EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository and the EU single assessment

3rd industry stakeholder platform - operation of EU pharmacovigilance legislation

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What is the repository?

The PSUR repository is a central storage place for all PSURs and their associated reports.

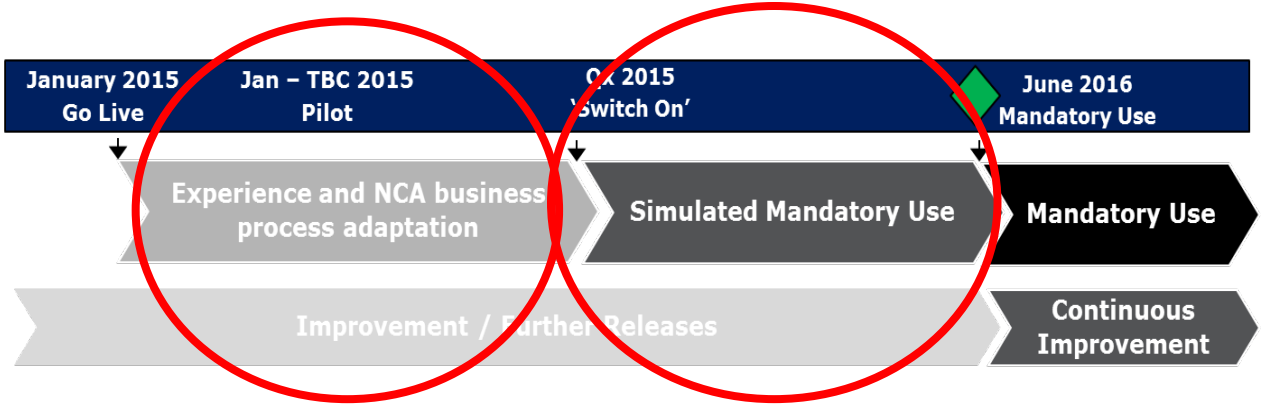
MAHs can submit their PSURs to the repository and once the documents are in the system they can be accessed by authorised users of NCAs and the EMA, the Commission, the PRAC, the CMDh and the CHMP.

The repository facilitates the assessment by providing query and download functionalities of PSURs and PSUR assessment reports to the a.m. authorised users.

Once the procedure is finalised the repository will host the associated committee outcome documents.

How is it implemented?

Phased implementation



1. Pilot
   - Phase 1 (Feb/Mar starts) –> CAPs only
   - Phase 2 (May starts +) –> CAPs + NAPs
     - PSUSA CAPs
     - PSUSA CAPs/NAPs
     - PSUSA NAPs

1. Switch-on: CAPs + NAPs
   - PSUSA CAPs
   - PSUSA CAPs/NAPs
   - PSUSA NAPs

What are the phases of the implementation?

Pilot

- repository to run in parallel to “as-is” business processes

Switch-on

- Some changes to NCA processes
- NCA submissions remain
- CAPs must submit to repository
- NAPs encouraged to submit to repository

Mandatory use

- ALL PSUR submissions to repository ONLY
- All NCA activities run through repository
- MAHs will continue to receive ARs and outcomes from EMA via Eudralink

Activity	Actor	Pilot	Switch-on	Mandatory phase
Submission of PSUR/supplementary information (MAH)	**MAH**	• Submission to NCA (standard requirements) • Submission to EMA		PSUR Repository
Retrieval of PSUR/ supplementary information	**NCA**	• Local NCA repository • PSUR Repository after receipt of notification		PSUR Repository
Circulation of AR and comments by NCAs	**NCA**	• Manual email • PSUR Repository upload	PSUR Repository	
Circulation of AR to MAH by EMA	**EMA**	Eudralink message		
Access to AR/Comments by NCA	**NCA**	• Manual email • PSUR Repository	PSUR Repository	
Access committee			• MMD	

What does this mean for industry?

- MAHs can access the user interface to create XML delivery files to support submission to the repository
- MAHs (CAP contacts and NAP QPPVs) are being invited to participate in pilot.
  - Participation confirmed if PRAC Rapporteur/Lead MS confirms wish to participate.
  - All MAHs for May procedure starts have been contacted and responses are being processed.
- During the switch-on phase.
  - CAPs must be submitted to the repository
  - In the case of NAPs, industry is strongly recommended to submit all PSURs included in the EU single assessment to the PSUR Repository
  - EMA will manually upload any NAP submissions not submitted to the repository following reconciliation with NCAs
- Until mandatory use Industry must continue to submit NAP PSURs directly to NCAs

How will the submissions work?

Submissions will be made using the eSubmission Gateway/Web Client with an additional XML delivery file:

- Dedicated user interface for the creation of the Repository specific XML delivery file (https://psur-repo.ema.europa.eu/psur-ui/prepare/submission.html). **No other software required**.
- Delivery file provides the required metadata allowing the EMA to process the PSUR.
- With the use of the XML delivery file, the use of the manual filenaming convention to provide the metadata is no longer needed.
- The XML delivery file must be provided within the submission package (i.e. in the relevant ZIP file).
- The Agency encourages applicants to use guidance provided in Annex 3 of the PSUR filenames for repository submissions when using the XML approach.

The Agency will phase out this dual approach and therefore strongly recommends users to switch to the XML deliver file option at their next opportunity.

Is it complicated?

DEMO

What do I need to do next?

- Register for the use of the Gateway / Web Client as soon as possible using the online registration form (https://esubregistration.ema.europa.eu/registration)

1. Check the EURD list to confirm:
    1. PSUSA number of the procedure
    2. Legally binding submission deadline
    3. Need to submit Art 10(1), 10a, 14 or 16a products
2. Check product data is correct in art 57 database to avoid validation issues when submitting:
    1. Is the product included in the database?
    2. Has it been entered with the correct legal basis?

Where can I find more information?

1. Key source of information - > dedicated PSUR Repository page on the **eSubmissions webpage**

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

- User documents
- Multimedia tutorials
- Training dates
  - PSUR Repository interactive Q&A sessions for MAHs - 05 and 19 March 2015, 09:00 am UK time.
- Who to contact – PSURRepository@ema.europa.eu
- Regular bulletins

2. Key announcements on **EMA public website** -> http://www.ema.europa.eu

Thank you for your attention

Further information

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