EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PSUR Repository
Webinar on API: Q&A on Preparedness for Usage

21 May 15
Chairs: Joris Kampmeijer (MEB) and Evdokia Korakianiti (EMA)

Agenda

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#	Topic	Resp	Time
1	Welcome and objective of the webinar	Chairs	10
2	Overview of the PSUR Repository	IR	15
3	The Post-audit functionalities	OS	10
4	Overview of the API	CEE	20
5	Expected impact of the API on your IT infrastructure	OS and CEE	10
6	Expected impact of the API on your business processes	IR	10
7	Feedback from the survey	IR and OS	10
8	Q&A	All	30
9	Proposed strategy to support NCAs in dealing with the impact of using the API Wrap-up	Chairs	10

1. Welcome and objective of the webinar (1/1)

Objective of today's meeting:

As part of the EMA's commitment to assist NCAs in preparing as much as possible for the usage of the API and integrating the usage of the API in your business processes, this webinar will address both technical and business-process related aspects.

2. Overview of the PSUR Repository (1/11)

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Legal context

- *Article 25a of Reg. (EC) 726/2004* further clarifies:

- The Agency shall, in collaboration with the national competent authorities and the Commission, and after consultation with the Pharmacovigilance Risk Assessment Committee, draw up the functional specifications for the repository.

→ PRAC adopted the auditable requirements, which were then endorsed by EMA MB Dec 2013

- The **Management Board** of the Agency shall, on the basis of an **independent audit report** that takes into account the **recommendations of the Pharmacovigilance Risk Assessment Committee**, confirm and **announce** when the repository has achieved full functionality and meets the functional specifications drawn up pursuant to the second paragraph.

→ Independent audit ✓

→ PRAC recommendation → April 2015 ✓

→ EMA MB announcement → June 2015

What is the repository?

- Mandated by legislation
- Central storage place for all PSURs and associated reports, incl. outcome documents
- Submission point of PSURs for MAHs
- Access by NCAs, the Commission, the PRAC, the CMDh and the CHMP
- Query and download functionalities to authorised users

Network involvement during planning, development, testing, deployment and audit

- There has been a close collaboration with the network throughout the planning, development, testing, and deployment phases.
- Network was involved in the planning of the Audit activities
- EU Telematics Governance Structure (IT DEC, IT Directors Plenary, EUTMB)
- PhV Governance structure through PRAG, PMG2, CMDh, CHMP and PRAC
- For example:
  - Consultation on API specifications
  - Other initiatives throughout 2015 – 2016 to support NCAs in their change management activities to support business process change for mandatory use

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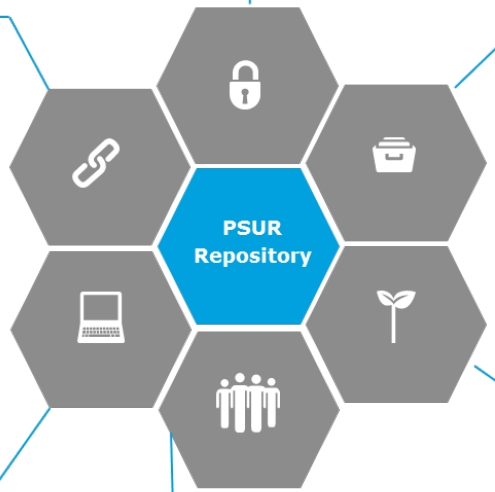
PSUR repository benefits

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

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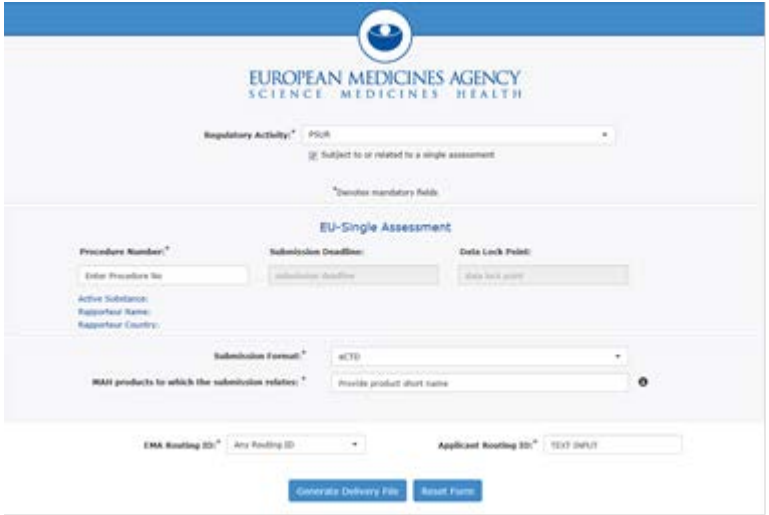
How does the PSUR repository work?

- Web-based user interface for NCAs, Industry and EC
- Master key: PSUSA procedure number for EU single assessment, DLP and active substance for non-EU single assessment procedure
- Industry: creation of xml delivery file via UI to be included in submission to EMA
- NCAs: search and download documents and upload documents



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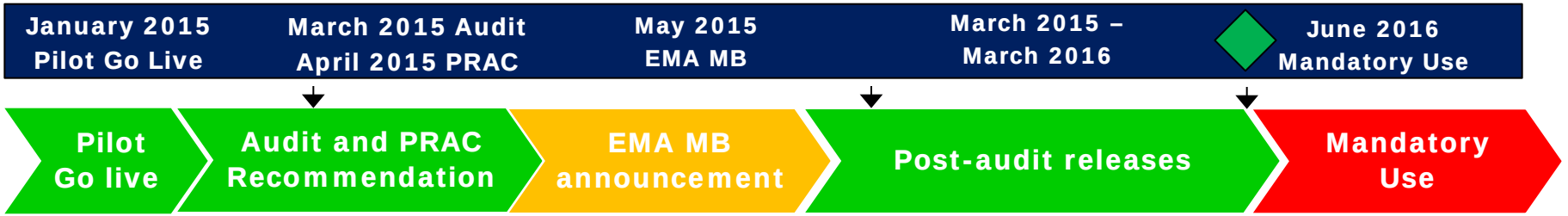
PSUR Repository - Phased Deployment and steps to mandatory use



- The PSUR 'go live in pilot phase' in January 2015
- Pilot ongoing with MAH and NCAs

- Positive audit outcome in March 2015
- PRAC Recommendation adopted in April 2015
- Final fieldwork to confirm EMA IPA planned for 1st week of June 2015

Based on independent audit outcome and PRAC recommendation

Plan has been audited and releases are being developed and planned:

- Audit findings – delivered ✓
- 4 Post-Audit functionalities incl. API (automated connection between NCA systems and the PSUR Repository) – ***December 2015*** release based on audited project plan binding for EMA
- New and improved functionality delivered based on prioritised change requests – multiple releases throughout 2015/2016

- Following announcement by EMA MB in June 2015 mandatory use within 12 months
- No further submission of PSURs to individual NCAs

2. Overview of the PSUR Repository (8/11)

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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 outcomes NCA	**NCA**	• MMD • PSUR Repository		

What was the basis for the current release?

10 auditable functionalities – 3 themes

1.Submission

2.Storage and Retrieval

3.Assessment

→ Detailed requirements based on these 10 auditable functionalities were elaborated by the PSUR repository advisory group (PRAG)

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4 Plan on post-audit functionalities

1. **Automated tracking** and **alerting** functionalities to assist the assessment procedure
2. **Automated two-way exchange** ('API') of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs
3. **Work-flow support** for assessors and assistance of PSUR Repository administration
4. **Allowing** for the **storage and retrieval** of PSUR related documents (already delivered in the auditable release)

→ These additional functionalities, beyond those to be audited, are to be provided **in future post-audit releases** of the PSUR Repository.

2. Overview of the PSUR Repository (11/11)

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Plan on future releases [content and timing]:

Milestone	Timing
"Audit Findings 2" release: ➢ EMA business admin screen (allowing for upload of late PSURs) ➢ Implementation of remaining IAPs resulting from the audit by PwC	May 2015
"Additional Functionalities" release: ➢ Additional change requests as prioritised by the Project Advisory Group and PMG2, in particular CR for additional context in Notifications when uploading ARs or comments	Mid Jul 2015 (contingency: mid Aug 15)
"Post-Audit functionalities" release: ➢The post-audit functionalities, especially the 'API' ➢Additional change requests that will be identified during the pilot phase and during the initial months after the "Switch-On". These will be prioritised by the Project Advisory Group and PMG2.	Nov 2015 (contingency: Dec 15)
"Mandatory use" release: ➢Additional change requests that will be identified during the pilot phase and during the initial months after the "Switch-On". These will be prioritised by the Project Advisory Group and PMG2.	Mar 2016 (contingency: Apr 16)

3. The Post-audit functionalities (1/6)

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3. The Post-audit functionalities (2/6)

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As has been agreed by a.o. the EUTMB, the PRAC and the EMA MB and documented in document “EMA/681848/2013” (aka the “Auditable Requirements”), section 4:

4. *Additional functionalities of the PSUR Repository (post-audit)*

Taking into account the provisions set out in Article 25a of Regulation (EC) 726/2004, the functionalities to be audited are those outlined in section 3.

As part of the consultation with Member States, the following additional key functionalities were requested to be included in the common PSUR Repository:

1. ***Automated tracking and alerting functionalities to assist the assessment procedure***
2. ***Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs***
3. ***Work-flow support for assessors and assistance of PSUR Repository administration***
4. ***Allowing for the storage and retrieval of PSUR related documents***

These additional functionalities, beyond those to be audited, are to be provided in future post-audit releases of the PSUR Repository for which further business requirements will be developed with Member States in consultation with the PRAC.

Based on the initial implementation experience, an iterative approach will be followed allowing for improvement of functionalities if necessary.

3. The Post-audit functionalities (3/6)

Agreed deliverables to fulfil the post-audit functionalities:

- 1. & 3.: Additional notification functionality as part of the “Post-audit” release
- 2.: A computer-interface (aka API) allowing NCA IT systems to perform automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository
- 4.: Already provided in the current system

3. The Post-audit functionalities (4/6)

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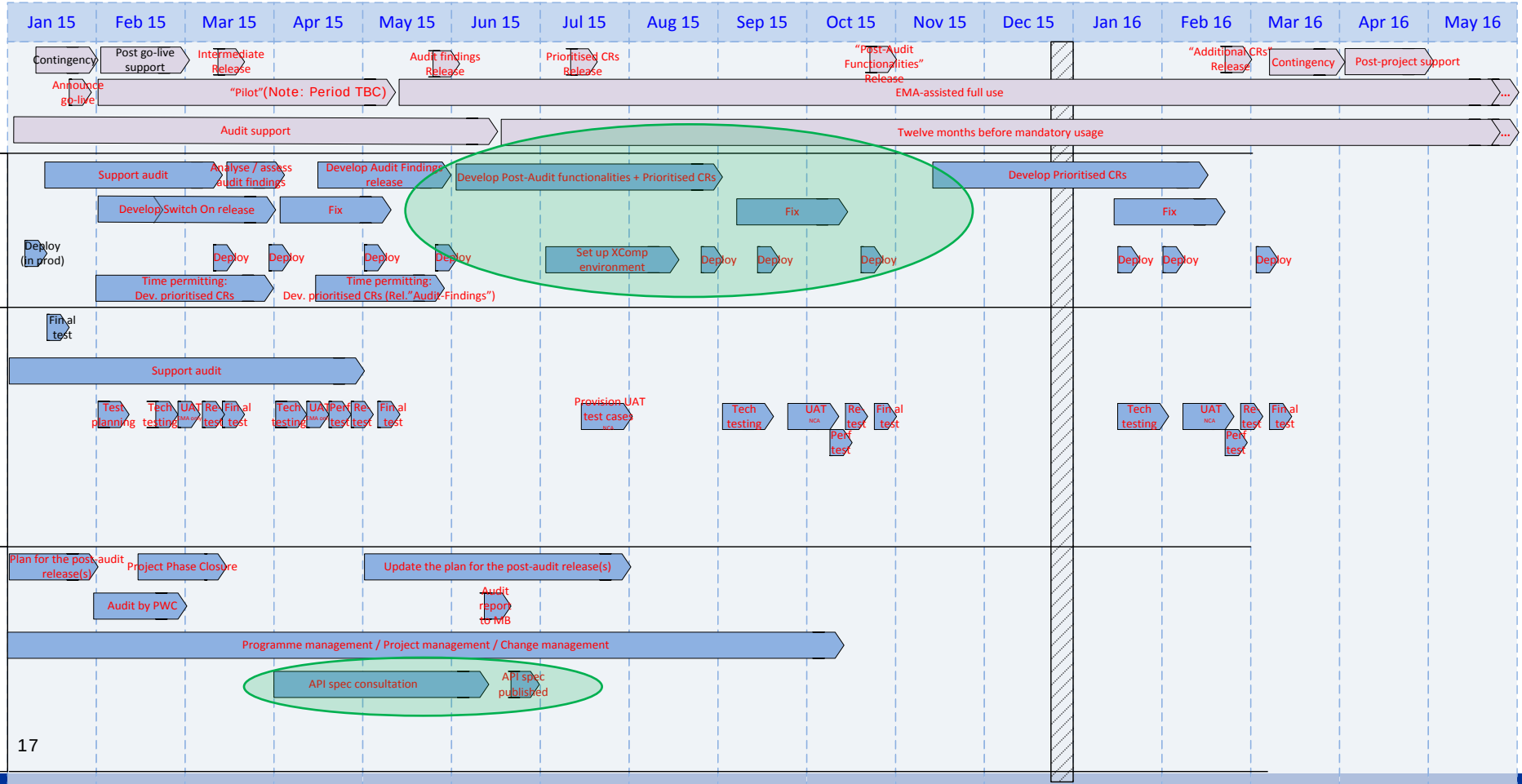

3. The Post-audit functionalities (5/6)

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Overview milestones:

- Nov –Mar:
  - Work with the NCA IT reps to draft the technical API specifications
  - Define with the Advisory Group the specifications for the Additional Notification System
- End Mar: Draft specifications available for API
  - Implementing post-audit functionality 2
- End Mar: Final specifications available for Additional Notification System
  - Implementing post-audit functionality 1 & 3
- Apr – May: Consultation within EMRN on the API specifications
  - Including the EU Telematics IT Directors group, the EU Telematics Enterprise Architecture Board, …
- 23 Apr – 15 May: Surveys on expected usage of the PSUR Repo API
- 21 May: Webinar to address both technical and business-process related aspects of the usage of the API
- Jun: Approved API specifications available
- Jun - …: Other initiatives throughout 2015 – 2016 to support NCAs in their change management activities related to the use of the API. The details of these will be driven by a.o. the feedback from the surveys and the 21 May webinar.

3. The Post-audit functionalities (6/6)

Overview milestones (cont'd):

- Jul:
  - Start development API and Additional Notification System at EMA
  - Start preparation modification NCA IT systems and business processes to use the API

- Jun: Call for EoI for participation in the UAT team

- Jul: Work with NCA IT and Bus Reps to define the user acceptance plan (UAT) plan, test cases and scripts

- Oct-Nov: UAT by NCA reps

- Nov: Start weekly TCs for:
  - Q&A on technical usage of the API and development of the required amendments to the NCA IT systems to consume the API.
  - Forum for NCA IT reps to share experience in developing for the API and using the API
  - Forum for NCA business to address questions on business processes

- End Nov: API and Additional Notification System available
  - EMA will provide a dedicated test system to test NCA IT systems until Jun 2016 (at least)

- 2016: Successive next iterations to implement changes as required

4. Overview of the API (1/10)

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4. Overview of the API (2/10)

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- The project must deliver a plan for implementing the Business requirement (BRQ-0002): Automated two-way exchange (Repository API)

Req-id	Name	MoSCoW
DR_001	Search query	Must
DR_002	Search query: Document type	Must
DR_003	Search query: Document submission date	Must
DR_004	Automated upload of a document related to EU single assessment	Could
DR_005	Automated upload of document related to Non-EU single assessment	Could

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Agency Representatives - as delegated by PRAG for the IT API specification workshops

Name	Agency	Name	Agency
Andrea Johnson	MHRA	Mikael Fredriksson	MPA
Rayden Foster	MHRA	Henriette Rafler	BfArM
Bridget Smith	MHRA	Claus Viehmann	BfArM
Glenda Gjoka	MHRA	Jose Simarro	AEMPS
David Dowling	HPRA	Said Ioughlissen	ANSM
Jennifer Lynch	HPRA	Ulrich Krach	PEI
Joris Kampmeijer	CBG-MEB	Christophe Pée	EMA

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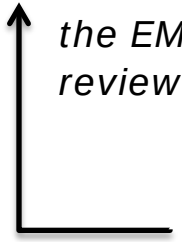
Approach to creating the API specification (1/2)

- Approach A:

  a candidate in the sub-group drafts a proposal for an API specification as a base for review and discussions.

- Approach B:

  the EMA development team drafts a proposal for an API specification as a base for review and discussions.



The API specification sub-group voted for this approach

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Approach to creating the API specification (2/2)

- 8 workshops organised weekly between **5/12/2014** and **30/01/2015**
- EMA:
  - Provided weekly additions and updates to the API specification document;
  - Circulated the document to the stakeholders;
  - Addressed comments made by API sub-group participants.
- PSUR Repository API sub-group:
  - Reviewed document and sent their comments and questions.
- EMA:
  - On **07/04/2015**, circulates draft API document of the specification to **IT directors** and **TEAB**.

Flexibility and constraints

- The API must meet your needs;
- NCAs have typically different needs as they have different business processes, IT infrastructures and budgets;
- Yet, there will be only 1 API;
- Important to draw the line between generic features (usable by all) vs. specific features (usable just by 1 or a few);
- Specific features must be implemented on your side and the API must allow for that.

API – A definition (1/2)

- Some aspects of an API (from Wikipedia)
  - *"It is a set of **routines**, **protocols**, and tools for building software applications."*
  - *"It expresses a **software component** in terms of its **operations**, **inputs**, **outputs**, and **underlying types**."*
- An API is *not*:
  - A software component that you install on a computer.
  - A process that automates human activities.
  - An end-to-end system where your NCA is 1 end and EMA the other end.

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API – A definition (2/2)

*"It expresses a **software component** in terms of its **operations**, **inputs**, **outputs**, and **underlying types**."*

Element	Description
Software component	System hosted at EMA
Operations	Search, read and write
Inputs	Search terms, documents, metadata attributes
Outputs	Documents, metadata attributes
Underlying types	PSUR (eCTD & NeeS), Assessment Reports, AR Comments, Recommendation, substances, products, …

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Use of controlled terms and other sources of data

Attribute	Source	Format	Example
Substance name	EURD list	Controlled term	abacavir, lamivudine, zidovudine
Procedure number	EURD list	Controlled term	PSUSA/00003144/201312
Product name	XEVMPD database	Text, as submitted by MAH	Januvia
Product short name	XEVMPD database	Expressed from text, as submitted by MAH.	Januvia
Product number (*EV Code*)	XEVMPD database	As generated by XEVMPD	PRD317097
MAH name	XEVMPD database	Text, as submitted by MAH	MERCK SHARP & DOHME LTD.
Country	EUTCT	Controlled term	100000000337 BE

API – Users and technicalities

- Users:
  - Registered users and with appropriate capabilities (ECD user database).
  - Restricted to EudraNet (VPN between EMA and NCAs)
- Technicalities:
  - Protocol: HTTP (secured)
  - Message representations: JSON (JavaScript Object Notation)
  - Architectural style: RESTful Web Services.

5. Expected impact of the API on your IT infrastructure (1/2)

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5. Expected impact of the API on your IT infrastructure (2/2)

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- You would need to develop functionality to:
  - Communicate with the API from within your IT infrastructure to download information from the PSUR Repo
  - Potentially automate the processing of the downloaded information so it is automatically uploaded in your IT systems (e.g. your DMS or case management system)
  - Communicate with the API from within your IT infrastructure to upload information to the PSUR Repo

- The API specification is available (Draft: now. Final: July) so you could already start developing your functionality

- EMA will make a permanently available test system available from September 2015 onwards

6. Expected impact of the API on your business processes (1/4)

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Submission

§§ 'electronic submission to the Agency' → implications:

- CMDh national submission requirements no longer applicable (no paper copies, CD/DVD, multiple copies, etc.) → different way of receiving, registering, distributing, saving and archiving of these submissions
- Non-EU PSURs business process also impacted!
- EMA cover letter for EU single assessment also for NAPs
- Life cycle management of eCTD and NeeS → need to identify relevant sequence in case of different sequence numbers for same PSUR in different MSs (do we want this for NeeS?)
- Validator/viewer tool for eCTD sequence
- Downloading PSURs for product life cycle management (competent NCA role) and/or for assessment (lead MS/Rapp role) → avoid confusion/duplication @assessment team

Assessment

- How to make the PSUR submission for assessment available to the assessor (automatic/manual/in NCA own system…)
- How to distinguish submissions to NCA role versus lead MS/Rapp role
- Upload of assessment reports and comments need search in UI by PSUSA number if not automated
- Notifications from repository (start of procedure, reminder for assessment reports/comments, notification of available assessment reports, etc.) need to have relevant internal distribution mechanism
- Availability of output documents (CHMP OP/CMDh position) via repository and no longer Eudralink → system in place to inform NCA functions responsible for national implementation

Storage and retention

- Need to consider legal obligations to store and retain PSUR documents for NAPs relevant to the NCA
- Business/IT system in place to ensure manual or automatic download into national repository
- Business/IT system in place to identify relevant PSUR submissions in case download only needed for NCA role (e.g. if multiple eCTD sequences of the same PSUR available in repository, important to select the correct one for national life cycle purpose)
- Distinguish between CAP and NAP → for CAP download, API connection to common repository already in place

7. Feedback from the Survey (1/3)

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7. Feedback from the Survey (2/3)

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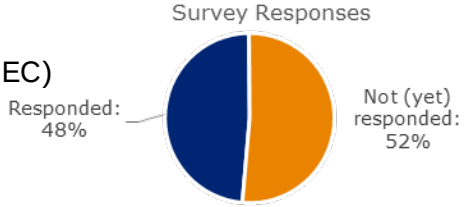
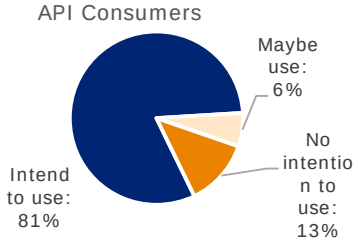
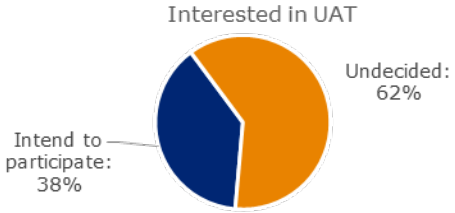
- Number of responses: 16 NCAs
  - Out of a possible 33 (32 NCAs + EC)



- Number of prospective API consumers:
  - Certain: 13
  - Maybe: 1



- Number of NCAs potentially interested to participate in the UAT: 5



- Date NCA systems ready to use the API: Range from early 2016 to late 2016

Note: The survey results above are based on the input received as at 19 May CoB

7. Feedback from the Survey (3/3)

- Main initial usage: Download from the PSUR Repository
  - Upload form the national systems in to the PSUR Repository would in most cases be implemented in a later phase or remain manual

- Main type of products to download:
  - PSURs related to products for which the NCA lead MS/Rapporteur and products which are authorised

- Almost all NCAs would use the API to support the assessment workflow.

- Main benefits mentioned from using the API:
  - More efficient tracking of PSUR dossiers
  - Faster download
  - Less staff needed to download PSURs
  - Reduced need to train staff in using the UI
  - Capability of integration with national workflow allowing the assignment of tasks to assessors and avoiding assessors having to switch between several applications depending on the tasks. The idea is to work in an integrated environment

Note: The survey results above are based on the input received as at 19 May CoB

8. Q&A (1/14)

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Questions we received prior to the webinar:

- *Is the API for the PSUR Repository different from the API for the Common Repository?*
  - One mechanism (i.e. RESTFul Web services) to call the services
  - Root-URL different to denote the type of information the service request applies to

- *Will the MRP/DCP/National PSURs be available in the Common Repository to avoid them to having to build connection to the Common Repository and separate connection to PSUR repository and having a connection to CESP?*
  - There would be no need for a separate connection to the PSUR Repository and the Common Repository, they can both be accessed via the same connection by calling the appropriate service
  - CESP is a different concept (transfer info via FTP instead of calling web services to query and download stored information)
  - The Common Repository currently only provides access to eCTD CP sequences
  - The next version of the Common Repository could provide access to other type of sequences (i.e. Nees, VNeeS, …) but only CP
  - Technically, if an NCA is interested, the CR could also host MRP/DCP/NP sequences.

Questions we received prior to the webinar:

- *How to relate a specific eCTD sequence to an eCTD motherdossier?*
  - The repository holds the submission sequences in the original zip folders, exactly as they were sent by the MAH with all relevant metadata (checksum and the eCTD envelope). There is no difference to receiving the submission on a CD/DVD or via CESP so in principle there is no change to how you relate the submission to the product today

- *It is unclear how in the PSUSA procedure technical validation issues are resolved, to make sure the eCTD lifecycle of the motherdossier at the MEB is not broken?*
  - Technical validation is only run at the very highest level, i.e. to check if the submission is in eCTD format by the repository. It is not possible to run full eCTD technical validation as the EMA does not hold the full lifecycle i.e. the other submission sequences for MRP/DCP/NAP products. It would be necessary to agree a business process to clarify who will contact the MAH in case the sequence is technically not valid and that resubmission is required

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Questions asked by participants during the webinar & the answers given:

Q1.When will the specification of the API be available?

A. The API specification has been sent to the IT Directors and the EUT Enterprise Architecture Board on 07 Apr 15 and in various mailings afterwards to the PSUR Repository Advisory Group, PMG2, PRAC, CMDh, … It is also available on the PSUR Repository webpage at http://esubmission.ema.europa.eu/psur/api/PSUR-Repository-API-Specification-DRAFT.doc.

Q2. Would the CAPs PSUR be duplicated in the Common Repository and in the PSUR Repository?

A. Yes, both repositories will contain CAP PSURs. The PSUR Repository will also contain the MS Word version working documents that might be submitted together with the PSUR. These are not available via the Common Repository at the moment

EUROPEAN MEDICINES AGENCY

Questions asked by participants during the webinar & the answers given:

Q3. Will EMA validate NeeS-submissions in NAP-PSUSA procedures as well?

A. EMA is not able to do a full validation on PSURs for non-CAP submissions as we don't hold the full lifecycle of the product. The technical validation criteria is currently set on 'tolerant' setting for both eCTD and NeeS submissions for NAPs.

EUROPEAN MEDICINES AGENCY

Questions asked by participants during the webinar & the answers given:

Q4.What type /extension of validation is done by EMA on the submissions, that will clarify what the NCA needs to do later on?

A. The validations EMA runs:

CAP eCTD: EU-eCTD 5.0.

Non-CAP eCTD: tolerant validation.

NeeS : very basic.

The EMA also executes a series of checks to validate that the procedure DLP has already been crossed but deadline has not yet been crossed, the products are recorded in Art 57.

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Questions asked by participants during the webinar & the answers given:

Q5. Will the reconciliation email-procedure (check completeness of PSUR submissions) still be necessary for the NCAs after implementation of the API?

A. The manual reconciliation of submissions made to NCAs in Member States via email will need to continue until the use of the PSUR Repository has become mandatory. This means that it would become redundant at the earliest in June 2016. This is one of the biggest direct helpful impacts of the PSUR Repository, once mandatory, i.e. that this cumbersome and workload-intensive administrative overhead for NCAs and EMA could be stopped and the obligation to submit correctly and in time to the relevant procedure would be fully delegated back to the MAHs.

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Questions asked by participants during the webinar & the answers given:

Q.6 Are CRs from the Pilot Phase be considered also for the API (when needed) or will be implemented only in the web application?

Since last month, the Advisory Group has put in place a procedure to process change requests, elaborate and agree on the corresponding requirement and then regularly prioritise them. All CRs that have already been identified during the pilot phase and that will be identified in the future, follow this process. We have already foreseen a few more releases in the plan to deal with change requests in order of the priority defined by the Advisory Group (aka PRAG).

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Questions asked by participants during the webinar & the answers given:

Q7.Will the API and the UI have the same scope of search criteria?

A. As per the requirements, the search terms in the API form a subset of the terms in the UI. The information returned is however rich and helps you being very granular in the processing of the response. The exhaustive set of terms and the description of the responses are explicated in the API specification document.

Q8.Will you be able to download Working documents via API?

A. Yes, the API will allow download of whole submission sequence including the word version working documents.

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Questions asked by participants during the webinar & the answers given:

Q9. If change requests may impact on API, the advisory group may not know about it, so how would we know?

A. This should be transparent for the Advisory Group. The idea is that the Advisory Group identifies (and prioritises) the business requirements, including whether each requirement should be accessible from the manual user interface (i.e the NCA UI) and via the automated mechanism (i.e. the API). It is then up to the technical team implement this in the UI and/or in the API.

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Questions asked by participants during the webinar & the answers given:

Q10.The PSUR has a certain format. Are you still working on the approach to extract patient exposure data from all PSURs, that are submitted?

A. The PSUR repository project is currently not looking into changing the way the PSUR document is presented *per se*, i.e. it remains for the time being a PDF format. However, in the long run, and once the repository is life, it would indeed have merit to consider a new project to see in how far creation, compilation and extraction of PSUR data could be placed into an interactive electronic format that would allow better summary evaluation across all datasets presented by different companies/products.

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Questions asked by participants during the webinar & the answers given:

Q11. (re: topic 6):Will this also mean that EMA has to adapt the cover letter?

A. The cover letter for the single assessment can (and will) be adapted to make sure national needs for information are met. Alternatively, a submission file could contain also national letters together with the EMA letter. Proposal: PRAG to discuss and agree a proposed way forward for cover letter(s) in mandatory submission phase to PSUR repository, to be consulted with PMG2 and agreed with CMDh.

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Questions asked by participants during the webinar & the answers given:

Q12.What is the technology used behind the scene for CR and PR?

A. It is built by Extedo on top of EURS; their technology stack is based on a Microsoft development stack (C, C#, …). PSUR Repository: Standard EMA development stack Java / Oracle Server / Oracle Weblogic JEE container combined (internally) with a Documentum platform. Both CR and PSUR Repository do make use of a RESTful approach to designing web services.

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Questions asked by participants during the webinar & the answers given:

Q13.Can you guarantee that we need to build just one connector to both CR and PR?

Since the requirement for the "connector" an NCA would need to build, would be the capability to send RESTful web service calls to the appropriate URLs depending on the type of information the calls refers to, there would be a need for only one connector.

9. Proposed strategy to support NCAs in dealing with the impact of using the API (1/2)

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#	Topic	Resp	Time
1	Welcome and objective of the webinar	Chairs	10
2	Overview of the PSUR Repository	IR	15
3	The Post-audit functionalities	OS	10
4	Overview of the API	CEE	20
5	Expected impact of the API on your IT infrastructure	OS and CEE	10
6	Expected impact of the API on your business processes	IR	10
7	Feedback from the survey	IR and OS	10
8	Q&A	All	30
9	**Proposed strategy to support NCAs in dealing with the impact of using the API Wrap-up**	**Chairs**	**10**

9. Proposed strategy to support NCAs in dealing with the impact of using the API (2/2)

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- Based on today's input, an updated change management plan will be sent round.
- The UAT activity (starting in July) will be initially the main forum to further elaborate the business impact via e.g. the test scenarios

Annexes

Annex 1: Referenced Documents

EUROPEAN MEDICINES AGENCY

Doc ID	Title
n.a.	Regulation (EU) No 1235/2010
n.a.	Directive 2010/84/EU
n.a.	Commission implementing regulation No 520/2012 of 19 June 2012
n.a.	Amending egulation (EU) No 1027/2012
n.a .	Amending Directive 2012/26/EU
EMA/681848/2013	Auditable functionalities as agreed by the EMA MB on 12 Dec 13
EMA/224103/2015	PSUR Repository API Specification
EMA/254263/2014	PSUR Repository - Notifications Requirements v3.0

Annex 2: Detailed Requirements, Deliverables and Plan for Delivery of the Post-Audit Functionalities

EUROPEAN MEDICINES AGENCY

10 auditable functionalities - 1. Electronic submission

1.1	• Provide for **secure electronic submission** to avoid unauthorised access including non-repudiation of message dispositions in accordance with ICH M2 recommendations.
1.2	• Maintain/adapt a **registration system** to uniquely **identify organisations and authorised users** to allow for a secure communication environment between trusted parties and to authorise access to the PSUR Repository. Authorised users are to be defined by NCAs, the EMA and the Commission for their respective staff. For the PRAC, CHMP and the CMDh authorised users are to be determined based on the official membership in one of these committees.
1.3	• Develop the electronic submission functionalities to allow for the **loading, processing, storage, retrieval and assessment of PSURs, PSUR assessment reports and PRAC recommendations** by use of metadata based on fields present in the EURD list for each active substance/combination of active substances.
1.4	• A **technical and business rule validation** is to be performed following receipt of PSURs based on the use of metadata. The outcome of the validation is to be notified to the senders of PSUR submissions. PSURs are to be stored in the repository, if they passed the technical and business rule validation.

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10 auditable functionalities - 2. Storage and Retrieval

2.1	• The **PSURs** and associated **metadata** are to be **extracted** from electronic submissions **and stored** in the PSUR Repository. Repository is understood as a common storage place.
2.2	• PSUR **assessment reports** and **PRAC recommendations** are to be stored in the PSUR Repository.
2.3	• The PSUR Repository is to provide **remote, secure document retrieval** through a user interface for authorised users of NCAs and the EMA, the Commission, the PRAC, the CHMP and the CMDh. • The user interface should **allow querying the PSUR Repository** by use of metadata based on fields present in the EURD list for each active substance/combination of active substances. • The query output is to **identify the PSUR(s) submission(s)**, which are to be assessed under a particular assessment procedure.

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10 auditable functionalities - 3. Assessment

3.1	•	The PSUR Repository is to allow authorised users of NCAs and the EMA, the Commission, the PRAC, the CHMP and the CMDh **to perform queries to retrieve PSURs, PSUR assessment reports and PRAC recommendations** by use of metadata based on fields present in the EURD list for each active substance/combination of active substances.
3.2	•	After performing a query in the PSUR Repository through the user interface (as defined under point 2.3), authorised users of NCAs and the EMA, the Commission, the PRAC, the CHMP and the CMDh are to be **able to download the documents** matching the query parameters based on PSUR metadata (see point 2.3).
3.3	•	**Notification** to Member States of new submissions, to assist the assessment.

Delivery of "Automated tracking and alerting functionalities ..." (1/2)

- Requirement:
  - As agreed by EMA MB in Dec 13:
    - "*1. Automated tracking and alerting functionalities to assist the assessment procedure*"
  - Detailed requirement as elaborated and agreed by the PSUR Repository Advisory Group on 15 Oct 14
    - See annex 3
- Proposed Deliverable:
  - Additional notification functionality as part of the "Post-audit" release
    - This will a.o. address the requirement to improve the current notification system (such as highlighting the need for discussion or recommendation for variation)

Delivery of "Automated tracking and alerting functionalities..." (2/2)

EUROPEAN MEDICINES AGENCY

- Milestone plan:
  - Start development EMA: Jul 15
  - EMA-internal testing: Oct 15
  - UAT: Oct-Nov 15
  - Functionality available: Dec 15
  - One or more additional releases will be planned for Jan – Jun 16 depending on the findings from the UAT testing of the post-audit functionalities and the usage during pilot phase: This caters for the requirement "…an iterative approach will be followed allowing for improvement of functionalities if necessary."

Delivery of “Two-way automatic…” (1/3)

EUROPEAN MEDICINES AGENCY

- Requirement:
  - As agreed by EMA MB in Dec 13:
    - “*2. Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs*”
  - Detailed requirement as elaborated and agreed by the PSUR Repository Advisory Group on 15 Oct 14
    - See annex 4
- Proposed deliverable:
  - EMA: A computer-interface (aka API) allowing NCA IT systems to perform automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository
    - See PSUR Repository API Specification in Annex 1
  - Interested NCAs: Adaptation of the NCA system to use the API as per the agreed API spec

Delivery of “Two-way automatic…” (2/3)

EUROPEAN MEDICINES AGENCY

- Milestone Plan:
  - Nov 14 – Mar 15: Drafting API specifications by group of NCA IT Reps
  - Publish for consultation: Apr 15 – May 15
  - Final API specification: Jun 15
    - Formally adopted by the EUT IT Directors Plenary via written procedure by end May.
  - Start development EMA API: Jul 15
  - Suggested start adaptation NCA system to use the API as per the agreed API spec: Jul 15
  - Specification UAT test cases by NCAs: Jul 15
  - EMA-internal testing: Oct 15
  - UAT: Oct-Nov 15
  - API available: End Nov 15
  - One or more additional releases will be planned for Jan – Jun 16 depending on the findings from the UAT testing of the post-audit functionalities and the usage during pilot phase: This caters for the requirement “…an iterative approach will be followed allowing for improvement of functionalities if necessary.”

Delivery of “Two-way automatic…” (3/3/)

EUROPEAN MEDICINES AGENCY

- Proposed UAT approach:
  - Challenge: Testing the API, requires a “consuming” system. Even if the NCAs start developing their systems in Jul 15, it is not certain that these will be significantly stable to be used for the UAT.
  - Proposed approach:
    - NCAs provide their test cases (scenarios) to EMA
    - EMA executes these test cases within the EMA infrastructure
      - NCA reps are welcome to actively participate in this
    - NCAs review the test reports

Delivery of “Work-flow support …” (1/2)

EUROPEAN MEDICINES AGENCY

- Requirement:
  - As agreed by EMA MB in Dec 13:
    - “*3. Work-flow support for assessors and assistance of PSUR Repository administration*”
  - Detailed requirement as elaborated and agreed by the PSUR Repository Advisory Group on 15 Oct 14
    - See annex 5
- Proposed Deliverable:
  - Additional notification functionality as part of the “Post-audit” release
    - This will a.o. address the requirement to improve the current notification system (such as highlighting the need for discussion or recommendation for variation)

Delivery of “Work-flow support …” (2/2)

EUROPEAN MEDICINES AGENCY

- Milestone plan:
  - Start development EMA: Jul 15
  - EMA-internal testing: Oct 15
  - UAT: Oct-Nov 15
  - Functionality available: Dec 15
  - One or more additional releases will be planned for Jan – Jun 16 depending on the findings from the UAT testing of the post-audit functionalities and the usage during pilot phase: This caters for the requirement “…an iterative approach will be followed allowing for improvement of functionalities if necessary.”

Delivery of "Storage and retrieval of PSUR related documents" (1/2)

EUROPEAN MEDICINES AGENCY

- Requirement:
  - As agreed by EMA MB in Dec 13:
    - "4. Allowing for the storage and retrieval of PSUR related documents"
  - Detailed requirement as elaborated and agreed by the PSUR Repository Advisory Group on 15 Oct 14
    - It was agreed that this functionality is already being provided as part of the auditable release under the use cases:
      - Create delivery file
      - Submit AR
      - Submit Comments
      - Submit Supplementary Information
      - Search & Retrieve Document
      - Send Receipt Notification
      - Upload File
- Proposed Deliverable:
  - (n.a.)

Annex 3: Detailed Requirements: Post-Audit Functionality 1 (1/1)

EUROPEAN MEDICINES AGENCY

Additional functionality as per B.09b_FINAL PSUR Repository auditable functionalities - section 4	Post-audit BRQ (and related refs.)	Comments
Automated tracking and alerting functionalities to assist the assessment procedure	BRQ-0001 (related: BRQ-0007 & BRQ-0003, BRQ-0011)	Discussed documented fully in miutes of meeting (page 3) on 17/07/2014: Minutes - 140717 EMA/456545/2014 https://docs.eudra.org/webtop/drl/objectId/090142b28298ff06 In summary: it was agreed that "automated tracking" most likely refered some aspect of notifications or workflow to support the assessment process. Therefore this functionalilty is already met in some parts by the notifications sent out in the initial auditable release and the remaining functionality would be agreed under the workflow aspect as per BRQ-0003. This requirement will be met be BRQ-0007 - additional notifications and BRQ-0003 - Workflow

- ✓ Notifications provided in the Auditable Functionalities release:
  - ✓ See doc “EMA/254263/2014 PSUR Repository - Notifications Requirements v3.0” in Annex 1

Annex 3: Detailed Requirements: Post-Audit Functionality 1 (2/2)

EUROPEAN MEDICINES AGENCY

✓ Detailed requirements corresponding to BRQ-0007:

Detailed requirements ID	Detailed requirements name	Description
DR_006	Notifications - Procedure start date	An email will be sent to the NCA mailbox for the relevant procedure when the prepared AR template is added to the repository. The notification will contain a hyperlink to the AR template. This notification only applies to the EU single assessment procedure. Notification format will be as per existing notification in release 1
DR_007	Notifications - PAR reminder before due date	The current PAR due date is calculated as procedure start date + 60 calendar days A email will be sent 7 days prior to the due date for a procedure. Notification format will be as per existing notification in release 1 It will be sent to the NCA as per the country listed in the EURD list for the procedure.
DR_008	Notifications - PAR reminder after due date	An email will be sent to the NCA mailbox 2 days after PAR due date. Notification format will be as per existing notification in release 1
DR_009	Notification - hyperlinks to documents	The following notifications will contain hyperlinks to documents: Notification of receipt of PAR Notification of receipt of UAR Notification of receipt of Comments on PAR

Annex 4: Detailed Requirements: Post-Audit Functionality 2

EUROPEAN MEDICINES AGENCY

Detailed requirements ID	Detailed requirements name	Description
DR_001	Search query	The PSUR repository will provide parametarised queries executed with the following parameters: EU single assessment non-EU single assessment Procedure number Country code Document type Submission date range Data lock point
DR_002	Search query: Document type	A user must be able to search for one or more of the following document types: PSUR submission (the original package that was submitted by the MAH) Supplemental Info (the original package that was submitted by the MAH) Documents uploaded in relation to non-EU single assessment Preliminary AR (applicable to EU single assessment only) Updated AR (applicable to EU single assessment only) Comments on PAR (applicable to EU single assessment only) PRAC recommendation (applicable to EU single assessment only) CHMP Opinion (applicable to EU single assessment only) CMDh position (applicable to EU single assessment only)
DR_003	Search query: Document submission date	The user will be able to specify a date range with a "from" and "to" date It will be possible for the user to only specify the "from date". The system will then search for document types where the date submitted matches the "from" date.
DR_004	Automated upload of a document related to **EU single assessment**	The PSUR repository will allow an assessment report to be automatically uploaded from a remote system. The document type and procedure number must be recorded.
DR_005	Automated upload of document related to **Non-EU single assessment**	The PSUR repository will allow an assessment report to be automatically uploaded from a remote system. The document type, MS and DLP must be recorded.

Annex 4: Detailed Requirements: Post-Audit Functionality 3 (1/1)

EUROPEAN MEDICINES AGENCY

Additional functionality as per B.09b_FINAL PSUR Repository auditable functionalities - section 4	Post-audit BRQ (and related refs.)	Comments
Work-flow support for assessors and assistance of PSUR Repository administration. This will include notifications and reminders relative to the procedure timetable.	BRQ-0003 (related: BRQ-0007)	Discussed documented fully in miutes of meeting (page 4) on17/07/2014: Minutes - 140717 EMA/456545/2014 https://docs.eudra.org/webtop/drl/objectId/090142b28298ff06 It was agreed that the workflow aspect would be covered by additional notifications as per the procedure timetable. The additional notifications will be defined under a similar requirement raised during initial requirements gathering for the auditable release. This is documented as BRQ-0007 Additional notification following business content validation.

✓ Detailed requirements corresponding to BRQ-0007: See annex 2

Annex 5: Detailed Requirements: Post-Audit Functionality 3 (1/1)

EUROPEAN MEDICINES AGENCY

Additional functionality as per B.09b_FINAL PSUR Repository auditable functionalities - section 4	Post-audit BRQ (and related refs.)	Comments
Allowing for the storage and retrieval of [other] PSUR related documents	BRQ-0004	Discussed documented fully in miutes of meeting (page 5) on 17/07/2014: Minutes - 140717 EMA/456545/2014 https://docs.eudra.org/webtop/drl/objectId/090142b28298ff06 It was agreed that this functionality is already being provided as part of the auditable release under the use cases: Create delivery file Submit AR Submit Comments Submit Supplementary Information Search & Retrieve Document Send Receipt Notification Upload File

Annex 6:
Composition PSUR Repository Advisory Group (NCA)

EUROPEAN MEDICINES AGENCY

Advisory and/or Consulting Groups: Representative Project Team 1 of Project 00305	• Said Ioughlissen (ANSM)
Advisory and/or Consulting Groups: Representative PRAC	• Margarida Guimaraes (Infarmed)
Advisory and/or Consulting Groups: Representative PSUR Work Sharing Working Group	• Anne Ambrose (MHRA) • Inma Corrales (AEMPS) • Ursula Drechsel-Bauerle (PEI)
Advisory and/or Consulting Groups: Representative Common Repository Implementation Group	• Jose Simarro (AEMPS) • Kevin Horan (IMB)
Advisory and/or Consulting Groups: Representative eSub CMB	• Karin Gröndahl (MPA)
Representatives of individual NCAs:	• BfArM: Main: Harriet Palissa o Backup: Anke Blumberg • Infarmed: Ana Sofia Martins o Backup: Leonor Chambel

Note: The above reflects the composition at the time of elaborating the post-audit requirements

Annex 7:
Process of approval post-audit requirements

Drafting and discussion post-audit requirements	Jun – Oct 14
Final version for approval to Advisory Group (See doc “Email to Project Advisory Group to approve post-audit detailed requirements – version 2.0” in Annex 1)	03 Oct 14
Consultation period	03 Oct 14 – 15 Oct 14
Closure consultation period Feedback consultation period: • Explicit approval received from: PEI (rep PSUR WSWG), MHRA (rep PSUR WSWG), Infarmed (Rep PRAC) • No feedback received so tacit approval assumed from: AEMPS, IMB, MPA, BfArM	15 Oct 14

- In accordance with Article 25a of Regulation (EC) 726/2004 , the Agency has the following obligations:
  - "The Agency shall, in collaboration with the national competent authorities (NCAs) and the Commission, set up and maintain a repository for periodic safety update reports (hereinafter the "PSUR Repository") and the corresponding assessment reports so that they are fully and permanently accessible to the Commission, the NCAs, the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee for Medicinal Products for Human Use (CHMP) and the coordination group referred to in Article 27 of Directive 2001/83/EC (hereafter referred to as CMDh)."

- The functionalities of that PSUR Repository as will be delivered by this project have been agreed by a.o. the EUTMB, the PRAC and the EMA MB and are documented in document "EMA/681848/2013" (aka the "Auditable Requirements").

Background (1/2)

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- In accordance with Article 25a of Regulation (EC) 726/2004 , the Agency has the following obligations:
  - "The Agency shall, in collaboration with the national competent authorities (NCAs) and the Commission, set up and maintain a repository for periodic safety update reports (hereinafter the "PSUR Repository") and the corresponding assessment reports so that they are fully and permanently accessible to the Commission, the NCAs, the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee for Medicinal Products for Human Use (CHMP) and the coordination group referred to in Article 27 of Directive 2001/83/EC (hereafter referred to as CMDh)."

- The functionalities of that PSUR Repository as will be delivered by this project have been agreed by a.o. the EUTMB, the PRAC and the EMA MB and are documented in document "EMA/681848/2013" (aka the "Auditable Requirements").

Background (2/2)

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- A commitment has also been taken to deliver additional functionality (aka “post-audit functionality) for the PSUR Repository in next version(s) of the solution.
  - Delivery of this functionality is not part of the scope of the first release. But the plan for delivery is to be audited.

- PRAC, as part of the governance overseeing the PSUR Repository, is herewith asked for their opinion on the proposed plan to deliver the post-audit functionality.

Post-Audit Functionalities

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As has been agreed by a.o. the EUTMB, the PRAC and the EMA MB and documented in document “EMA/681848/2013” (aka the “Auditable Requirements”), section 4:

4. *Additional functionalities of the PSUR Repository (post-audit)*

Taking into account the provisions set out in Article 25a of Regulation (EC) 726/2004, the functionalities to be audited are those outlined in section 3.

As part of the consultation with Member States, the following additional key functionalities were requested to be included in the common PSUR Repository:

1. ***Automated tracking and alerting functionalities to assist the assessment procedure***
2. ***Automated two-way exchange of documents held in the PSUR Repository between NCA systems and the PSUR Repository to reduce administrative burden for NCAs***
3. ***Work-flow support for assessors and assistance of PSUR Repository administration***
4. ***Allowing for the storage and retrieval of PSUR related documents***

These additional functionalities, beyond those to be audited, are to be provided in future post-audit releases of the PSUR Repository for which further business requirements will be developed with Member States in consultation with the PRAC.

Based on the initial implementation experience, an iterative approach will be followed allowing for improvement of functionalities if necessary.

Delivery of additional functionality
(i.e. on top of the post-audit functionalities)

EUROPEAN MEDICINES AGENCY

- Additional functionalities have been identified and more can be expected:
  - Functionality already identified by the Project Advisory Group
  - New requirements that arise during usage of the PSUR Repository during the pilot phase and after
  - …
- These will be elaborated by the Project Advisory Group, prioritised by PMG2/EMA and included in consecutive releases as appropriate

Overview Delivery Post-Audit and Additional Functionalities

EUROPEAN MEDICINES AGENCY

- Delivery of the first release of the PSUR Repository (aka the Auditable Functionalities release) has taken place on 26 January
- The four post-audit functionalities have defined by the EMA MB (a.o.) in Dec 13 and have been detailed by the Project Advisory Group, consisting of representatives of NCA groups such as PT1, PRAC, PSUR WSWG, eSub CMB, … (See annex 4)
- The plan for the post-audit functionalities is being audited.
- Subject to approval of the audit report by the EMA MB in June, development will start in July of:
  - the post-audit functionalities
  - plus additional functionalities to prioritised by PMG2/EMA
- The deliverables required for the four post-audit functionalities will be made available for user acceptance testing (UAT) in October 15
- Subject to positive outcome of the UAT, the post-audit functionalities will be available in December 15