EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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PSUR Repository Implementation Plan

Introduction of concepts of go-live, pilot and switch on

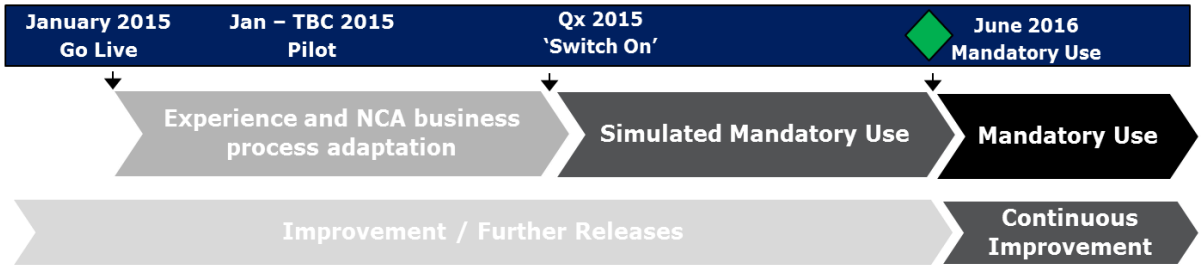
1. Purpose

EMA has worked together with the NCAs and industry representatives in a specifically constituted PSUR Repository Advisory Group (PRAG) to define the business requirements for the system and has subsequently developed the repository in close collaboration with NCAs. The PSUR repository project currently expects an EMA Management Board agreement on the system's functionality on 11 June 2015. The legislation foresees that 12 months after such announcement, the use of the repository for the submission, storage and retrieval of all PSURs and related documents (assessment reports) in the European Union will become mandatory (June 2016). Instead of a rapid switch at that point of time, the EMA proposes a phased implementation. The main benefits of this approach are:

- Allow NCAs and Industry to gain experience with the system;
- A more mature system when it is mandated due to the possibility of feedback aimed at improvements for next releases

The phased approach will be as follows:

- Go-live (26 January 2015)
- Pilot (26 January 2015 – TBC in April/May 2015 with network)
- Switch-on (as of agreed date – mandatory use June 2016)



A summary overview of the phases and their impact on NCAs and Industry can be found in section 3.4.

To aide placing this document and other communications and presentations into the right context, an overview of the communication and training plan is provided in section 4.

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2. What is 'go-live'?

It is anticipated that the system will be installed in a live, production environment on 26th of January 2015. As of this date, the EMA will start the pilot phase with Industry and the Network. In addition, the system is available to all registered NCA users and industry wishing to use the XML delivery file option for creating the submission package for PSURs for electronic submission to the repository.

Impact on NCAs:

The user interface for the NCAs will be available from go-live. In order for the NCAs to connect to the repository a user profile needs to be set up (all NCAs have been requested to provide, in a separate communication on 22 January 2015, the names and contact details of staff members who will to access the repository. Please also see detailed communication plan in section 4). The registration form will be available on the dedicated PSUR Repository webpage.

There are 2 different user profiles:

- Reviewer: search, query and download documents from the repository
- Contributor: search, query, download documents from the repository and upload assessment reports and comments.

Examples of reviewer profiles would be those of PRAC and CMDh members, assessors, and other NCA staff downloading PSURs and supplementary information sequences from the repository to the relevant national system. A contributor profile would be that of a person additionally uploading the Assessment Reports and comments to the AR in to the Repository. Only named users are able to access and use the repository.

Once the NCA users have been registered with appropriate profile (reviewer or contributor), they will be able to access the repository and search, query and download PSURs, that have been submitted by the MAHs. They will also be able to upload (submit) assessment reports and comments for those PSURs. It is not possible to upload an assessment report for a procedure for which no submission has been received.

From the system go-live, the automatic notification system (via emails from the repository to functional email addresses, i.e. not linked to individual user profiles) will be available. NCAs wishing to receive these notifications should provide the Agency with the email address to be used for that purpose. Without this information, the notification system will not be available. However, email addresses can be added or modified upon request to PSURrepository@ema.europa.eu. The Agency strongly recommends using a dedicated functional mailbox for this purpose. A separate communication for the email address for notification was sent on 20 January 2015 to the PSUR contact points at NCAs (see also detailed communication plan in section 4).

Impact on industry:

From the anticipated go-live (26th January 2015) the user interface for the MAH to create delivery files to support submission to the Repository will be available

EU-single assessment:

MAHs continue making submissions via the existing eSubmission Gateway/Web Client and when the XML delivery file is attached[1] to the submission they will be automatically uploaded to the PSUR Repository following a technical compliance check.

MAHs can continue to submit their PSURs via the eSubmission Gateway using the existing file naming convention. In this case the submission will arrive to the EMA and will be made available via the Common Repository.

Note: the submissions are available via the PSUR Repository only if a delivery file has been created and included in PSUR submission package.

Non-EU single assessment:

MAHs are able to submit PSURs for products outside the EU Single Assessment Procedure i.e. PSURs for products for which the active substance has been authorised in one member state only. These can be submitted to the repository via the eSubmission Gateway/Web Client. In this case the use of the XML delivery file is required; it is not possible to submit non-EU single assessment PSURs to the EMA using the file naming convention.

3. What are the pilot, 'switch on' and the mandatory use?

3.1. Pilot

3.1.1. EU single assessment procedure

The pilot will start once the Repository is installed in a live environment as the first phase towards full implementation. Participation in the pilot is optional for all NCAs and MAHs. The objective is to pilot the full procedure workflow to familiarise the users with the Repository and to identify potential improvement opportunities to be used for the future development of the system.

The pilot will have two stages:

Stage 1: For the initial pilot on the EU single assessment procedure coordinated by the Agency, PSUSA containing CAPs only are targeted, as the Agency has a full oversight of their MAHs. CAP MAHs who have an upcoming PSUR submission deadline between 26.1.2015 and 11.3.2015 have been contacted and invited to take part in a pilot.

On the 13th January 2015 training on how to submit to the PSUR Repository was given to those MAHs based on submission deadlines. During this training the MAHs have been asked to confirm if they are willing and able to take part in the pilot phase i.e. to submit to the repository.

Stage 2: As requested by the network, the pilot is being extended past March 2015, including both CAP and NAP procedures (PSUSA CAP/NAP and NAP/NAP) under the EU single assessment. This second phase of the pilot will continue until the system is switched on (see section 3.2.

[1] Details of the submission process can be found on the EMA's dedicated PSUR repository webpage

Impact on NCAs

Following confirmation from the MAHs on their wish to participate in the pilot, the lead member state/Rapporteurs of each of these PSUR procedures will be contacted directly to confirm their willingness and ability to take part in the pilot. Participation is optional. However, it is strongly recommended that all NCAs participate in one of the pilot stages, as once the PSUR repository goes into "switch-on" stage, all NCAs will require to use the repository (see 3.2.1. , Impact on NCAs).

If the lead member state/Rapporteur confirms their participation in the pilot, all other NCAs are invited to participate in the pilot use for that particular product/procedure for provision of comments. It is not possible to include procedures/products in the pilot if the lead member state does not wish to take part in the pilot.

If a MAH for a NAP chooses to submit their PSUR to the repository during the pilot period we will follow the same processes as for CAPs to include these submissions in the pilot should the respective lead member state/Rapporteurs wish to take part.

All NCAs will be invited to training sessions (see section 4.2. to allow participation in the pilot and to explain how to:

- Search and download PSURs and supplementary information
- Submit assessment reports and comments
- Retrieve assessment reports and comments submitted by other NCAs
- View and retrieve final procedure outcomes

No change for NCAs for PSURs for EU Single Assessment (PSUSAs) outside the pilot ('as-is' procedure).

PSUR submissions and PSUSA assessment procedure via existing channels and repository:

- **It is important to note that the existing submission channels to NCAs will remain unchanged during the pilot.**
- **PSUSAs not part of the pilot will be processed in the 'as-is' procedure.**
- **PSUSAs that are part of the pilot will have both processes (communication via repository and the 'as-is' procedure) run in parallel**

The MAH has a legal obligation to submit PSURs for CAPs to the Agency and the NCAs. Submission to the Agency has to be via the existing eSubmission Gateway/Web Client, whether the repository is additionally used or not. PSURs of NAPs have to be submitted directly to the NCA(s) where the NAP is authorised and the participation in the pilot does not remove this obligation. The EMA encourages submissions of NAPs to the repository, however, cannot enforce such a request.

During the pilot the NCAs are able to retrieve all PSURs and supplementary information submissions as per the current process provided directly by the MAH.

All existing communications via manual emails will continue to be sent during the pilot use. This means that for example when an Assessment Report is submitted to the repository, the repository sends a notification to all NCAs, and simultaneously, the submitting lead member state/rapporteur will send the email with the AR attached to all NCAs using the relevant EudraNet mailboxes, such as e.g. EMA-H-

Pharmacovigilance (exactly as today). This means that duplicate messages are received by NCAs. This will enable the NCA to confirm that the system works as expected, hence gaining confidence in its use.

This will also allow the NCAs to make relevant changes to the current business processes by allowing a comparison of their current 'as is' process to their future 'full repository use' process, hence allowing an estimation of the required changes in the working processes.

3.1.2. Non-EU single assessment procedure

The national PSUR procedures are not governed by the EURD list and hence any NCA can invite/request submissions to the PSUR repository as soon as it is available (anticipated go-live 26 January 2015) and subsequently pilot the functionalities and processes for these procedures. This timing is in the hands of each NCA up until the mandatory use. EMA strongly recommends the use of the repository for all procedure types to allow all parties to gain experience with the system before June 2016 however, the initiative to run pilot on pure, single NAPs should be driven by each member state.

The EMA will assist the NCAs by publishing communication on national pilots on the PSUR Repository website.

3.2. 'Switch on'

3.2.1. EU single assessment procedure

To start achieving the benefits of the availability of the repository prior to its mandatory use, the concept of 'Switch on' has been proposed.

This would mean:

- Full end to end use of the PSUR Repository for EU Single Assessment Procedures
- CAPs must be submitted to the repository using the XML delivery file
- After switch on until the mandatory use Industry must submit NAP PSURs directly to NCAs
- In the case of NAPs, industry is strongly recommended to submit all PSURs included in the EU single assessment to the PSUR Repository in addition of the submission to the relevant NCA
- EMA will manually upload any NAP submissions not submitted to the repository following reconciliation with NCAs

No change for pure, single NAP process (products for which the active substance has been authorised in one member state only). The NCAs are free to organise corresponding pilot/switch on for these submissions.

Impact on NCAs

Once the repository is switched on all NCAs are required to use the repository as all PSURs for EU Single Assessment Procedure are included in the switch on and as parallel manual email distribution processes will no longer be in place. The benefits of the system availability cannot be fully rationalised and achieved if parallel processes remain to be supported.

All PSURs will be available through the repository; however these will continue to be available via the existing submission channel directly to the NCAs as well as through the Common Repository. If the MAH has only submitted a NAP PSUR to NCAs only, the EMA will upload this PSUR to the repository following the reconciliation process with NCAs. Following this upload, all related processes will be handled via the repository.

Assessment Reports and Comments are uploaded directly to the repository by the NCAs and no longer sent via manual emails.

All NCAs will be invited to attend training sessions to ensure they are able to use the repository and that the changes to the processes are clear.

There is no change for NCAs for PSURs outside the EU Single Assessment (non-EU PSUSA) procedure.

PSUR submissions via existing channels and repository:

The MAH has a legal obligation to submit all PSURs directly to the NCAs and the switching on of the repository does not remove this obligation. During the transitional period, i.e. until mandatory use, NCAs can therefore either retrieve the PSURs and supplementary information submissions from the repository (if submitted) or as per the current process receive them directly from the MAH.

Assessment Reports and Comments via repository:

Existing communications via manual emails would no longer be sent after the switch on. This means that for example when an Assessment Report is submitted to the repository, the system will send a notification to all NCAs replacing the need for the lead member state/Rapporteur to send an email with the AR attached to all NCAs. This means that **no** duplicate messages are received by NCAs (different from the pilot), hence streamlining the working processes. Similarly, when comments are submitted to the repository by concerned member states, a notification is sent to the lead member state to inform of arrival of new comment, and NCAs will no longer be required to circulate the comments via email, again streamlining all communications via the repository.

Impact on Industry

All CAPs must be submitted to the Repository.

It is strongly recommended to submit all PSURs directly to the repository in addition to the parallel process of submitting NAP PSURs directly to the NCAs. It must be emphasised that until mandatory use, Industry will have to continue to additionally submit PSURs of nationally authorised medicinal products to the NCA where the product is authorised.

3.2.2. Non-EU single assessment procedure

No change for pure, single NAP process (products for which the active substance has been authorised in one member state only). The NCAs are free to organise corresponding pilot/switch on for these submissions.

3.2.3. Why 'switch on' and not pilot till mandatory use?

The key benefits of a switch on phase are:

- Allow all NCAs and Industry (not only the ones who participated in the pilot) to gain experience with the system;

- A more mature system when it is mandated due to the possibility of feedback aimed at improvements for next releases

A pilot like approach till mandatory use will not provide all the benefits of a centralised and automated storage and retrieval system to the network and create the following possible drawbacks:

- Additional workload for NCAs due to the need to work in a dual approach for more than 1 year as both the repository and the non-repository business processes need to be adhered to (i.e. both uploading an AR into the system and sending it via email to the applicable mailing)
- Incorrect prioritisation of changes implemented
- Legacy of 'incomplete' procedures (i.e. there is a chance that PSURs were submitted to the Repository, but afterwards only the 'as is' process used, meaning that the corresponding assessment report would not be retrievable from the system)
- No 'true' readiness of system and business processes at the time of mandatory use

Therefore, the PSUR repository project believes that a well-timed introduction of the switch on phase would be beneficial to the network. The date for the switch on needs to be agreed with the Member States.

3.3. Mandatory use

12 months after the EMA Management Board decision, which is currently anticipated on 11 June 2015, the use of the repository will become mandatory. This means that in June 2016, National Competent Authorities, Industry and the Agency will have to rely solely on the repository in terms of storage and retrieval for all PSURs and their associated documents. This applies to all types of authorisations, i.e. both national and central procedures, as well as all types of PSUR procedures, covering the EU single assessment and the non-EU single assessment.

3.4. Summary table of actions and changes during pilot, after switch on and once the use of the Repository is mandatory

Activity	Pilot	Switch on	Mandatory use
MAH to Submit PSUR/ Supplementary Information	**To EMA**: eSubmission Gateway with file naming convention (results in non-inclusion in the pilot) or **To EMA** (participation in the pilot): eSubmission Gateway with xml delivery file **To NCA**: no change	**CAPs to EMA**: eSubmission Gateway with xml delivery file ***EMA to upload NAP PSURs to repository if not directly received*** **To NCA**: No change	**To EMA:** All PSURs submission via eSubmission Gateway with xml delivery file **To NCA:** *no* submission to NCAs. Retrieval of *all* PSURs from PSUR Repository only
NCA Retrieve PSUR/ Supplementary Information	• Local NCA repository • PSUR Repository after receipt of notification		• PSUR Repository after receipt of notification
NCA Circulate AR/Comments	• Manual email • PSUR Repository upload	• PSUR Repository upload	
MAH access to AR	• EMA circulates manual email		
NCA access AR/Comments	• Manual email • PSUR Repository after receipt of notification	• PSUR Repository after receipt of notification	
Access committee outcome	• MMD • PSUR Repository		
Access the Commission Decision	• PSUR Repository		

4. Communication and Training Overview

4.1. Detailed Communication Plan

The purpose of this section is to give an overview of the upcoming communication and training activities in relation of the PSUR Repository becoming available to the network and industry.

~	Communication Description	Audience	When	Format/Channel	Comment
1	Communication Plan Inform on Deployment and Consult around the Switch On date	Governance Structure see Governance Slide	04-Dec-14	Short Slide Deck	Make sure that CMDh website consultation is on the agenda for next meeting
3	1st News item Event/Letter to industry	All, eSubmission and corporate website	26-Jan-15	Content for website and Letter	
4	Website update of webpages	All	26-Jan-15	Web Content	
5	Pilot QPPV Emails 1st and 2nd round of pilot	Selection of QPPVs who need to submit	10-Dec-14 10-Feb-15	Email	NAPs included in 2nd round of pilot
6	Request to inform about the target mail-address for the Notification System	All NCAs via their PSUR contact points, together with the relevant Committees	20-Jan-15	Email	Email address or mailbox address needed as recipient of the automatic messages (Notifications) for each NCA
7	User registration request	All NCA via their PSUR contact points, together with the relevant Committees	22-Jan-15	Email	User login-IDs required to allow individual NCA user access to system

~	Communication Description	Audience	When	Format/Channel	Comment
8	White paper to describe in detail concepts of go-live, pilot and switch on	All NCAs via the relevant Committees plus PT2, PRAG and PSUR WS WP	21-Jan-15	Email cover note plus White Paper	This guidance is aimed at clarifying the phased approach to the Network. Guidance for Industry on submission is available on the eSubmission webpage
9	Pilot Rapporteurs / Lead Member States pilot invitation 1st round and 2nd round	Dedicated NCA's	30-Jan-15 10-Mar-15	Email	To invite to take part in the pilot as confirmation from Industry on repo usage received
10	2nd News Item - Switch On	Corporate submission CMDh NCA	To be decided	Content for website and Letter	
12	3rd PV Forum - Stakeholder For a Slide Deck EFPIA, CIGA	Industry Organisations	12-Jan-15	Short Slide deck tightly aligned with the new item	
13	3rd PV Newsletter	All	01-Mar-15	PV Newsletter	
14	Continuous updates – news bulletins	Network	Ongoing	Email, webpage, Meetings	Regular updates to the network created in consultation with PRAG

4.2. Detailed Training Plan

#	Training Session	To Whom	When	Comms channel	Format	Comment
1	Industry 1 Gateway Users	Gateway & User Interface (Industry)	10th Feb	Communication in the first news item 19th Jan	Adobe/Silent	This will be recorded for future use
2	Industry 2 New Gateway Users	Gateway & User Interface (Industry)	12th Feb	Communication in the first news item 19th Jan	Adobe/Silent	This will be recorded for future use
3	Industry Submitting - QPPV 1 Feb -12th March submission invite for a webinar 2nd phase of pilot – QPPV invitations with link to recorded webinar	Gateway & User Interface	13th Jan Always	QPPV Communication sent 10th Dec Invite to be sent Recorded training available on eSubmission webpage	Adobe/Q&A up to 100	Smaller focused group based on Feb/March submissions All interested parties
4	NCA/EC – Assessors experience, upload and download	Rapporteurs, Assessors and Lead Member States	10th Feb	Direct invite via user registration request	Adobe/Silent	This will be recorded for future use and made available on eSubmission webpage

#	Training Session	To Whom	When	Comms channel	Format	Comment
5	NCA/EC – Assessors experience, upload and download	Rapporteurs, Assessors and Lead Member States	26th Mar and 12th May	Announced in the 1st News item Registration process detailed on eSubmissions webpage	Interactive Q&A with up to 100 interested users (100 is limitation of webinar system)	This will be recorded for future use
7	EMA BUS & EMA B-PM	Work-stream	3rd Feb	Outlook Invitation, Large room, MMS	Classroom	
9	Industry Q&A Stream	Gateway & User Interface (Industry)	Last week of each month starting Feb for industry until needed	Training and Webpage	Adobe Q&A limited by 100	Participants need to register
10	NCA Q&A Stream	Rapporteurs, Assessors and Lead Member States	Last week in every month starting from May	Training and Webpage	Adobe Q&A limited by 100	Participants need to register
10	User Guide and Q&A	ALL	Feb 2015		User Guidance/Q&A	

Link to PSUR Repository webpage:

eSubmission website PSUR Repository page:
http://esubmission.ema.europa.eu/psur/psur_repository.html