EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Making best use of the PSUR Repository

Periodic Safety Update Report Information Day

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What is the PSUR Repository

- The PSUR repository is a central storage place for **all** PSURs and their associated reports
- MAHs have to submit their PSURs to the repository electronically (eCTD or NeeS)
- Submitted documents can be accessed by authorised users of NCAs, the PRAC, the CMDh, CHMP and the EMA
- An automatic notification system linked to MAH and NCA activities facilitates the assessment procedure
- The repository hosts the associated committee outcome documents
- All documents linked by procedure number facilitating search and retrieval

What are its benefits?

Central Submission Point for PSURs

- Provides a single, secure electronic submission point for all PSURs streamlining submissions access for Member States and Assessors

Simplification of PSUR submissions

- Provides a simplification of PSUR submissions and processing, benefiting the pharmaceutical industry and seeks to avoid duplication

PSUR Consolidation

- The solution will include all PSURs, including those that follow the PSUR Single Assessment (PSUSA) and those PSURs which are not part of a Single Assessment

Enhanced Capabilities

- Provision of an enhanced version of existing eSubmission Gateway / Web Client
- The file naming convention replaced by delivery file

Common Storage Place

- Delivers a common storage place for PSURs, PSUR assessment reports, documents supporting the evaluation process and the final outcomes

Resource Efficiencies

- Introducing more effective and efficient best practices
- Reallocation of resources

Important tips to optimise use of PSUR Repository

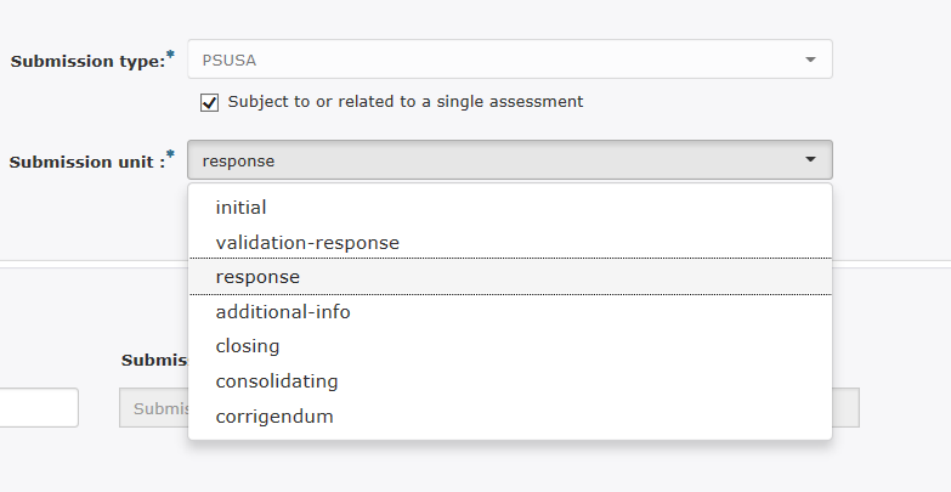
1. Reliance on XML delivery file data vs cover letter
   - EMA fully relies on the data contained in the XML delivery file
   - Electronic data overrides content of pdf cover letter
   - Electronic submission is considered the company declaration of the products submitted and utmost care should be taken when selecting products in scope of procedure
   - EMA does not follow up on listing of products

Important tips to optimise use of PSUR Repository

2. Handling of submission units

- Submission units aligned with new EU Module 1 specification
- No need for closing sequence/translations
- For any responses use “response”
- All previously “supplemental info”

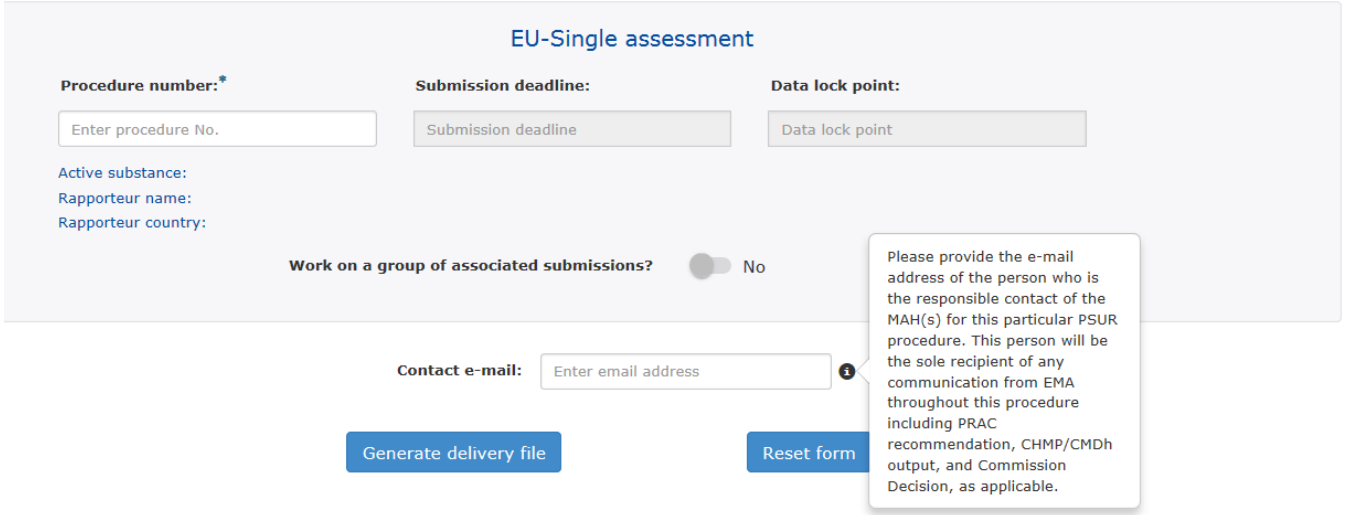
is now covered by validation-response, response, additional-info, corrigendum.



Important tips to optimise use of PSUR Repository

3. Regulatory contact person

- provision of valid email is critical. Not recommended: PSUR_RMP@MAH.com, info@MAH.com, no_reply@MAH.com
- no reliance of cover letter contact details



Important tips to optimise use of PSUR Repository

4. No submission of Post-Authorisation Measures (PAMs) to repository

- PAMs must not be submitted to the PSUR Repository. The submission of PAMs for CAPs must be done in eCTD format via the eSubmission Gateway/Web Client, and will be considered delivered to all National Competent Authorities' representatives, alternates and scientific experts.
- As a general principle no follow-up measures for NAPs should be requested as there is no regulatory/legal framework to assess them in a consistent manner. Should there be, exceptionally, follow up data for NAPs outside of the PSUSA procedure, this would also be handled outside of the repository.

Important tips to optimise use of PSUR Repository

5. Submission of withdrawn PSURs for products without valid marketing authorisation

- Article 107b of Directive 2001/83/EC: legal obligation to submit a PSUR on MAHs.
  - Legal obligation to submit does not apply to applicants for marketing authorisation**, former MAHs which no longer hold a marketing authorisation** or to companies which provide medicinal products through named patient or compassionate use programs.
- Article 25a of Regulation (EC) No 726/2004: the EMA is legally required to "*set up and maintain a repository for periodic safety update reports (hereinafter the 'repository') and the corresponding assessment reports*".
- **There is no legal requirement for the PSUR Repository to hold PSURs other than those whose submission is legally required by Article 107b of Directive 2001/83/EC.**
- ***Any submission of a PSUR for a withdrawn product must be handled outside of the PSUR repository prior consultation with NCA and EMA.***

Important tips to optimise use of PSUR Repository

6. Active substances not on EURD list – workaround solution

- Situations for MRP/DCP product where EURD list entry is not yet established and legally binding – submission via EU Single assessment mode not possible.
- In such cases the Non-EU single assessment mode of the PSUR Repository has to be used and the MAH can only create one delivery file per country.
- MAH to select only the 'RMS' as the country to submit, include all products in a single xml delivery file and submit a single package.
- Notification sent by the RMS to a all CMS(s) dedicated e-mail address.
- MAH to request EURD list update via EURDList@ema.europa.eu, and contact EMA Service Desk

Important tips to optimise use of PSUR Repository

7. PSUR Repository has an integrated automated workflow system for AR tracking

- Preliminary AR due in 7 days

Dear xxx (United Kingdom),

Please note that the assessment report for the above procedure is due on 03/10/2016

As you are aware, PSUR outcomes are binding on MAHs, who cannot rely on a re-examination phase. It is therefore of the utmost importance that the 30-day deadline given for the MAH to comment is respected.

As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt circulation of the assessment report is highly appreciated.

To upload your assessment report please log in to the PSUR Repository with your login credentials. https://psur-repo.eudra.org/psur-ui/

- Outstanding AR (48h)

Dear xxx (Germany),

Please note that the assessment report for the above procedure was due on 03/10/2016

As you are aware, PSUR outcomes are binding on MAHs, who cannot rely on a re-examination phase. It is therefore of the utmost importance that the 30-day deadline given for the MAH to comment is respected.

As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt circulation of the assessment report is highly appreciated.

Guidance and useful information

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

Periodic safety update reports: questions and answers

Technical queries: EMA Service Desk

Procedural queries:

- CAPs, CAP/NAPs procedures – allocated procedure manager
- NAPs - allocated procedure manager or PSURquery@ema.europa.eu

Thank you for your attention

Further information

[Insert relevant information sources or contact details as applicable.]

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