



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository

Industry Stakeholder platform - Operation of EU pharmacovigilance legislation

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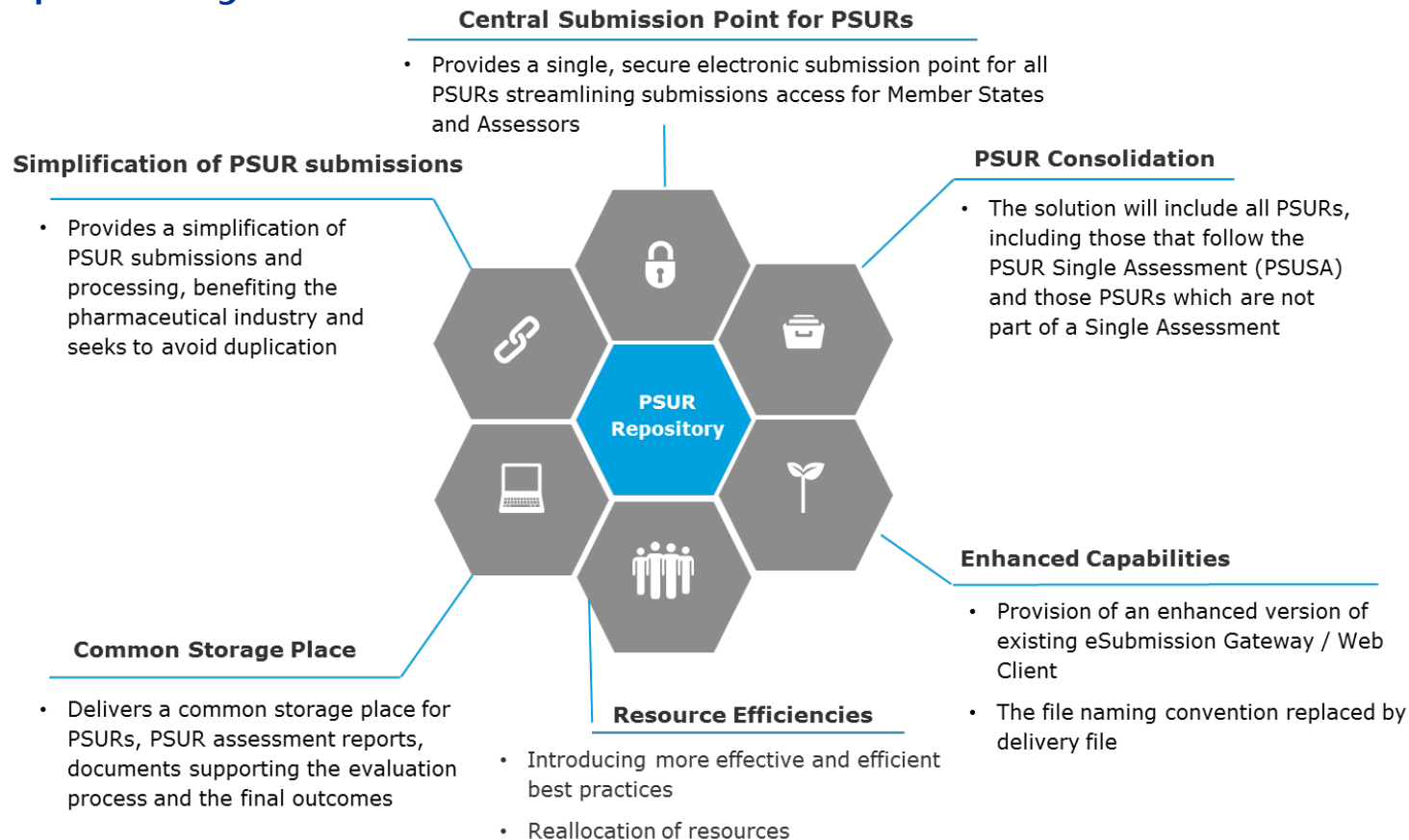
Background

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. The PSUR Repository has to adequately support the following processes:

- a. The **electronic submission** of PSURs and PSUR assessment reports allowing the EMA to receive these documents.
- b. The **storage and retrieval** of PSURs and PSUR assessment reports by authorised users of NCAs and the EMA, the Commission, the PRAC, the CHMP and the CMDh.
- c. The **assessment** by providing access, query and download functionalities of PSURs and PSUR assessment reports to authorised users of NCAs and the EMA, the Commission, the PRAC, the CHMP and the CMDh.



PSUR repository benefits





Timelines – what has already happened?

- ✓ Project (incl governance) approved by EU Telematics: 14 Mar
- ✓ Kick-off Advisory Group (includes industry members): 31 Mar
- ✓ Detailed requirements elaboration for auditable version: 30 Apr
- ✓ Detailed requirements elaboration for post-audit versions: Jun – Sep
 - Note that , although the requirements gathering and the provision of a plan is part of this project, the actual delivery of the post-audit functionalities is part of a separate project.
- ✓ UAT of the solution by NCAs and Industry Nov 2014
- ✓ Dedicated webpage with evolving information published Dec 2014 (http://esubmission.ema.europa.eu/psur/psur_repository.html)

January 2015
Go Live

Q2 2015
'Switch On'

June 2016
Mandatory Use

Implementation

Go Live and Transition

Switched On

Mandatory Use

Timelines – what will happen next?

- System go-live: anticipated end Jan 2015
- Induction webinar to Industry for the pilot phase
- Pilot phase with Industry and NCA volunteers from go-live until 'switch-on'
- Independent audit of functionality
- Webinars to all Industry in Feb 2015 followed by weekly Q&A sessions as needed
- 'switch on'* of the repository anticipated for Q2 2015 for the EU single assessment
- Mandatory use of the repository anticipated from June 2016

*'Switch on' – all PSUR submissions made to the Agency via the gateway will have to use the repository's xml delivery file user interface (more details in back-up slide)



What changes for Industry?

- MAH to submit to the PSUR Repository via the eSubmission Gateway/Web Client using the new XML delivery file instead of current filenaming convention
- Need to participate in Webinars and review guidance documents
- Check regularly PSUR Repository webpage on eSubmission website
- From 'switch on':
 - All CAP PSURs must be submitted to the Repository
 - All MAH strongly encouraged to submit EU Single Assessment PSURs to the repository, however the NCAs will continue receiving NAP PSURs locally
 - All PSURs for PSUSA procedures available via the Repository as EMA will pro-actively upload submissions made to NCAs only following reconciliation
- Very little change to industry with the key difference being an enhanced submission using XML delivery file instead of filenaming conventions!



Thank you for your attention

Further information

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Back-up slides



MAH participants in the PSUR Repository UAT

UAT Industry Participants
Almirall
Billev Pharma (Representing EGA)
Bristol-Myers
CINFA, S.A
Grupo Uriach
JNJ
Merck & Co
Novo Nordisk A/S
Pharminvent
SANDOZ
TEVA UK



What exactly is 'switch on'?

- Proposal to use the repository with all its consequences for all submissions for the EU single assessment as of 12 March 2015 (subject to technical and business feasibility)
- Mandatory to submit CAP PSURs to the Repository using XML delivery file
- All MAH strongly encouraged to submit EU Single Assessment PSURs to the repository, however the NCAs will continue receiving NAP PSURs locally
- Allows for learning and preparation in readiness for mandatory use (anticipated June 2016)