



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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[PSUR Repository]

Supplementary Specification:

[Additional Email Notifications]

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1. This document purpose

The purpose of this document is to identify and describe additional specifications PSUR Repository notification

The audience for this document is PSUR Repository Advisory Group (PRAG) and EMA Procedure management.

2. Context

Following the first release of the PSUR repository system implementing the core notifications, this document details three additional notifications to implement the post-audit requirements 1 & 3. (See referenced document *B.09b_FINAL PSUR Repository auditable functionalities, section 4*. Please also see referenced document *PSUR post-audit detailed requirements.xls – worksheets "Detailed Requirements" and "Traceability for post-audit"*).

The detailed requirements have already been agreed and approved on the 18th December, 2014.

This document specifies the contents of the three additional notification requirements.

3. List of main functional requirements

Extract of detailed requirements previously agreed.

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	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

Content and format of notifications will be as follows:

ID Notification: PSUR Procedure start		
DR_006	Trigger	When an assessment report template is added to the repository.
	To	PRAC Rapp/Lead MS as per the EURD list for the procedure.
	Subject	PSUR assessment report template for<active_substance> , <PSUSA/NNNNNNNN/YYMM>
	Email Body	<p>The Preliminary Assessment Report template for the above mentioned procedures, which already includes all the administrative information, has been uploaded to the repository.</p> <p>Please log in to the PSUR Repository with your login credentials and download the template.</p> <p>https://psur-repo.eudra.org/psur-ui/</p>

ID Notification: PAR reminder before due date		
DR_007	Trigger	7 week days prior to the due date for a procedure.
	To	PRAC Rapp/Lead MS as per the EURD list for the procedure
	Subject	<active_substance> , <PSUSA/NNNNNNNN/YYMM>
	Email Body	<p>Please note that the assessment report for the above procedure is due on <procedure PAR due date>.</p> <p>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.</p> <p>As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt upload of the assessment report is highly appreciated.</p> <p>To upload your assessment report please log in to the PSUR Repository with your login credentials.</p> <p>https://psur-repo.eudra.org/psur-ui/</p>

ID		Notification: PAR reminder after due date
DR_006	Trigger point:	2 days after PAR due date.
	To:	PRAC Rapp/Lead MS as per the EURD list for the procedure
	Subject	<active_substance>, <PSUSA/NNNNNNNN/YYMM>
	Email Body	<p>Please note that the assessment report for the above procedure was due on <procedure PAR due date>.</p> <p>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.</p> <p>As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt upload of the assessment report is highly appreciated.</p> <p>To upload your assessment report please log in to the PSUR Repository with your login credentials.</p> <p>https://psur-repo.eudra.org/psur-ui/</p>

4. Related documents

The list of detailed requirements can be found in

PSUR post-audit business requirements

EMA/403608/2014

<https://docs.eudra.org/webtop/drl/objectId/090142b282ccaf75>

5. About this document

5.1. Document location

5.2. Referenced documents

Doc ID	Title	Locator
EMA/681848/2013	B.09b_FINAL PSUR Repository auditable functionalities	

Doc ID	Title	Locator
EMA/254263/2014	PSUR Repository - Notifications Requirements v3.0	
EMA/588894/2014	PSUR post-audit detailed requirements	

5.3. Document approval

Date	Version	Submitted by	Approved by	Approver Role

5.4. Document history

Version	Who	Date	What
1.0	Wasif Sabir	27/03/15	Original
2.0	Wasif Sabir	30/03/15	Update the context to include explicit reference to post-audit requirements implemented. Circulated to PRAG for approval.