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User Guidance for National Competent Authorities for PSUR Repository



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Document History

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1.0	12/11/14	Draft circulated to UAT participants.	Wasif Sabir
1.1	12/01/15	Added a couple of extra screen shots for search.	Wasif Sabir
1.2	20/01/15	Review.	Christophe Pée
1.3	23/01/15	Update and Review.	Kristiina Puusaari
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8.0	01/12/16	Clarification on the access to the repository by MAHs (no access), notifications for non-EU single assessment procedure ARs and clarification on the requirement by the NCAs to send ARs to the MAHs for non-EU single assessment procedures (these are not sent to the MAH by the Repository).	Kristiina Puusaari
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12.0	09/06/20	Updated to reflect changes implemented in v1.17.0.0 and other editorial changes and updates.	Kristiina Puusaari
13.0	03/07/23	Updated to reflect the version change due to the technical changes implemented in v2.1.0.0.	Kristiina Puusaari

1. Introduction

This document serves as a simple guide for NCA users to help them use the PSUR repository functions for uploading, searching and downloading PSURs and related documents.

2. Scope of the PSUR Repository

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 repository is accessible to the EMA, EC and Member State users only. There is no access to the PSUR Repository by the Marketing Authorisation Holders.

As per the Article 107b paragraph 1 and Article 28(2) regulation 726/2004) all PSUR procedures shall be submitted electronically to the PSUR Repository. The use of the repository is mandatory from 13 June 2016.

The obligation to submit to the PSUR Repository does not apply to products that have been given a positive CHMP scientific opinion under Article 58 of Regulation (EC) No 726/2004. For information on how to submit PSURs for Article 58 products please refer to the guidance on [Dossier requirements for Centrally Authorised Products \(CAPs\)](#).

Non-interventional PASS studies should not be submitted to the PSUR Repository. The PASS 107 submissions should be submitted to EMA using eSubmission Gateway / Web Client using the relevant submission type. PASS 107 submissions are available to the NCAs via the Common Repository. For more information on the PASS 107 submissions please see [EMA regulatory Post-Authorisation Guidance](#)

3. Secure log on

All users needing access to the repository will need to be registered with EMA and have received their log on details. There are two roles available to NCA users: Reviewer and Contributor.

The "Reviewer" role allows the user to search and retrieve documents from the repository. Users belonging to this role **cannot** upload documents to the repository.

In addition to capability of the reviewer role the "**Contributor**" role **allows the user to upload assessment reports and comments** to the repository.

The registration form is available in the PSUR Repository webpage:

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

The registration form should be submitted to the EMA service desk through the service portal:

<https://servicedesk.ema.europa.eu>

The NCA user interface with search and upload screens can be reached via the following link:

<https://psur-repo.eudra.org/psur-ui>

PSUR Repository

Username

Password

[Need help?](#)

4. Searching the PSUR Repository

Users must be logged on to access the search screen. The search screen can be reached via the link: <https://psur-repo.eudra.org/psur-ui>.

Note to users: Majority of the screenshots have **not** been updated to reflect changes introduced in the technical update from AngularJS to Angular in July 2023. There are no changes to the features and functionalities, the change is purely technical framework change.

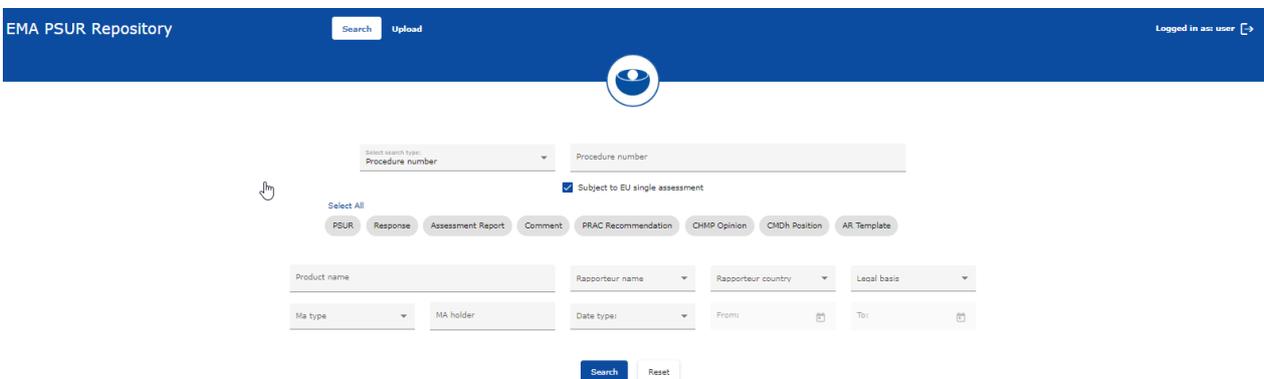
4.1. EU Single Assessment search Screens

The user interface is defaulted to open in the search screen. If you have used the upload window, select Search tab from the top of the screen.

The search can be conducted using a variety of search criteria. The full search criteria is displayed and it is easy to use the procedure number for a quick search on the top of the screen. The date range search can be performed using 2 different attributes and it's easy to toggle between 'Date received' and Data lock point' searches. If you wish to search for a date further away, it might be easier to click to the month/year name on the top of the date selection box to show the month selection and then drill down to the exact date by selecting the date or selecting 'today'.

Information on the [eCTD EU M1](#) can be found from the [eSubmission website](#).

Screen extract 1 - Default search criteria (updated to reflect the technical change in look and feel)



4.2. Non-EU single assessment

The non-EU single assessment functionality doesn't currently allow the MAHs to select more than a single member state for each submission. This is an issue with some procedures that are handled outside the EU Single Assessment Procedure, however, contain products authorised in multiple member states (MRP/DCP). As a workaround solution, the MAHs are asked to submit to the PSUR Repository using the non-EU single assessment functionality. When RMS receives the notification for these types of submissions it is requested that this notification is forwarded to the relevant CMSs until the non-EU functionality is further developed to cater for this particular scenario.

Screen extract 2 – Default search criteria (non-EU single assessment) (updated to reflect the technical change in look and feel)

The screenshot shows the EMA PSUR Repository search interface. At the top, there is a blue header with 'EMA PSUR Repository' on the left, 'Search' and 'Upload' buttons in the center, and 'Logged in as: user' on the right. Below the header is the EMA logo. The main search area has a 'Select search type' dropdown set to 'Active substance' and a text input field containing 'Active substance'. There is a checkbox for 'Subject to EU single assessment' which is currently unchecked. Below this, there are buttons for 'Select All', 'PSUR', 'Response', and 'Related Document'. The search filters include 'Member state' (dropdown), 'MA number' (text input), 'MA holder' (text input), 'Date type' (dropdown), 'From' (calendar icon), and 'To' (calendar icon). At the bottom of the search area are 'Search' and 'Reset' buttons.

Screen extract 3 – setting date range for searches (updated to reflect the technical change in look and feel)

The screenshot shows the EMA PSUR Repository search interface with the date range selection process. The 'Select search type' dropdown is set to 'Procedure number' and the text input field contains 'Procedure number'. The 'Subject to EU single assessment' checkbox is checked. Below this, there are buttons for 'Select All', 'PSUR', 'Response', 'Assessment Report', 'Comment', 'PRAC Recommendation', 'CHMP Opinion', 'CMDh Position', and 'AR Template'. The search filters include 'Product name' (text input), 'Rapporteur name' (dropdown), 'Rapporteur country' (dropdown), 'Legal basis' (dropdown), 'Ma type' (dropdown), and 'MA holder' (text input). The 'Date type' dropdown is set to 'Data received'. The 'From' field is set to '25/06/2023' and the 'To' field is empty. A calendar widget is open, showing the month of June 2023. The date '25' is selected. At the bottom of the calendar are 'Today', 'Clear', and 'Apply' buttons. Below the search area, there is a footer with the text: 'For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) | © European Medicines Agency | PSUR \$(rev)'. A mouse cursor is visible over the calendar.

Screen extract 4 – Example results grid for EU-single assessment search

Procedure number and active substance for which the search results are shown. Select different procedure by clicking to the procedure number to show results for that procedure/active substance. The list is shown in alphabetical order.

These fields will allow the user to filter the results, see example below

Clicking Headings allows for sorting of the columns

Tooltip will display the full contents of the cell when underlined text is clicked once. Close the tooltip by clicking the underlined text again.

The screenshot shows a search interface with a blue header bar containing a logo, 'Search', and 'Upload' buttons. Below the header, there is a search box with 'Procedure number' and 'PSUSA/00000015/201604'. A checkbox 'Subject to EU single assessment' is checked. Below this are several filter buttons: 'PSUR', 'Response', 'Assessment Report', 'Comment', 'PRAC Recommendation', 'CHMP Opinion', 'CMDh Position', and 'AR Template'. Further down are input fields for 'Product name', 'Rapporteur name', 'Rapporteur country', 'Legal basis', 'MA type', 'Date type', 'From', 'To', and 'MA holder'. A 'Search' button and a 'Reset' button are at the bottom of the filter section.

Results

Document Type	Submitter	Country	Date Received	Prod
PSUR	-	-	05/06/2018 12:...	Zytiga (Janssen-cilag international nv, EU/1/11/714/001)
PSUR	-	-	01/06/2017 14:...	Zytiga (Janssen-cilag international nv, EU/1/11/714/001)
PSUR	-	-	05/06/2018 11:...	Zytiga (Janssen-cilag international nv, EU/1/11/714/001)
PSUR	-	-	30/05/2017 10:...	Zytiga (Janssen-cilag international nv, EU/1/11/714/001)
Comment	user1	UK	08/06/2018 10:...	
Comment	user1	UK	08/06/2018 10:...	
Comment	user1	UK	08/06/2018 10:...	
Updated Assess...	user1	UK	12/06/2018 16:...	

Hyperlink to navigate to Document in DREAM

Timestamp showing the date and the time when the submission was received.

Column containing buttons to 'invalidate' a submission that is technically invalid lifecycle eCTD sequence and to 'revoke' this invalidation if the submission is found valid with further clarification with the MAH.

Clicking this icon provides the ability to select & download historic versions of the Assessment Report

4.2.1. Detailed instructions for searching the PSUSA procedures

Step	Description	Notes
1.	Log in to the repository using reviewer or contributor access and start typing the procedure number in the 'procedure number' field to launch a simple search. The more you type, the more the list is filtered. Select the procedure by clicking the correct procedure number from the list and proceed to add the document type (e.g. PSUR, Assessment Report) and any additional criteria if you wish to filter the results even further.	<ol style="list-style-type: none"> 1. Select "EU single assessment" if you have a PSUSA number. 2. Select non-EU to upload a document for a local assessment procedure.

<p>2.</p>	<p>It is possible to also run a quick search on the 'active substance' name. The more you type, the more the list is filtered. Select the active substance by clicking the name on the list and proceed to add the document type (e.g. PSUR, responses, Assessment Report) and any additional criteria if you wish to filter the results even further.</p> <p>Note: search results for attribute 'responses' will in show all supplementary submissions from the MAHs with the submission unit that was selected by the MAH in the delivery file i.e. search for 'responses' may will bring results showing validation response, additional information, closing, consolidation, corrigendum).</p> <p>Please note that as of v1.17.0.0 (June 2020) the allowed submission units for PSUR/PSUSA submissions are 'initial' and 'response' only. The closing sequences will not be available in the PSUR Repository, but only in the Common Repository.</p>	<p>Note: The search attribute for supplemental submissions has been changed from supplementary information to 'responses' in line with the updated eCTD EU Module 1 specification. All submissions submitted prior to this change are shown in search results as 'responses'. New submissions will be shown in the list of search results with the relevant submission unit as selected by the MAH on the delivery file. Submissions created using eCTD EU M1 specification v2.0 are also submitted using the new, updated delivery file.</p>
<p>3.</p>	<p>More detailed searches can be run with any combination of available search criteria, e.g. on product name, rapporteur name etc.</p> <p>Date searches can be run on 'date submitted' or 'data lock point' basis.</p>	<p>Remember to select the relevant document types to launch the search.</p> <p>To perform a new search with different search criteria press 'reset'. If you wish to change only some parameters you do not need clear the search, just change the relevant selections and click search.</p>

Procedure number

Subject to EU single assessment

Deselect All

Rapp Country

- Rapporteur country
- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Italy

- To perform a new search with new criteria press 'reset'. If you wish to change only some parameters you do not need clear the search, just change the relevant selections and click search.

4.3. Search results

The results section of the search screen is divided into two main sections:

- This section will list all the PSUSA procedures that match the search criteria. The list is shown in alphabetical order based on the active substance name(s). The user can select each item, using a single mouse click, in turn to view the list of documents in the repository. For non-EU single assessment, the system will show the MS and DLP that was used for the submission.
- The list of documents stored in the repository for the PSUSA selected in section 1. Changes to the names of document types submitted by the MAH have been introduced inline with the changes to the eCTD EU M1. All submissions that have been submitted prior to the change in the EU Module 1 are shown as 'responses'. All new submissions are shown with the relevant submission unit, for example responses. More information on the [eCTD EU M1](#) can be found from the [eSubmission website](#).

Screen extract 6 – search results

Results

1

2

	Document Type	Submitter	Country	Date Received	Products (MAH) -
PSUSA/0000009/201503 5-aminolevulinic acid (glioma)					
	Response	-	-	14/02/2017 12:...	Gliolan (Medac gmbh, EU/1/07/413/001), Gliolan
PSUSA/0000015/201604 abiraterone	PSUR	-	-	08/11/2016 16:...	Gliolan (Medac gmbh, EU/1/07/413/001), Gliolan
	PSUR	-	-	01/02/2017 09:...	Gliolan (Medac gmbh, EU/1/07/413/002), Gliolan
PSUSA/0000015/201410 abiraterone	Preliminary Assessment Report	user1	UK	12/06/2018 16:...	
	Template of Assessment Report	senguttu...	EU	14/03/2018 13:...	
	Comment	wallacem	N/A	01/12/2016 11:...	
PSUSA/0000089/201509 aliskiren, aliskiren / amlodipine, aliskiren / hydrochlorothiazide	Comment	user1	UK	31/01/2017 16:...	
	Comment	user1	UK	11/06/2018 09:...	
PSUSA/00000385/201601 besilesomab					
PSUSA/00010420/201602 dinutuximab					

Total Items: 8

4.3.1. Document Type Hyperlinks

The Document Types are displayed with a hyperlink to the physical location of the document. The user can mouse click the link whereby the user is prompted to enter their DREAM login credentials and access the document directly from DREAM. This allows for easier cross navigation to the documents

4.3.2. Search results – Deduplication

It is possible to deduplicate the view of PSURs submitted for a given procedure if the MAH has grouped together associated submissions. This allows the NCAs to view only 'unique' PSURs in the search results.

The deduplication functionality is designed to be used for those procedures for which there are multiple different products submitted in eCTD or mixed eCTD and NeeS formats where the MAH has prepared a single PSUR document but due to eCTD rules must submit the PSUR multiple times as a part of each products lifecycle. The NCAs can now select to view all submitted PSURs or only those that have been deduplicated i.e. same PSUR has been sent for multiple products.

As this functionality has to be manually selected by the MAH when submitting the PSURs it is not possible to perform an automated sanity check of the results. It might also mean that not all MAHs use the functionality for all submissions.

The search results are shown as submitted initially – i.e. no deduplication is shown in the initial search view – the new minus  and plus  buttons can be used to hide and show the full list of documents.

Screen extract 6 – example of deduplication

Full results

Results

Document Type...	Submitter	Countr...	Date Received	Products (MAH)
PSUR	-	-	10/09/2015	Peritriptyl (Orion oyj, 4473), Triptafen (Mercury pharmaceuticals ltd., PL 1.
Updated Assess...	wallacem	EU	11/09/2015	
Comment	wallacem	EU	11/09/2015	
PSUR	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 19609/22-
PSUR	-	-	11/09/2015	Peritriptyl (Orion oyj, 4472)
PSUR	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 39523/21-9-2009),
Supplemental Infor...	-	-	10/09/2015	Mutabon mite (Neopharmed gentili s.r.l., 021460074), Peritriptyl (Orion oy
Supplemental Infor...	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 39523/21-9-2009),
Supplemental Infor...	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 19609/22-11-2011)
PSUR	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 39521/21-
PSUR	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 19609/22-11-2011)
PSUR	-	-	11/09/2015	Mutabon mite (Neopharmed gentili s.r.l., 021460074), Peritriptyl (Orion oyj, 4472)
Supplemental Infor...	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 19609/22-11-2011)

Total Items: 13

Deduplicated results

Results

Document Type...	Submitter	Countr...	Date Received	Products (MAH)
PSUR	-	-	10/09/2015	Peritriptyl (Orion oyj, 4473), Triptafen (Mercury pharmaceuticals ltd., PL 1.
Updated Assess...	wallacem	EU	11/09/2015	
Comment	wallacem	EU	11/09/2015	
PSUR	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 19609/22-
Supplemental Infor...	-	-	10/09/2015	Mutabon mite (Neopharmed gentili s.r.l., 021460074), Peritriptyl (Orion oy
PSUR	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colcotronis bros sa, 39521/21-

4.4. Additional functions of the search grid

The search results allow users to filter and sort by any of the columns displayed.

The submission level details of the product are now displayed in the improved tooltip window. When you click the product name in the column 'Products (MAH)' a tooltip window will open. This window remains open until you re-click (anywhere in the same window). The tooltip window also allows copying.

MA type Date type From: To: MA holder

Search Reset

Results

Document Type	Submitter	Country	Date Received	Product
PSUR	-	-	22/04/2016 16:...	Apleek (Bayer ab, 51611), Apleek (Bayer ab, IS/1/14/023/01), Apleek (Bayer austria gmbh, 1-35535), Apleek (Bayer bv, RVG 112679), Apleek (Bayer d.o.o, 5363-1-640/14), Apleek (Bayer healthcare, 34009 278 845 2 8), Apleek (Bayer healthcare, 34009 278 846 9 6), Apleek (Bayer healthcare, 34009 586 743 6 5), Apleek (Bayer hellas sa, 22062), Apleek (Bayer hellas sa,

Tooltip: Apleek (Bayer ab, 51611), Apleek (Bayer ab, IS/1/14/023/01), Apleek (Bayer austria gmbh, 1-35535), Apleek (Bayer bv, RVG 112679), Apleek (Bayer d.o.o, 5363-1-640/14), Apleek (Bayer healthcare, 34009 278 845 2 8), Apleek (Bayer healthcare, 34009 278 846 9 6), Apleek (Bayer healthcare, 34009 586 743 6 5), Apleek (Bayer hellas sa, 22062), Apleek (Bayer hellas sa,

4.4.1. Sort

To sort by a column simply click the name of the column e.g. Date Received, shown in the screenshot above and choose the sort order.

4.4.2. Filter results

The results can be filtered by any column displayed in the grid.

Basic filtering can be performed by simply typing in the text you want filter by. The system will immediately begin to filter results for records that match letters you are typing. For example, the screenshot below shows the results filtered by the records that begin with "fos". The filtering function is not case sensitive.

Screen extract 7 – example of basic filtering

Results

Document Type	Submitter	Country	Date Received	Products (MAH)
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="fos"/>
<input checked="" type="checkbox"/>	PSUR	-	21/04/2016 17:...	Fosavance (Merck sharp & dohme ltd., EU/1/05/3...
<input type="checkbox"/>	PSUSA/0000079/201601			alendronic acid / colecalciferol, alendronic acid / calcium / colecalciferol
<input type="checkbox"/>	PSUSA/0000226/201505			apixaban
<input type="checkbox"/>	PSUSA/0000226/201411			apixaban
<input type="checkbox"/>	PSUSA/00002948/201512			ticagrelor

The system allows the use of the asterisk (*) to facilitate partial matches of text. The text you want to search for must be enclosed with asterisks on either side, e.g. *takeda*

Screen extract 8 – example of wildcard filtering

Results

Document Type	Submitter...	Countr...	Date Received	Products (MAH)
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="*takeda*"/>
<input checked="" type="checkbox"/>	PSUR	-	10/04/2015	Amitriptyline nycomed (Takeda pharma as, 232898), Amitriptyline nycomed (Take...
<input checked="" type="checkbox"/>	PSUR	-	10/04/2015	Amitriptyline nycomed (Takeda pharma as, 232898), Amitriptyline nycomed (Take...
<input type="checkbox"/>	PSUSA/00000168/201501			amitriptyline
<input type="checkbox"/>	PSUSA/00009204/201501			

4.5. Downloading documents

The user can choose to download one or more documents by clicking the checkbox beside the row which is displaying the document type.

Results

Document Type	Submitter	Country	Date Received	Products (MAH)
<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input checked="" type="checkbox"/>	Template of Asse...	psur_admin	N/A	11/04/2016 15:...
<input checked="" type="checkbox"/>	PSUR	-	11/03/2016 13:...	Aas (Sanofi-aventis sa, 42.991)
<input checked="" type="checkbox"/>	Updated Assessm...	user1	UK	04/05/2016 09:...

Total Items: 3 (Selected Items: 1)

Download Upload

To download all documents shown simply click the topmost checkbox shown by the column heading "Document Type".

Results



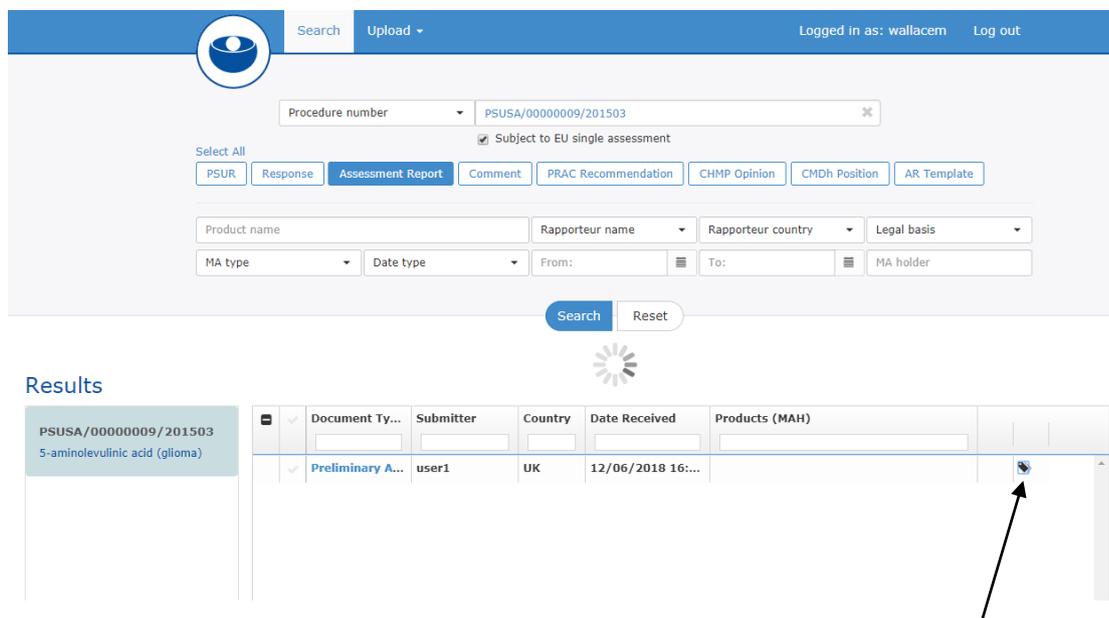
<input checked="" type="checkbox"/>	Document Type	Submitter	Country	Date Received	Products (MAH)
<input checked="" type="checkbox"/>	Template of Asse...	psur_admin	N/A	11/04/2016 15:...	
<input checked="" type="checkbox"/>	PSUR	-	-	11/03/2016 13:...	Aas (Sanofi-aventis sa, 42.991)
<input checked="" type="checkbox"/>	Updated Assessm...	user1	UK	04/05/2016 09:...	

If more than one document is selected for download the system will create a "Zip" file before the download begins. If a single document is selected then the system will simply download the original document that was submitted.

When submissions from MAHs are downloaded it is good to note that MAHs are able to submit, for Nationally Authorised products, a single 'Nees' sequence covering multiple different products for which a single PSUR document has been prepared. This single sequence may be downloaded and inserted in each relevant products lifecycle once renamed as per the relevant sequence number for the respective member state. The sequence number is available in the line listing provided in the notification email.

4.6. Viewing Historic Assessment Reports documents

Users can view all historic versions of Assessment Reports both Preliminary & Updated; along with seeing the submitter and date received for each version of the report. Users can choose to view and download from any of the historic versions.



Search Upload Logged in as: wallacem Log out

Procedure number PSUSA/00000009/201503

Select All Subject to EU single assessment

PSUR Response Assessment Report Comment PRAC Recommendation CHMP Opinion CMDh Position AR Template

Product name Rapporteur name Rapporteur country Legal basis

MA type Date type From: To: MA holder

Search Reset

Results

<input checked="" type="checkbox"/>	Document Ty...	Submitter	Country	Date Received	Products (MAH)	
<input checked="" type="checkbox"/>	Preliminary A...	user1	UK	12/06/2018 16:...		

Download versions

Assessment reports for procedure : PSUSA/00000009/201503

Document Type	Submitter	Date Received
✓ Preliminary Assessment Report	user1	12/06/2018 16:35:51
✓ Updated Assessment Report	user1	08/06/2018 12:43:03
✓ Preliminary Assessment Report	user1	08/06/2018 12:38:17
✓ Preliminary Assessment Report	user1	08/06/2018 10:14:50
✓ Updated Assessment Report	user1	07/06/2018 10:39:10
✓ Preliminary Assessment Report	user1	02/02/2018 12:55:03
✓ Preliminary Assessment Report	user1	02/02/2018 12:48:34
✓ Preliminary Assessment Report	user1	02/02/2018 12:21:47
✓ Updated Assessment Report	user1	31/01/2017 16:02:48
✓ Preliminary Assessment Report	user1	31/01/2017 15:37:19
✓ Preliminary Assessment Report	wallacem	01/12/2016 11:46:23

Download Close

Users can then navigate and select and download which specific historic version they wish to view or download.

Clicking this icon opens an additional window to view historic versions of the Assessment Report

5. Uploading documents to the PSUR Repository (contributor access only)

The upload process can be used to upload documents either for an EU single assessment procedure or a non-EU single assessment procedure (a local national assessment).

Uploads can now be made for all procedures for which a PSUR or supplemental submissions are available in the PSUR repository. It is possible to upload an assessment report and/or comments for procedures for which only the supplemental submissions (responses) have been received.

The maximum size of a document to be uploaded to repository by an NCA user is **50 MB**.

Assessment Reports and comments must be provided in **word** format only, this is to enable easier reviewing and processing of these documents. The Assessment Reports and comments must not be uploaded in PDF format.

There are two ways of accessing the 'Upload' functionality:

- Via dedicated 'Upload' screen
- Via 'Upload' button in the search screen

When Assessment Reports are uploaded to the system by the Rapporteur/Lead Member State or by the relevant member state for non-EU single assessment, they are **not** automatically sent to the Marketing Authorisation Holder. For PSUSA procedures, the AR is sent to the MAH by the EMA. For non-EU single assessment PSUR procedures, the responsibility to send the Assessment Report to the MAH remains with the relevant member state.

If an assessment report or a comment has been uploaded in an incorrect PSUSA procedure or an incorrect assessment report or comment has been uploaded for EU PSUSA procedure, it is now possible to delete these comments from the system using the EMA Super Admin functionality. Please submit a request for deletion of a comment via the [EMA Service Portal](#).

When the procedure is closed, i.e. the PRAC outcome has been uploaded in the PSUR Repository, it is no longer possible to upload assessment report templates, preliminary or updated assessment reports or comments for the procedure in question. This has been implemented to prevent any unintentional upload of documents to already closed procedures.

5.1. Uploading documents for EU single assessment procedure

Screen extract 9 – upload directly from the search screen

Subject to EU single assessment

Deselect All

PSUR Assessment Report Comment Supplemental Information PRAC Recommendation CHMP Opinion CMDh Position

AR Template

Product name Rapporteur name Rapporteur country Legal basis

MRP Date type From: To: MA holder

Search Reset

Results

Document Type	Submitter	Co...	Date Received	Products (MAH)
PSUR	-	-	06/04/2016 20:07:03	Apo-go (Britannia pharmaceuticals ltd., 1-27540), Apo...
PSUR	-	-	06/04/2016 20:05:03	Apo go pen (Britannia pharmaceuticals limited, 20536), ...
Template of Asse...	psur_admin	N/A	28/04/2016 11:42:25	

Total Items: 3

Download Upload

Screen extract 10 – Upload via dedicated upload screen

Search Upload Logged in as: coolidgeb Log out

① EU single assessment
② Non-EU single assessment

Active substance Active substance

Subject to EU single assessment

Select all

PSUR Assessment Report Comment Supplemental Information PRAC Recommendation CHMP Opinion CMDh Position

More Search Reset

EMA Logo Search Upload Logged in as: wallacem Log out

Upload document for EU single assessment

Procedure number*

Active substance: [latanoprost \(products with paediatric indication\)](#)
 Rapporteur name: [Julie Williams](#)
 Rapporteur country: [United Kingdom](#)

Screen extract 11 - Upload details and document type

EMA Logo Search Upload Logged in as: U

Upload document for EU single assessment

Procedure number*

Active substance: [acetylsalicylic acid](#)
 Rapporteur name: [Julia Pallos](#)
 Rapporteur country: [Hungary](#)

Document type*

Is a regulatory action suggested?*

Document type

- Document type
- Preliminary Assessment Report
- Updated Assessment Report
- Comment

Select regulatory action

- Silent adoption
- Plenary discussion

Screen extract 12 - Browse for file to upload

File Explorer window showing file selection:

Name: comments for PSUSA0034201509

File name: All Files

Open Cancel

File input*

Screen extract 13 - Document to be uploaded (updated to reflect the technical change in look and feel)

EMA PSUR Repository Search Upload Logged in as: user

Upload document for EU single assessment

Procedure number: PSUSA/00002023/201903

Active Substance: methylaltraxone bromide

Rapporteur name: Martin Huber

Rapporteur country: Germany

Document Type: Comments

Is a regulatory action suggested?*

Yes No

Select regulator... Silent adoption Plenary discussion

Additional comments

We have an important comment on this procedure.

153/500 characters remaining.

Name	Size	Status	Actions
Comment on PSUSA1234562023.docx	0.253 MB		

Upload

5.2. Detailed instructions for uploading documents for EU single assessment procedure

5.2.1. Detailed instructions for uploading documents for EU single assessment using the search screen function

Step	Description	Notes
1.	Perform a search following instructions in section 3. and once you have found the required procedure proceed to upload. There is no need to select the documents (by ticking one or more PSURs on the list – it does not matter if all or just one of the received PSURs have been selected – the upload will be for the procedure level). Click the 'Upload' button next to 'Download' button to access the upload screen.	<ol style="list-style-type: none">1. Select "EU single assessment" if you have a PSUSA number.2. Select non-EU to upload a document for a local assessment procedure.

Procedure number

Subject to EU single assessment

Deselect All

Product name
Rapporteur name
Rapporteur country
Legal basis

MA type
Date type
From:
To:
MA holder

Results

Document Type	Submitter	Country	Date Received	Products (MAH)
PSUR	-	-	06/04/2016 20:...	Apo-go (Britannia pharmaceuticals ltd., 1-27540),...
PSUR	-	-	06/04/2016 20:...	Apo go pen (Britannia pharmaceuticals limited, 20...
Template of Asse...	psur_admin	N/A	28/04/2016 11:...	

Total Items: 3

- The procedure number, active substance, Rapporteur and country are prepopulated as per the selection in the search screen
- Check the details displayed are correct

Upload document for EU single assessment

Procedure number*

Active substance: apomorphine

Rapporteur name: Doris Stenver

Rapporteur country: Denmark

Document type*

Is a regulatory action suggested?* Yes No

Select regulatory action

Silent adoption

Plenary discussion

Additional comments

500 characters remaining.

File input*

ze	Progress	Status	Action
----	----------	--------	--------

3.	<p>Select the document type</p> <p>It is not possible to upload UAR or comments if the PAR has not uploaded.</p>	<p>Assessment Reports should only be uploaded by the Rapporteur/Lead Member state.</p>
----	--	---

The screenshot shows a form with a 'Document type' dropdown menu. The dropdown is open, displaying the following options: 'Document type', 'Preliminary Assessment Report', 'Updated Assessment Report', and 'Comment'. The 'Document type' label is highlighted in blue with an asterisk. Below it, the text 'Is a regulatory action suggested?' is also highlighted in blue with an asterisk.

4.	<p>If Preliminary Assessment Report is selected, it is possible to indicate if a 'regulatory action' is suggested. The possible regulatory actions to be selected from the dropdown menu are;</p> <ul style="list-style-type: none"> • Variation • Revocation and • Suspension <p>It is possible to add 'additional comments'. The comments are visible in the notification only.</p>	<p>Information on the regulatory action is considered a 'workflow facilitator'. These workflow facilitators are communicated to the network via system notifications only. It is not possible to view the suggested regulatory actions or additional comments in the repository user interface.</p>
----	---	--

5.	<p>Indicate if Regulatory action is suggested by ticking the relevant 'yes or no' button and select the required regulatory action.</p>	<p>Regulatory actions available depend on the document selected.</p>
----	---	--

The screenshot shows a form with the following elements: 'Document type' dropdown set to 'Preliminary Assessment Report'; 'Is a regulatory action suggested?' with 'Yes' checked and 'No' unchecked; and a 'Select regulatory action' dropdown menu open, showing options: 'Select regulatory action', 'Variation', 'Revocation', and 'Suspension'. There is also an 'Additional comments' text area.

6.	<p>If no regulatory action is suggested, it is possible to indicate if a silent adoption or plenary discussion is foreseen.</p> <p>It is possible to add 'additional comments'. The comments are visible in the notification only.</p>	
----	--	--

Document type* Preliminary Assessment Report

Is a regulatory action suggested?* Yes No

Select regulatory action

Silent adoption

Plenary discussion

Additional comments

7. If **Updated Assessment Report** is selected, it is possible to indicate if a 'regulatory action' is suggested. The possible regulatory actions to be selected from the dropdown menu are;

- Variation
- Revocation and
- Suspension

All the regulatory actions may be suggested for 'plenary discussion' only. It is not possible to suggest 'silent adoption' with a regulatory action. It is possible to add 'additional comments'. The comments are visible in the notification only.

Document type* Updated Assessment Report

Is a regulatory action suggested?* Yes No

Variation

Silent adoption

Plenary discussion

8. If **Comment** is selected, it is not possible to suggest regulatory action, however it is possible to add 'additional comments'.

It is not possible to indicate 'agreement with rapporteur' using the workflow facilitators.

All legally binding information should be provided in the comments document which must be uploaded to the system.

9. You can enter additional comments if necessary.

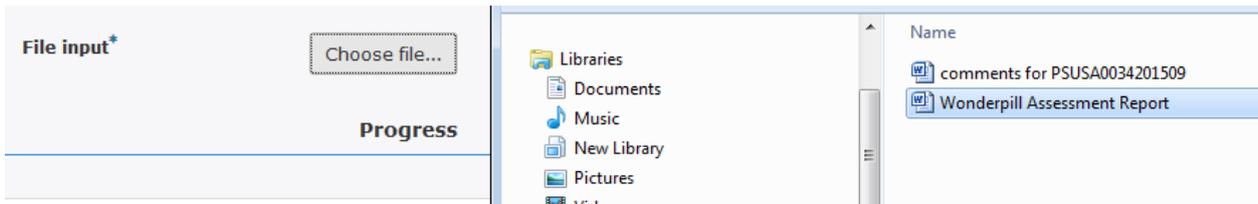
The field should be used to include additional information that is today included in the email message, for example; deadline for comments, extended deadline for comments due a delay etc.

It should **not** be used for legally binding information that must be included in the comments document or the PAR/UAR.

Note: The additional comments are provided in the notification but are not visible in the user interface and **cannot** be sent without an attached document.

Document must be uploaded, it is not possible to just add comments.

10. Browse to select the document and check that the correct file has been selected.



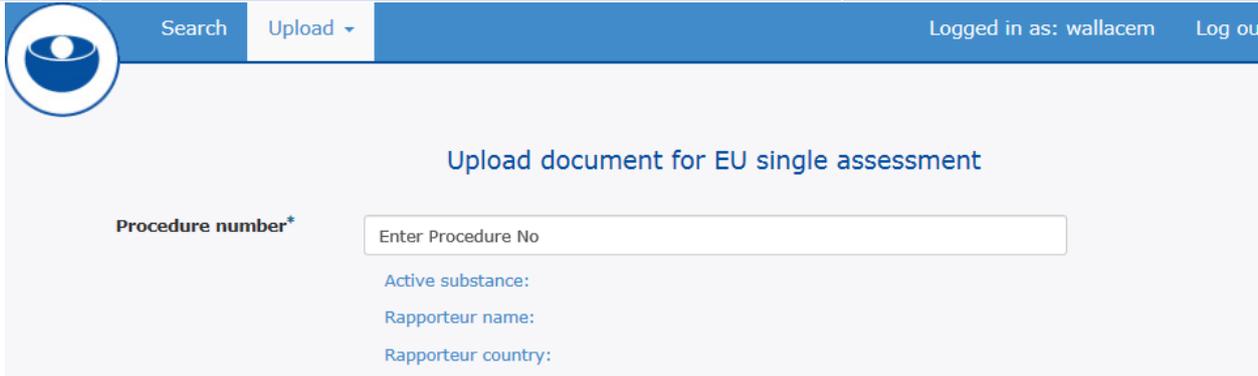
11.	Click the "upload" button to make the document available in the repository. (Error! Reference source not found.).	To choose another file, before the upload is done, click the "Remove" and then "Choose file" button.
-----	--	--



12.	The system will display a message to indicate the success or failure of the upload.	In cases of failure, please check the details and try again or contact EMA.
-----	---	---

5.2.2. Detailed instructions for uploading documents for EU single assessment using the dedicated upload screen function

Step	Description	Notes
1.	Select 'Upload' from the top of the screen to navigate to the Upload page. Enter the procedure number in the 'Procedure number' field and selected the relevant procedure from the list.	Any four digits of the number can be used to search for the full procedure number.



2.	Active substance, Rapporteur name and country are displayed for visual confirmation. Check the details displayed are correct and continue from step 3 of section 4.2.1.	
----	---	--

Search
Upload ▾

Logged in as: user1

Upload document for EU single assessment

Procedure number*

Active substance: besilesomab
 Rapporteur name: Julie Williams
 Rapporteur country: United Kingdom

Document type*

Is a regulatory action suggested?* Yes No

Select regulatory action ▾

Silent adoption

Plenary discussion

Additional comments

500 characters remaining.

File input*

Size
Progress
Status

5.3. Uploading documents for non-EU assessment procedure (local assessment procedure)

When Assessment Reports are uploaded to the system by the relevant member state for non-EU single assessment, they are not automatically sent to the Marketing Authorisation Holder. For non-EU single assessment PSUR procedures, the responsibility to send the Assessment Report to the MAH remains with the relevant member state.

5.3.1. Detailed instructions for uploading documents for non-EU assessment procedure (local assessment procedure) from search screen

1.

For **Non-EU Single assesement** select the member state and the DLP from the dropdown menu and click 'find submissions'. Proceed to upload the Assessment Report. Multiple Assessment Reports may be uploaded. There is no option to provide comments or workflow facilitators.

EMA Logo Search Upload Logged in as: wallacem Log out

Active substance Active substance

Subject to EU single assessment

Deselect All PSUR Related Document Supplemental Information

Member state MA number MA Holder Date received 01/01/2015 05/08/2015

Less Search Reset

Results

Document Typ...	File Name	Submitter...	Date Received...	Products (MAH)	Substances
<input checked="" type="checkbox"/>	PSUR delivery.zip	zzgwfh	12/05/2015	Tetanus immunoglobuline and te...	Human tetanus immunoglobulin,Teta...

Total Items: 1 (Selected Items: 1)

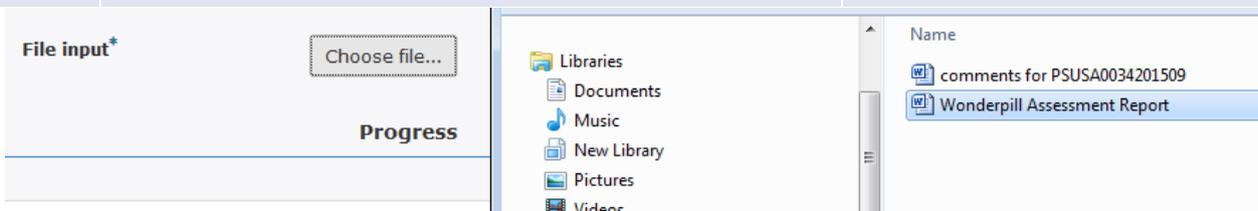
Upload Download

Upload document for non-EU single assessment

Member State * Netherlands Data lock point * 01/01/2015 Find submissions

MAH Name	Product Name	National M.A. No...	Sequence No...	Substances
BILTHOVEN BIOLOGICALS B.V.	TETANUS IMMUNOGLOBULIN...	RVG 18561	0016	TETANUS TOXOID ADSORBED, HUMAN...

- Browse to select the document and check that the correct file has been selected.



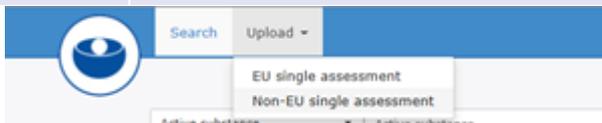
- Click the "upload" button to make the document available in the repository. To choose another file, before the upload is done, click the "Remove" and then "Choose file" button.

File input* L:\PAR-wonderdrug-PSUSA-1111-201507.doc

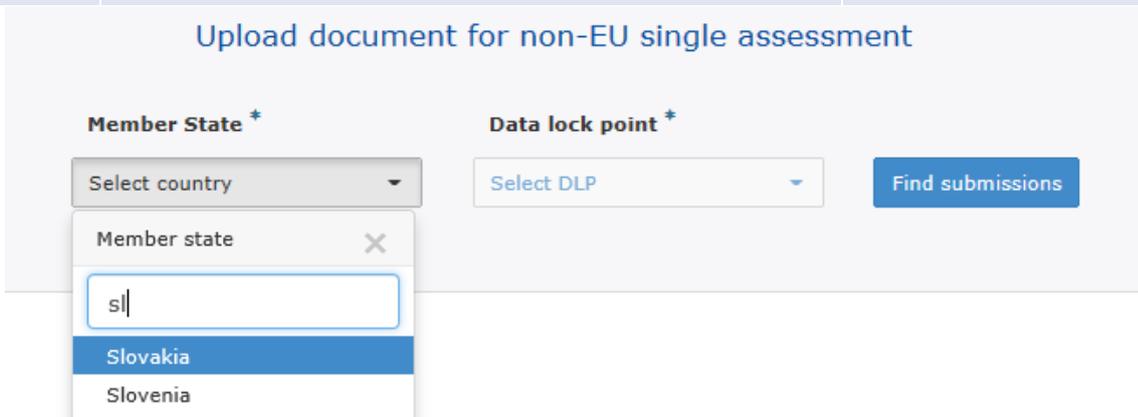
Status	Action
	<input type="button" value="Upload"/> <input type="button" value="Cancel"/> <input type="button" value="Remove"/>
4. The system will display a message to indicate the success or failure of the upload.	<p>In cases of failure, please check the details and try again or contact EMA.</p> <p>There are no notifications to the NCAs when ARs are uploaded to the system.</p> <p>The NCA should provide the Assessment Report to the MAH via usual mechanism.</p>

5.3.2. Detailed instructions for uploading documents for non-EU assessment procedure (local assessment procedure) using the dedicated Upload screen function

Step	Description	Notes
1.	Select 'Upload' from the top of the screen to navigate to the Upload page and select 'Non-EU single assessment'.	



2.	Select the Member State from the list by typing the name or clicking on the dropdown list.	
----	--	--



3.	Select the correct Data lock point for the procedure for which you wish to upload the assessment report and click 'Find submissions'.	
----	---	--

Upload document for non-EU single assessment

Member State * **Data lock point ***

Spain Select DLP **Find submissions**

Data Lock Point ✕

Select DLP

- 31/12/2014
- 01/02/2015
- 01/03/2015
- 01/04/2015

4. The Member State, Data lock point and product details are pre-populated. Check the details displayed are correct.

Upload document for non-EU single assessment

Member State * **Data lock point ***

Spain 01/04/2015 **Find submissions**

MAH Name	Product Name	National M.A. No...	Sequence No...	Substances
LABORATORIOS NORMON, S.A.	NORMOREUM	61146	0000	HARPAGOPHYTUM PROCUMBENS

5. Proceed as from step 10. From section 4.2.1 to browse and upload the assessment report.

There are no notifications to the NCAs when ARs are uploaded to the system.

The NCA should provide the Assessment Report to the MAH via usual mechanism.

6. Marking MRP/DCP/National product eCTD submission invalid / revoking of the invalidation

A full eCTD technical validation is run upon receipt of PSUR and supplemental submissions (responses) to the PSUR Repository for Centrally Authorised Products. The EMA does not have the full product lifecycle for products authorised under Mutual Recognition, Decentralised and the National processes and hence is unable to run a full technical lifecycle validation for these eCTD submissions. Functionality has been introduced allowing the NCAs to indicate submissions 'invalid' in the system. It is possible for multiple NCAs indicate the same submission invalid.

Technical validation report from eCTD validation tool must be uploaded to the system when the invalidation is performed. This technical validation report will be sent, via an automated email, to the email address of the MAH contact point.

It may happen that after closer investigation and discussion between the relevant NCA and the MAH it is deemed that the PSUR submission is in fact valid and the invalidation issue was caused by an issue in a previous submission, the NCA can 'revoke' the invalidation. Once this revocation is performed an

automated message is sent to the relevant MAH. If one of the NCAs revokes the invalidation, all the invalidations made by other NCAs are also revoked.

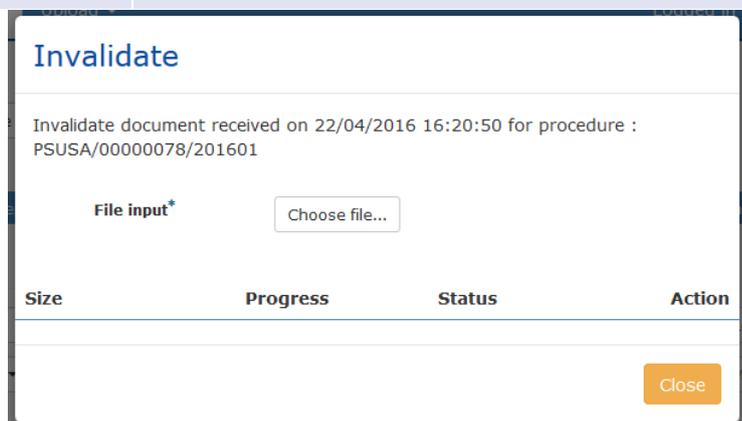
6.1. Detailed instructions how to invalidate eCTD submission in PSUR repository

Step	Description	Notes
1.	Search for the procedure / submission as described in section 3. of this document. The submissions that can be invalidated by your NCA are indicated with an X in the right hand column of the search results.	Only the NCA who has the product in the market in their member state can invalidate the submission.

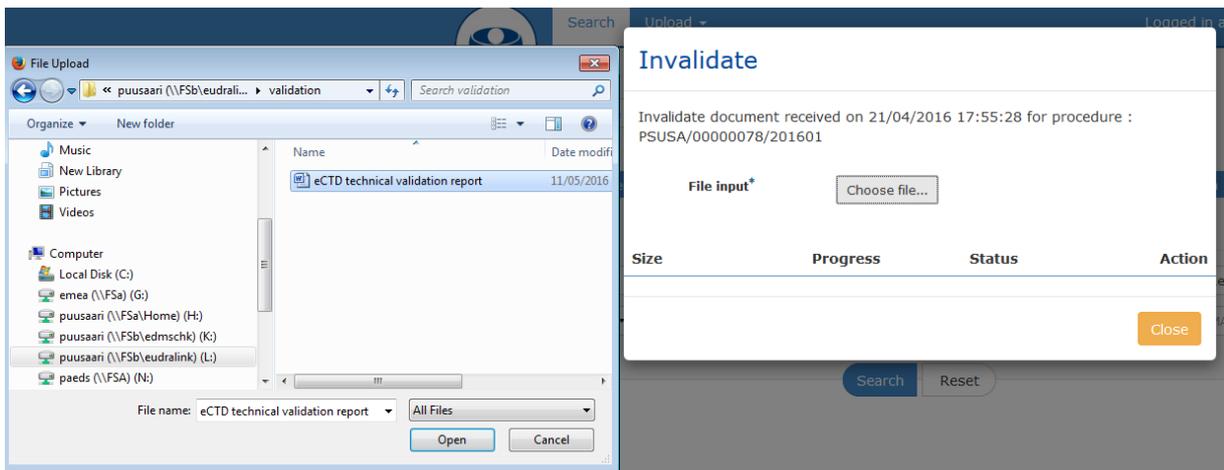
Results

Document Type	Submitter	Country	Date Received	Products (MAH)	
PSUR	-	-	22/04/2016 16:...	Fosamax (Msd belgium bvba/spri, BE 174307)	X
PSUR	-	-	21/04/2016 17:...	Fosamax (Msd belgium bvba/spri, BE 174307)	X

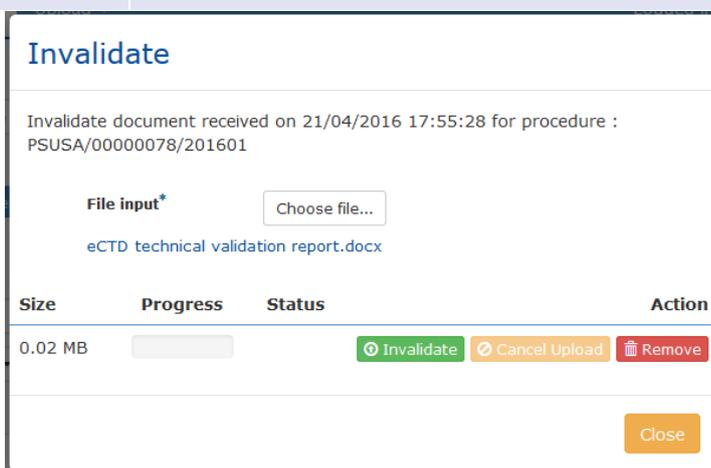
2.	Click the X in the last column to perform the invalidation.	Ensure you have the technical eCTD validation report from your eCTD validation tool in hand before performing this action.
3.	A pop up window will open that gives the date when the submission was received and the procedure number for visual confirmation.	The eCTD technical validation report is required to assist the MAH to rebuild the eCTD sequence.



4.	Click 'choose file' button to upload the technical eCTD validation report from your validation tool.	
----	--	--



5. Check that you have uploaded the correct document i.e. the technical validation report and click 'invalidate' button



6. The submission is now shown highlighted in pink and the row contains the symbol that enables revocation of the invalidation.

Results

Document ID	Document Type	Submitter	Country	Date Received	Products (MAH)	
PSUSA/00000078/201601 alendronate						
	PSUR	-	-	21/04/2016 17:...	Fosamax (Msd belgium bvba/sprl, BE 174307)	✕ ↺
	PSUR	-	-	22/04/2016 16:...	Fosamax (Msd belgium bvba/sprl, BE 174307)	✕

7. An automated message containing the eCTD validation report is sent to the MAH to the email address they provided in the delivery file when making the submission to the PSUR Repository. The NCAs do not receive copy of this invalidation email.

Subject: INVALID: PSUR, alendronate, *BE*, PSUSA/00000078/201601, 15/01/2016

Message  eCTD technical validation report.docx (22 KB)

Submission of;

PSUSA number: PSUSA/00000078/201601
 Data Lock Point: 15/01/16
 Submission deadline for the procedure was: 14/04/2016
 Active substance: alendronate
 PRAC Rapporteur/Lead MS: Julie Williams
 Country: Belgium
 Product name(s): FOSAMAX
 eCTD sequence number: 0024

has been identified as invalid due to lifecycle validity issues by Belgium. Please find the eCTD validation report attached.

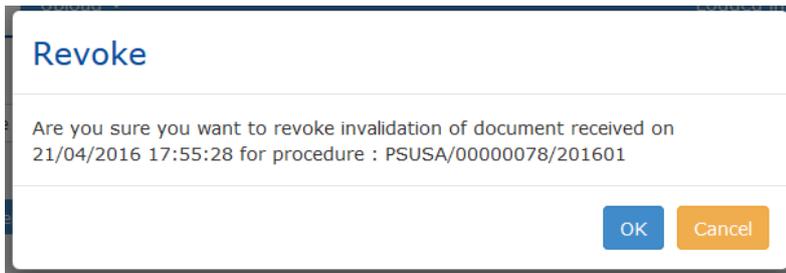
After solving the technical eCTD validation issue, please resubmit the package, using the same eCTD sequence number, to the [PSUR Repository](#) using new xml delivery file as soon as possible, but within 14 working days after receiving this message.

More information on the validation issue can be obtained from Belgium NCA contact via user1@xeudra.be

8.	The MAH may contact the NCA who invalidated the submission to obtain further information. The email address of the person who performed the invalidation is available in the notification email to the MAH.	The NCAs do not receive copy of this invalidation email.
9.	The MAH should proceed to resubmit the PSUR/Supplemental submission (e.g. responses) to the PSUR repository using the same sequence number.	

6.2. Detailed instructions how to revoke the invalidation eCTD submission in PSUR repository

Step	Description	Notes																								
	Search for the procedure / submission as described in section 3. of this document. The submissions for which the invalidation can be revoked are highlighted in pink and are indicated with a symbol  in the right hand column of the search results.	Only the NCA who has the product in the market in their member state can revoke the invalidation of a submission.																								
	<table border="1"> <thead> <tr> <th></th> <th><input checked="" type="checkbox"/></th> <th>Document Type</th> <th>Submitter</th> <th>Country</th> <th>Date Received</th> <th>Products (MAH)</th> <th></th> </tr> </thead> <tbody> <tr> <td><input type="text"/></td> <td></td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> <td>PSUR</td> <td>-</td> <td>-</td> <td>21/04/2016 17:...</td> <td>Fosamax (Msd belgium bvba/sprl, BE 174307)</td> <td> </td> </tr> </tbody> </table>		<input checked="" type="checkbox"/>	Document Type	Submitter	Country	Date Received	Products (MAH)		<input type="text"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	PSUR	-	-	21/04/2016 17:...	Fosamax (Msd belgium bvba/sprl, BE 174307)	 							
	<input checked="" type="checkbox"/>	Document Type	Submitter	Country	Date Received	Products (MAH)																				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>																				
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	PSUR	-	-	21/04/2016 17:...	Fosamax (Msd belgium bvba/sprl, BE 174307)	 																			
	<p>Click the  in the last column to perform the revoking of the invalidation.</p> <p>A pop up window will open that gives the date when the submission was received and the procedure number for visual confirmation.</p>	When any of the NCAs who have invalidated the submission performs the revoking, the submission will no longer be shown as invalidated. If a further issue is discovered or pertains for other NCAs they will need to perform a new invalidation.																								



	The submission is no longer shown as invalidated in the repository.	
	An automated message informing of the revoking of the invalidation is sent to the MAH to the email address they provided in the delivery file when making the submission to the PSUR Repository.	The NCAs do not receive copy of this email.

Subject: INVALIDATION REVOKED: PSUR, alendronate, *BE*, PSUSA/00000078/201601, 15/01/2016

Submission of;

PSUSA number: PSUSA/00000078/201601
 Data Lock Point: 15/01/16
 Submission deadline for the procedure was: 14/04/2016
 Active substance: alendronate
 PRAC Rapporteur/Lead MS: Julie Williams
 Country: Belgium
 Product name(s): FOSAMAX
 eCTD sequence number: 0024

has been confirmed technically valid following further investigation by Belgium and the MSD BELGIUM BVBA/SPRL.
 Resubmission is not required.

7. Notifications

The PSUR Repository sends out different types of notifications to relevant recipients at well-defined times during the procedure. It is not possible to set up notifications specific to each member state/NCA however it is possible to set up rules for automated filtering and auto-forwarding of notifications that concern procedures that your agency is interested to see.

Most notifications concerning CAPs are now copied to the relevant Product Shared Mailbox, provided that the products are correctly linked to the PSUSA procedure in question. **Please note:** Due to the nature of this feature, it has not been possible to test all notifications/changes to notifications fully as a part of the User Acceptance Testing. Any potential issues related to new notifications/changes in notifications which will be discovered following the release go-live, will be addressed in the next release.

It should be noted that there are **no** notifications to the NCAs when Assessment Reports are uploaded for non-EU single assessment PSUR procedures as the notification would be sent to the same NCA who uploaded the Assessment Report and it was noted by NCAs during the requirements gathering that this notification is not necessary.

7.1. Detailed summary of all notifications from the system

7.1.1. PSUR start of procedure notification

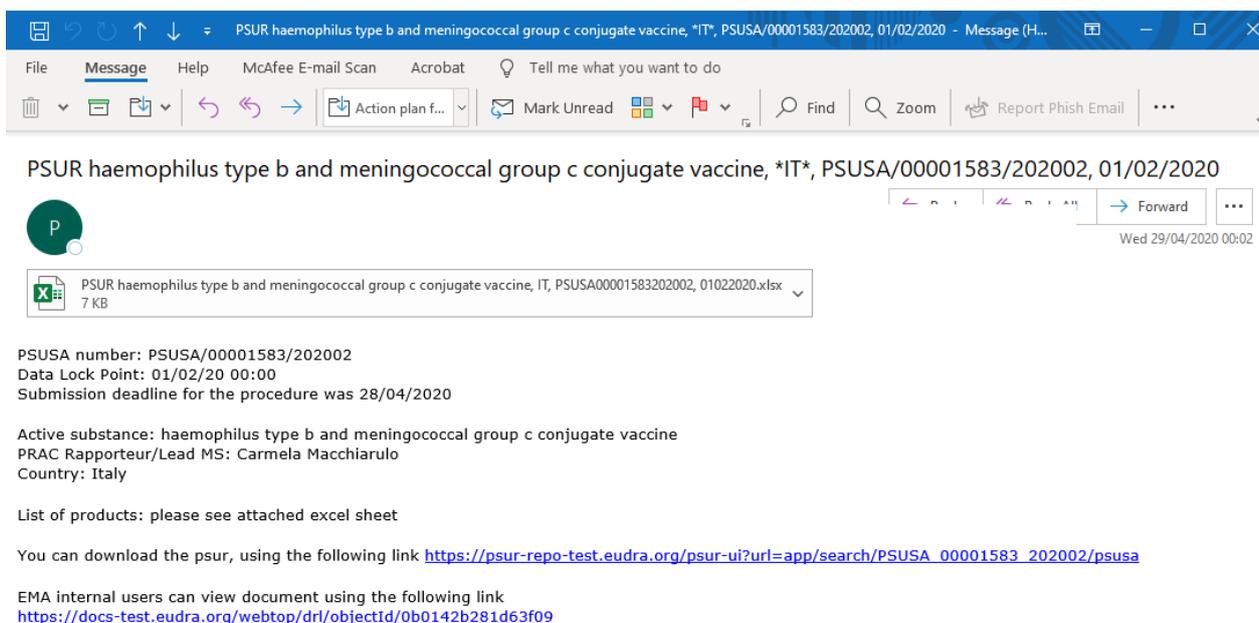
To reduce the number of notifications from the system, there are no individual notifications to each NCA every time a PSUR is submitted to the PSUR Repository. **A single notification** is sent, at midnight immediately after the submission deadline, to all NCAs and the EMA.

The notification contains a list of products that have been submitted for that particular procedure. The excel table listing of submitted products also contains the product ATC code. For CAPs only, the listing also shows whether the submission contains Risk Management Plan (RMP) with relevant RMP number.

The attachment has been renamed (previously 'products') to reflect the name of the procedure.

The notification contains a link to the PSUR repository which opens the procedure in question. An additional link to the EMA document management system, DREAM is also now included. This link will only work for EMA users.

The name of the Rapporteur country / Lead member state is stated in between star symbols * in the subject line to allow filtering and setting up autoforwarding rules in NCAs.



PSUR haemophilus type b and meningococcal group c conjugate vaccine, *IT*, PSUSA/00001583/202002, 01/02/2020

PSUR haemophilus type b and meningococcal group c conjugate vaccine, IT, PSUSA00001583202002, 01022020.xlsx
7 KB

PSUSA number: PSUSA/00001583/202002
Data Lock Point: 01/02/20 00:00
Submission deadline for the procedure was 28/04/2020

Active substance: haemophilus type b and meningococcal group c conjugate vaccine
PRAC Rapporteur/Lead MS: Carmela Macchiarulo
Country: Italy

List of products: please see attached excel sheet

You can download the psur, using the following link https://psur-repo-test.eudra.org/psur-ui?url=app/search/PSUSA_00001583_202002/psusa

EMA internal users can view document using the following link
<https://docs-test.eudra.org/webtop/drl/objectid/0b0142b281d63f09>

Procedure	Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised	Drug Ingredient	Legal basis	Actual submission date	Primary contact email	Sequence number	MA type	Product Ev Code	ATC Code	Is updated RMP	Updated RMP version
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7.1.2. PSUR start of procedure notification to MAH

A new start of procedure notification including the procedure timetable will be sent to the MAH(s) who have submitted PSUR(s) to the repository. The procedure assistant and procedure manager are in copy of this new notification from the system.

Confirmation of start of procedure for haemophilus type b and meningococcal group c co..., *IT*, PSUSA



PSUR-REPO-TEST@ema.europa.eu

To

Cc Dhiman Vikas; Loukeri Pinelopi

Reply

Reply

Action Items

Dear MAH contact person,

Please be informed that the above procedure started and will follow the below timetable:

Start of procedure:	01/05/2020
PRAC Rapporteur's/Lead Member State's preliminary assessment by:	05/05/2020
PRAC Rapporteur's/Lead Member State's and MAH comments on the Lead Member State preliminary assessment by:	10/05/2020
PRAC Rapporteur's/Lead Member State's updated assessment report by:	05/06/2020
PRAC recommendation:	10/06/2020

Note to MAH:

Amendments to the EURD list entries such as changes of PSUR submission frequency can be proposed in the frame of this PSUSA procedure.

Such requests should be duly justified and can be included as part of the MAH's comments to the preliminary assessment report by the deadline specified in the above timetable. The requests have to be made using the specific template published on the EMA website ["Requests for amendments of the EU reference dates list"](#).

Please note that changes in the EURD list come into force 6 months after its publication. Therefore, the frequency amendment will become effective from the PSUR that follows the publication.

For more details on how to submit amendments to the list, please refer to the [EURD list Introductory cover note](#).

Should the MAH contact details for this procedure change, please contact us immediately and provide us with the updated information.

Should you have any queries, please do not hesitate to contact me or the procedure manager Pinelopi Loukeri by email pinelopi.loukeri1@ext.ema.europa.eu.

Please note that for future communication on this procedure an Eudralink account is required.

You can find the guidance here:

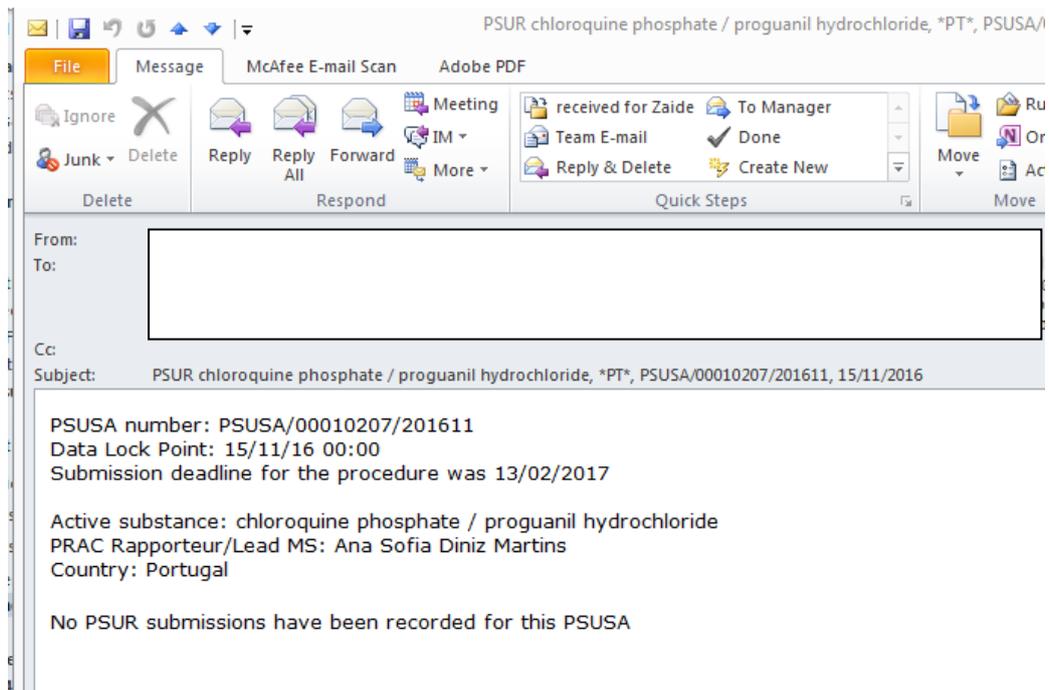
<https://eudralink.ema.europa.eu/EudraLink-User-Guide.pdf>

For help with requesting an account please contact my colleagues via <https://servicedesk.ema.europa.eu>

7.1.3. PSUR start of procedure notification – no PSURs received (CAP only and mixed CAP/NAP procedures only)

If **no submissions** have been received for a procedure by the submission deadline an automated notification is nevertheless triggered to inform the Rapporteur/Lead Member State that no submissions have been received for that procedure. This notification does not contain attachment or link to the procedure.

Please note that these notifications for NAP only procedures have been replaced by different notifications which are sent to EMA only.

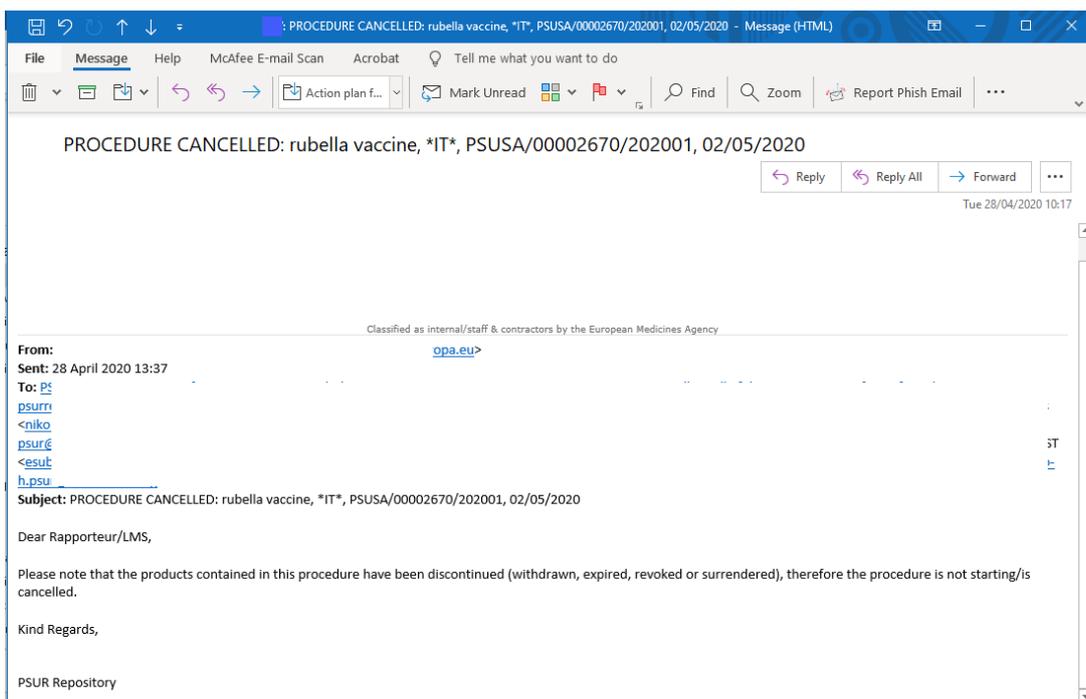


7.1.4. Cancelled procedure notification

A new feature has been implemented in v1.17.0.0 of the PSUR Repository where PSUSA procedure can be cancelled by the EMA PSUSA admin. When the procedure is cancelled, an automated notification is sent to the NCA detailing the reason for the cancellation (No submissions received, Products authorised in only 1 MS (revert to Non-EU), Procedure cancelled due to discontinued product(s)).

When procedures are cancelled, the Assessment Report deadline reminder notification and the Preliminary Assessment Report delay reminder notification are disabled.

Example of the notification providing the reason for the cancellation.

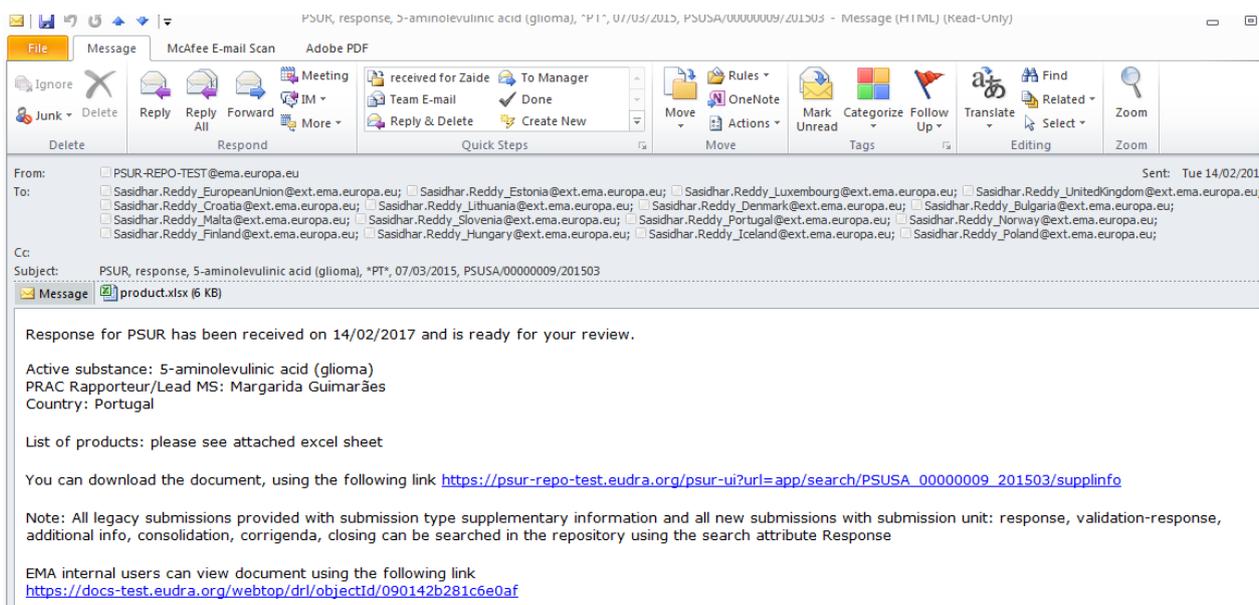


7.1.5. Revocation of the cancellation notification

Occasionally, it may be necessary to revoke the cancellation. In those cases, the usual notifications pertain to the procedure.

7.1.6. Supplemental submission (e.g. responses) notification

When **supplemental sequence (responses)** is submitted a notification is sent to all NCAs and the EMA. The email includes a link to the EMA document management system, DREAM. This link will only work for EMA users.



7.1.7. Assessment Report template notification

When EMA procedure assistant uploads the **Assessment Report template** in to the PSUR repository a notification is sent to the Rapporteur/Lead Member State. This notification includes links to the PSUR submission and the AR template as well as information related to the procedure, for example the procedure timetable and the contact details of the relevant procedure assistant.

It is now possible to delete incorrectly uploaded Assessment Report templates from the system by super user.

AR Template received for hydromorphone, *SI*, PSUSA/00001686/201511, 30/11/2015

psur-repository-notification-noreply@ema.europa.eu

Sent: Wed 11/05/2016 16:00

To: sihcmd-pharmacovigilance@jazmp.si

Dear Gabriela Jazbec/Slovenia,

The Agency received a PSUR for hydromorphone.

Please find attached the Preliminary Assessment Report template for the above mentioned procedure, which already includes all the administrative information along with the PSUR submission of the nationally authorised products in the enclosed zip file.

The Marketing Authorisations concerned are included in the appendix table in the Assessment Report.

For your information please find below the assessment timetable for this procedure.

Start of procedure:	06/05/2016
PRAC Rapporteur's preliminary assessment report by:	05/07/2016
PRAC and MAH comments on the Rapporteur preliminary assessment by:	04/08/2016
PRAC Rapporteur's updated Assessment report by:	19/08/2016
PRAC recommendation:	02/09/2016

The MAHs will be given 30 days to respond. A delay in submitting the preliminary assessment report could result in non-compliance with the regulatory and procedural timelines laid down in the legislation. This non-compliance can potentially open the door to legal challenge based on procedural grounds should the MAH(s) disagree with the outcome. Therefore, we would ask you to avoid such situation and adhere to the original timelines.

Please note that only one assessment report should be prepared covering all products involved in the procedure. Submission of RMP updates cannot be accepted together with the PSUR single assessment procedures involving NAPs/CAPs.

Should you have any queries, do not hesitate to contact me or the procedure manager (as specified in the Assessment report template).

Yours sincerely,

Kapralova Daniela
Daniela.Kapralova@ema.europa.eu

You can download the Assessment Report Template, using the following link https://psur-repo.eudra.org/psur-ui?url=app/search/PSUSA_00001686_201511/ar_template

You can download the PSUR, using the following link https://psur-repo.eudra.org/psur-ui?url=app/search/PSUSA_00001686_201511/psusa

7.1.8. Assessment Report template upload reminder notification

A new notification for EMA procedure assistant will be sent in case the AR template has not been uploaded in to the PSUR repository at the time of the procedure start.

7.1.9. Assessment Report deadline reminder notification

A week before the submission deadline of the Preliminary Assessment Report the system sends a **workflow support notification** to the Rapporteur/Lead Member State. If no PSURs have been received for a PSUSA procedure, the procedure is marked cancelled by the EMA procedure assistant and this reminder notification is not sent to the Rapporteur/Lead Member State.

Kind reminder: terazosin, *NL*, PSUSA/00002895/201511, 20/11/2015 – Preliminary AR due in 7 days

psur-repository-notification-noreply@ema.europa.eu

Sent: Tue 03/05/2016 00:16

To: PSUR_Repository@cbg-meb.nl

Dear Sabine Straus (Netherlands),

Please note that the assessment report for the above procedure is due on 10/05/2016

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.

As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt circulation of the assessment report is highly appreciated.

To upload your assessment report please log in to the PSUR Repository with your login credentials. <https://psur-repo.eudra.org/psur-ui/>

Yours sincerely,

Hesse Iris

Iris.Hesse@ema.europa.eu

7.1.10. Assessment Report notification

Once the Rapporteur/Lead Member State uploads the **Preliminary Assessment Report** in to the system a notification is sent to all NCAs. The notification includes a link to the Assessment Report.

Preliminary AR received: benzydamine, *IT*, PSUSA/00000375/201510, 31/10/2015

psur-repository-notification-noreply@ema.europa.eu

Sent: Wed 11/05/2016 08:30

To: PSUR_Repository@cbg-meb.nl; PSUR-REPO-IS@ima.is; sihcmd-pharmacovigilance@jazmp.si; psur@anmdm.ro; eudrapur@aeaps.es; hpsur@zva.gov.lv; PSUR_repository@mpa.se; psurh@fagg.be; repository@ages.at; PSURRepository@hpra.ie; no-h.psur@no-h.eudra.org; psurrepository@eof.gr; HPHARMACOVIGILANCE@mpa.se; UK-H CPMP; psur-psusa@sukl.sk; psur@infarmed.pt; fi-h.psurrepository@fimea.fi; psurrepository@raviamet.ee; psur_repository@ansm.sante.fr; sante-d5-psur-repo@ec.europa.eu; FOS-Box@dkma.dk; psurrepository@halmed.hr; psur@bfarm.de; PSUR-REPO-IT@aifa.gov.it;

A preliminary assessment report has been received on 11/05/2016 and is ready for your review.

Active substance: benzydamine

PRAC Rapporteur/Lead MS: Amelia Cupelli

Country: Italy

Is regulatory action suggested? No

Suggested regulatory action:

Additional comments: Comments are kindly awaited by 9th of June . Suitable for plenary discussion.

You can download the document, using the following link https://psur-repo.eudra.org/psur-ui?url=app/search/PSUSA_00000375_201510/ar

7.1.11. Preliminary Assessment Report delay reminder notification

If there is a delay in the upload of the Preliminary Assessment Report to the repository, the system sends an **automated reminder message** to the Rapporteur/Lead Member State reminding of the deadline to submit to the repository. If no PSURs have been received for a PSUSA procedure, the procedure is marked 'cancelled' by the EMA procedure assistant and this reminder notification is not sent to the Rapporteur/Lead Member State.

Kind reminder: stiripentol, *UK*, PSUSA/00002789/201511, 04/11/2015 - Outstanding AR

PSUR-REPO-XCOMP@ema.europa.eu

Sent: Thu 14/04/2016 00:15

From: esubUAT_UnitedKingdom@ext.ema.europa.eu

Dear Julie Williams (United Kingdom),

Please note that the assessment report for the above procedure was due on 11/04/2016

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.

As the timelines given in the legislation do not allow for extensions to the Rapporteurs or MAHs, your prompt circulation of the assessment report is highly appreciated.

Yours sincerely,

7.1.12. Updated Assessment Report notification

Once the Rapporteur/Lead Member State uploads the **Updated Assessment Report** in to the system a notification is sent to all NCAs. The notification includes a link to the Assessment Report.

Updated AR received: 5-aminolevulinic acid (glioma), *PT*, PSUSA/00000009/201503, 07/03/2015 - Message (HTML) (Read-Only)

From: PSUR-REPO-TEST@ema.europa.eu Sent: 07/03/2015 10:03:00

To: Sasidhar.Reddy_Germany@ext.ema.europa.eu; Sasidhar.Reddy_EuropeanUnion@ext.ema.europa.eu; Sasidhar.Reddy_Estonia@ext.ema.europa.eu; Sasidhar.Reddy_Luxembourg@ext.ema.europa.eu; Sasidhar.Reddy_UnitedKingdom@ext.ema.europa.eu; Sasidhar.Reddy_Croatia@ext.ema.europa.eu; Sasidhar.Reddy_Lithuania@ext.ema.europa.eu; Sasidhar.Reddy_Denmark@ext.ema.europa.eu; Sasidhar.Reddy_Bulgaria@ext.ema.europa.eu; Sasidhar.Reddy_Malta@ext.ema.europa.eu; Sasidhar.Reddy_Slovenia@ext.ema.europa.eu; Sasidhar.Reddy_Portugal@ext.ema.europa.eu; Sasidhar.Reddy_Norway@ext.ema.europa.eu; Sasidhar.Reddy_Finland@ext.ema.europa.eu; Sasidhar.Reddy_Hungary@ext.ema.europa.eu; Sasidhar.Reddy_Iceland@ext.ema.europa.eu

Cc: PSUR-REPO-TEST@ema.europa.eu

Subject: Updated AR received: 5-aminolevulinic acid (glioma), *PT*, PSUSA/00000009/201503, 07/03/2015

An updated assessment report has been received on 31/01/2017 and is ready for your review.

Active substance: 5-aminolevulinic acid (glioma)

PRAC Rapporteur/Lead MS: Margarida Guimarães

Country: Portugal

Is regulatory action suggested? Yes

Suggested regulatory action: VARIATION

Plenary discussion: Yes

Additional comments:

You can download the document, using the following link https://psur-repo-test.eudra.org/psur-ui?url=app/search/PSUSA_00000009_201503/ar

EMA internal users can view document using the following link <https://docs.eudra.org/webtop/drl/objectId/090142b281c6deaa>

7.1.13. Comment notification

When any NCA uploads **comments** in to the system a notification is sent to the PRAC Rapporteur/Lead Member State. The notification includes a link to the comment document in the repository.

COMMENTS from *PT*, rabeprazole, PSUSA/00002601/201510, 13/10/2015

psur-repository-notification-noreply@ema.europa.eu

Sent: Tue 10/05/2016 16:30

To: repository@ages.at; HPHARMACOVIGILANCE@mpa.se

A document containing comments from a PRAC member has been received on 10/05/16 16:23 and is ready for your review.

Active substance: rabeprazole

PRAC Rapporteur/Lead MS: Jan Neuhauser

Country: Austria

Commenting country: PT

Additional comments:

You can download the document, using the following link https://psur-repo.eudra.org/psur-ui?url=app/search/PSUSA_00002601_201510/comments

7.1.14. CMDh position notification

Notifications are sent to all NCAs when the CMDh position is uploaded to the system by the EMA procedure assistant.

From: PSUR-REPO-TEST@ema.europa.eu

To: Reddy Sasidhar V; Sasidhar.Reddy_Germany@ext.ema.europa.eu; Sasidhar.Reddy_EuropeanUnion@ext.ema.europa.eu; Sasidhar.Reddy_Luxembourg@ext.ema.europa.eu; Sasidhar.Reddy_UnitedKingdom@ext.ema.europa.eu; Sasidhar.Reddy_Czechia@ext.ema.europa.eu; Sasidhar.Reddy_Lithuania@ext.ema.europa.eu; Sasidhar.Reddy_Denmark@ext.ema.europa.eu; Sasidhar.Reddy_Bulgaria@ext.ema.europa.eu; Sasidhar.Reddy_Malta@ext.ema.europa.eu; Sasidhar.Reddy_Slovenia@ext.ema.europa.eu; Sasidhar.Reddy_Portugal@ext.ema.europa.eu

Cc:

Subject: CMDh position-FINAL added for vernakalant hydrochloride, *NL*, PSUSA/00003109/201508, 31/08/2015

A final CMDh position has been added to the repository.

You can download the document, using the following link https://psur-repo-test.eudra.org/psur-ui?url=app/search/PSUSA_00003109_201508/cmdh_position

7.1.15. PRAC recommendation notification

Notifications are sent to all NCAs when the PRAC recommendation is uploaded to the system by the EMA procedure assistant.

From: PSUR-REPO-TEST@ema.europa.eu

To: Reddy Sasidhar V; Sasidhar.Reddy_Germany@ext.ema.europa.eu; Sasidhar.Reddy_EuropeanUnion@ext.ema.europa.eu; Sasidhar.Reddy_Estonia@ext.ema.europa.eu; Sasidhar.Reddy_Luxembourg@ext.ema.europa.eu; Sasidhar.Reddy_UnitedKingdom@ext.ema.europa.eu; Sasidhar.Reddy_Croatia@ext.ema.europa.eu; Sasidhar.Reddy_Lithuania@ext.ema.europa.eu; Sasidhar.Reddy_Denmark@ext.ema.europa.eu

Cc:

Subject: PRAC recommendation-FINAL added for vernakalant hydrochloride, *NL*, PSUSA/00003109/201508, 31/08/2015

A final PRAC recommendation has been added to the repository.

You can download the document, using the following link https://psur-repo-test.eudra.org/psur-ui?url=app/search/PSUSA_00003109_201508/prac_recommendation

7.1.16. CHMP opinion notification

Notifications are sent to all NCAs when the CHMP Opinion is uploaded to the system by the EMA procedure assistant.

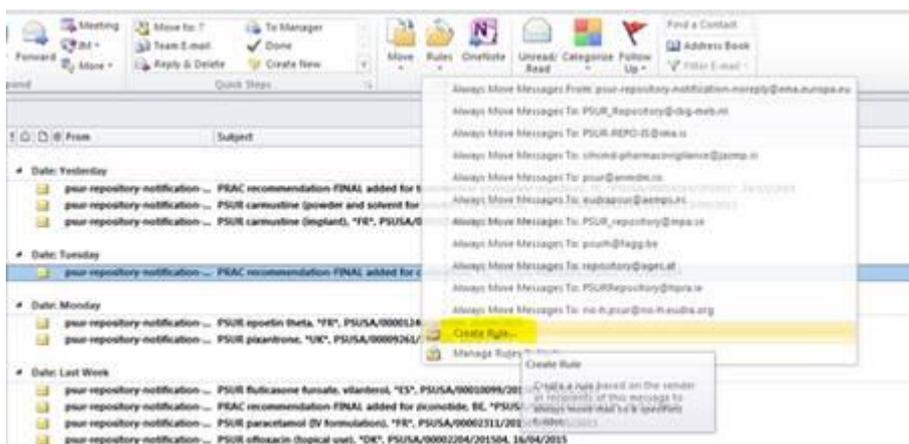


8. Filtering and auto-forwarding notifications

In Microsoft Outlook you can create a rule based on senders or recipients or on certain conditions of a message:

A rule can be quickly created from any message / notification sent from the PSUR Repository. The advantage of creating a rule in this manner is that rules are suggested based on the message sender or recipients. For example, when you start with a message, one rule that is suggested moves all messages from that sender to a folder that you choose.

For rules options that are based on the sender, recipients, or subject of the message, click **Create Rule**- screenshot of the menu as following:



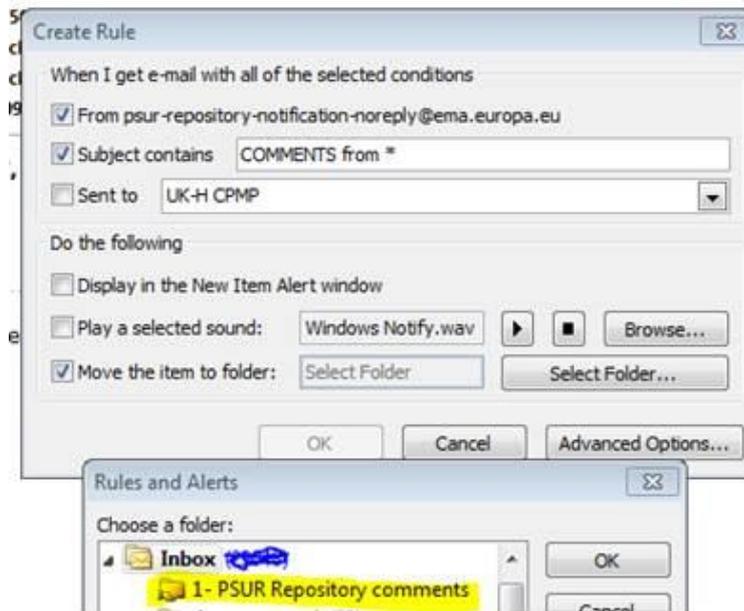
Once the **Create Rule** dialog box appears continue with the following steps:

1. Under **When I get e-mail with all of the selected conditions**, select the check boxes for the conditions that you want, e.g.

a. You can specify conditions such as PSUSA procedure number or the member state in two letter format as on the subject line e.g. FI (derived from the EURD information in the subject).

b. Select the folder where notification emails from EMA should be sent to.

Screenshot of above steps as following:



2. Under **Do the following**, select the check boxes for the action that you want the rule to take when the specified conditions are met.
3. Select the **Move the item to folder** check box.
4. Click an existing folder or click **New** to create a folder to store the messages.
To add more conditions, actions, or exceptions to the rule, click **Advanced Options**, and then follow the rest of the instructions in the **Rules Wizard**. This is the same wizard that appears when you click **Manage Rules & Alerts** in the Backstage view (by clicking the **Filetab**).
5. Click **OK**.

9. Browser Support

The following browsers are supported by the PSUR Repository web application:

Internet Explorer v9+ and recent versions of Firefox, and Google Chrome

9.1. Download configuration

Please note that your browser may be configured to automatically download documents to pre-defined location. In this case you will not be asked to choose a specific location but the documents will be downloaded and saved to the default location.

Please check with your IT support on how to change this setting if needed.

10. Troubleshooting

For PSUR repository interface, eSubmission Gateway and/or the Web Client questions, issues and requests for services, please contact us through the [Service Desk portal](#). This portal improves the efficiency of the technical support by allowing users to report issues, track progress of their queries and obtain answers to frequently asked questions. This portal replaces previously used mailboxes. All technical queries concerning these IT systems, such as e.g. Web Client/Gateway set-up, registration details or the transmission failures of files in the production or test environment must also be reported using the [Service Desk portal](#).

If you wish to propose a change to the PSUR Repository system functionality please use the [Service Desk portal](#) to raise your request.

In case of a system failure a communication to the Network will be launched and where possible, information will be published on the eSubmissions website and on the EMA Service Desk Portal. Status updates will be provided at regular intervals, and the EMA will issue recommendations regarding the upload of procedural documentation and submission of PSURs. The system has built-in functionality to allow for the late submissions.