PSURquery@ema.europa.eu
- Technical validation issues (e.g. missing or 'Failure' Acknowledgements):
<https://servicedesk.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:** <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> or 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

<https://servicedesk.ema.europa.eu>

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