EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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User Guidance for National Competent Authorities for PSUR Repository

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Document History

Version	Date	Changes applied	Author
1.0	04/11/14	Original – documented usage of production selection function.	Wasif Sabir
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
2.0	15/04/15	Updated to reflect new filter & sort functionality in search grid. See 3.4. Additional functions of the search grid. Also added list of browsers supported.	Wasif Sabir
3.0	06/08/15	Updated to reflect the new functionality from release 01.03.00 e.g. inclusion of additional information for comments and ability to indicate if regulatory activity is suggested.	Kristiina Puusaari
4.0	12/10/15	Updated to reflect the new functionality from release 01.04.00 e.g. deduplication and change in the search screen.	Kristiina Puusaari
5.0	14/05/16	Updated to reflect the new functionality from release 01.06.00 e.g. invalidation of technically invalid eCTD sequences in the repository and detailed information on notifications.	Kristiina Puusaari
6.0	13/06/16	To reflect the mandatory use of the PSUR Repository.	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.

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.

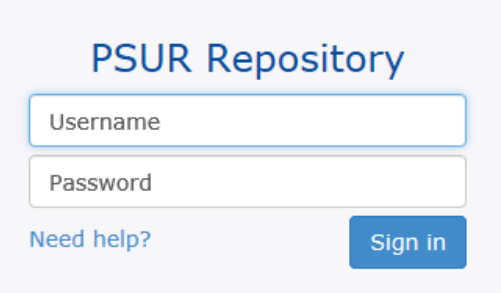
The registration form is available in the PSUR Repository webpage:

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



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.

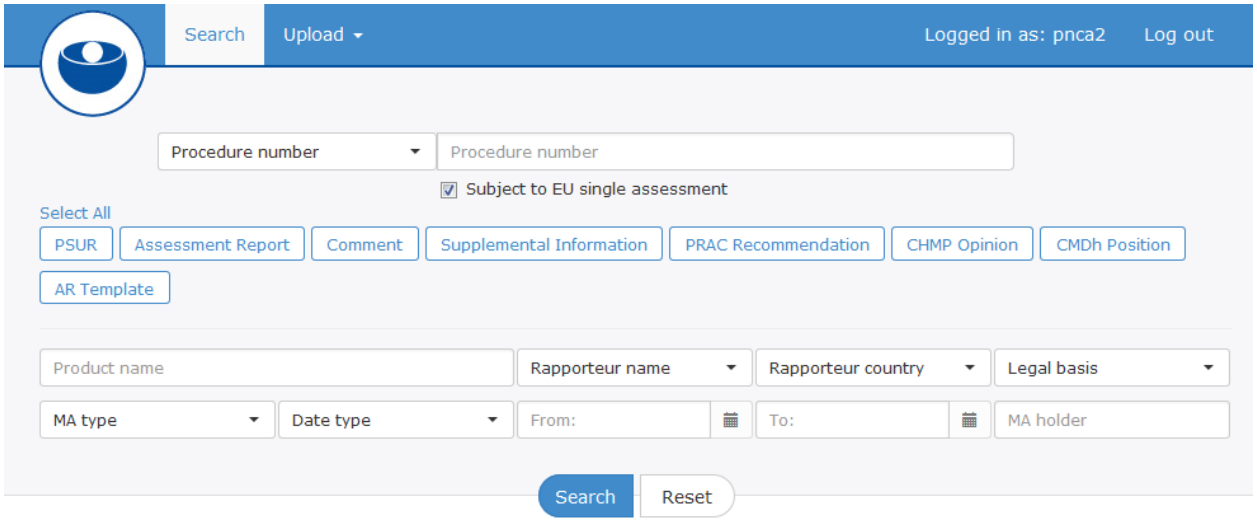
4.1. EU Single Assessment search Screens

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 now 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'.

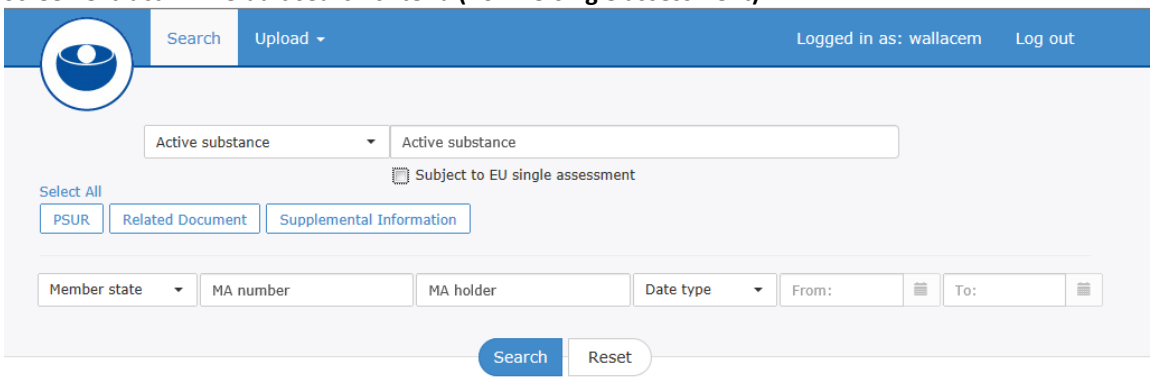
A change to the search screen inline with the changes to the eCTD EU M1 will be introduced in a next version of the system planned for release around the time of the new specification entering into force. More information on the eCTD EU M1 can be found from the eSubmission website.

Screen extract 1 - Default search criteria

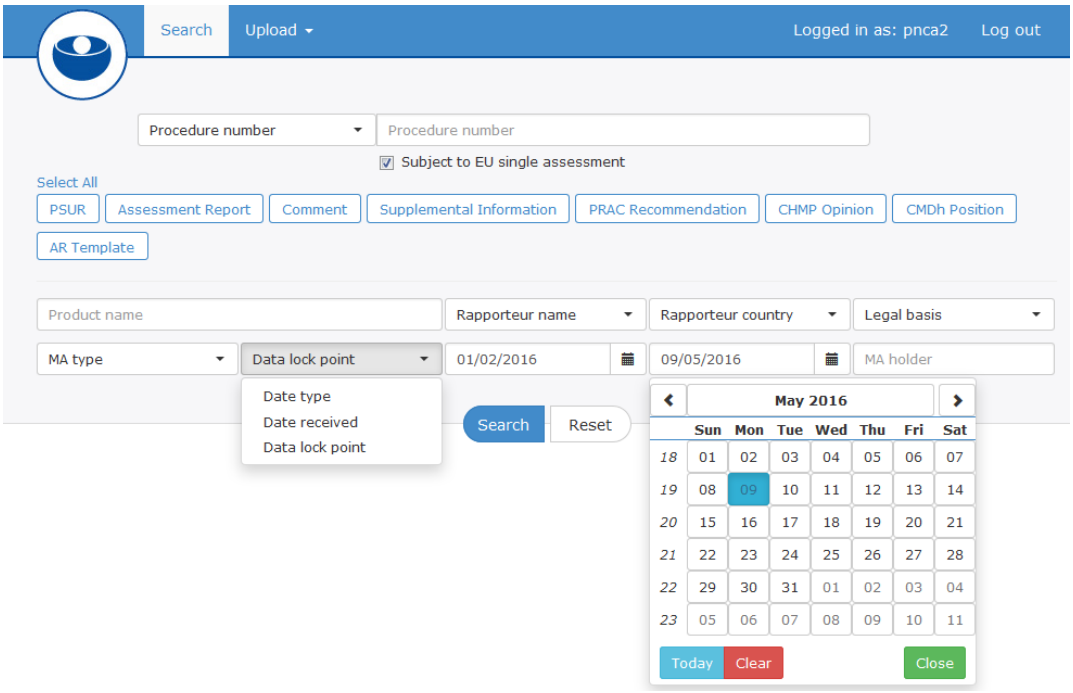


4.2. Non-EU single assessment

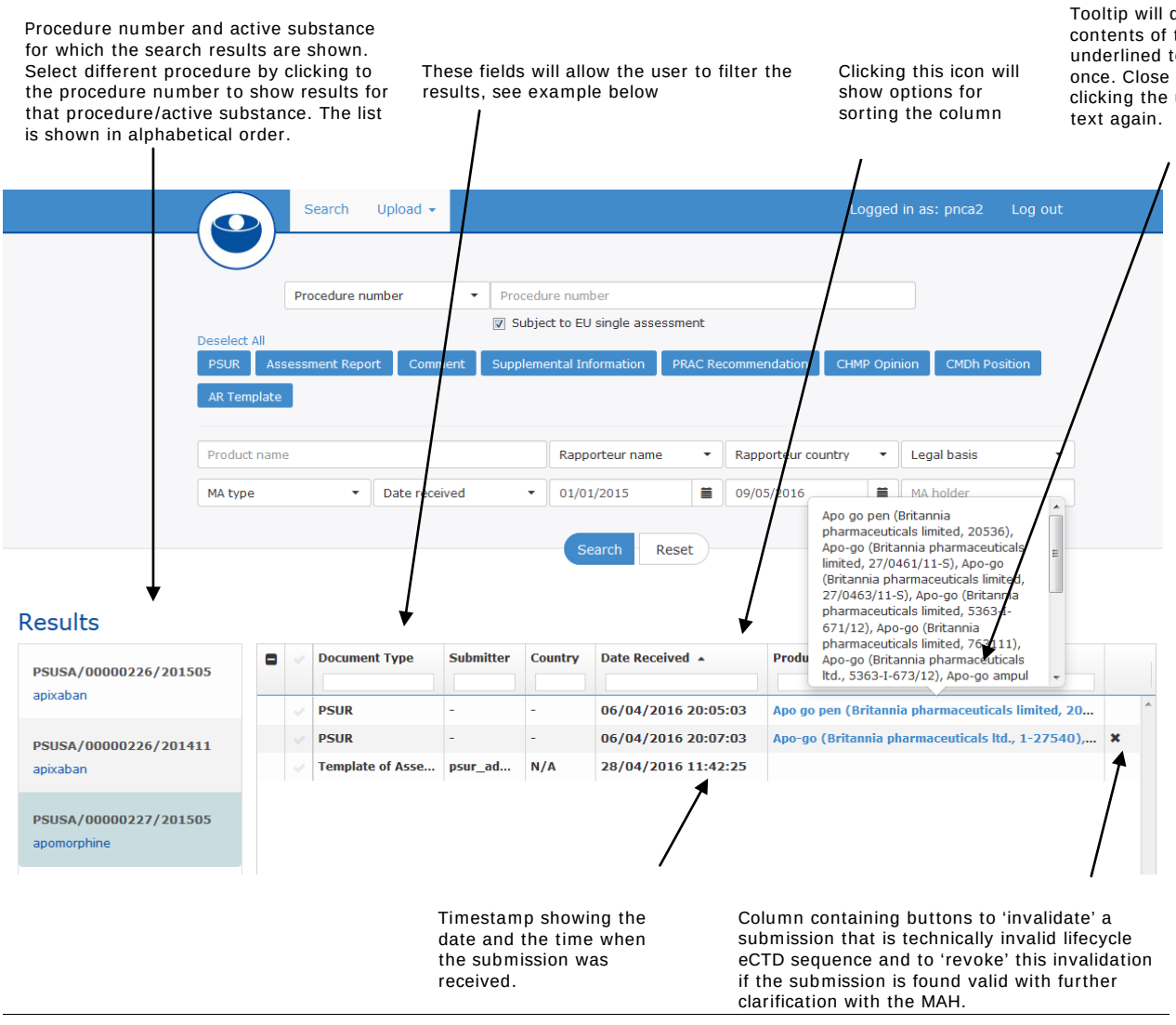
Screen extract 2 – Default search criteria (non-EU single assessment)



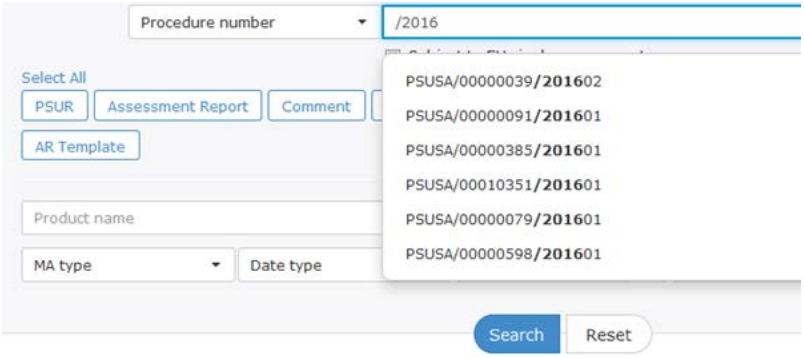
Screen extract 3 – setting date range for searches

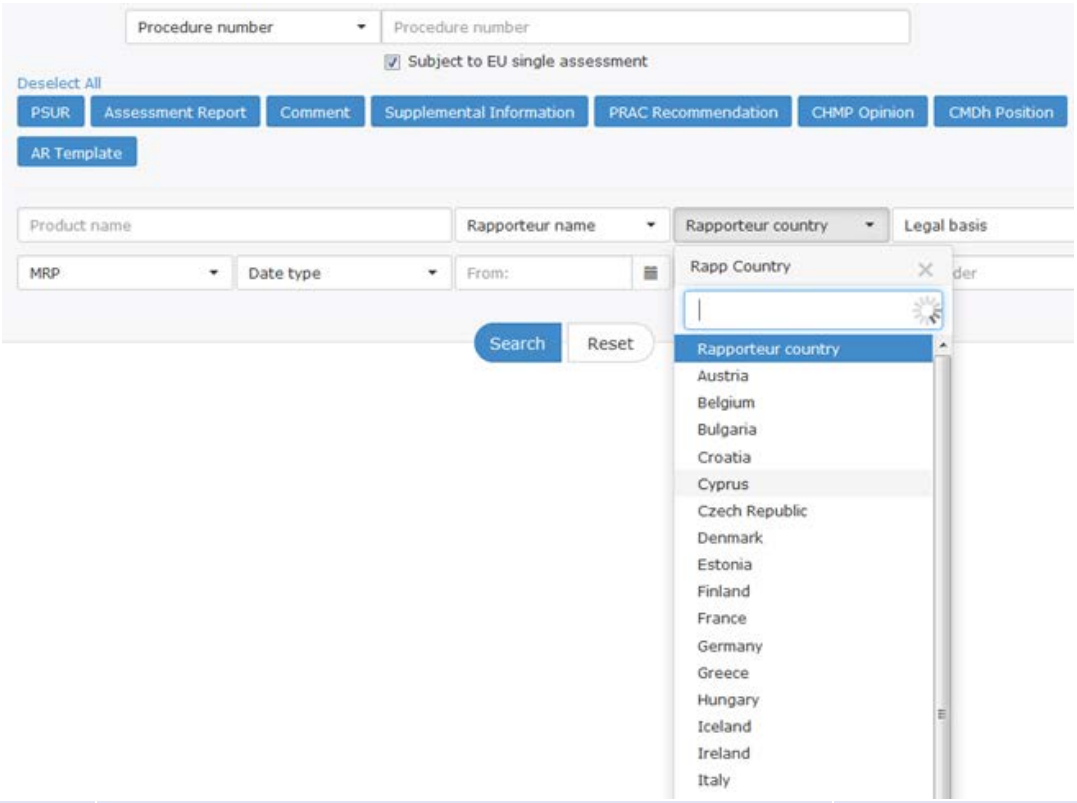


Screen extract 4 – Example results grid for EU-single assessment search



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.	1. Select "EU single assessment" if you have a PSUSA number. 2. Select non-EU to upload a document for a local assessment procedure.
		
2.	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, Assessment Report) and any additional criteria if you wish to filter the results even further.	
3.	More detailed searches can be run with any combination of available search criteria, e.g. on product name, rapporteur name etc. Date searches can be run on 'date submitted' or 'data lock point' basis.	Remember to select the relevant document types to launch the search. 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.



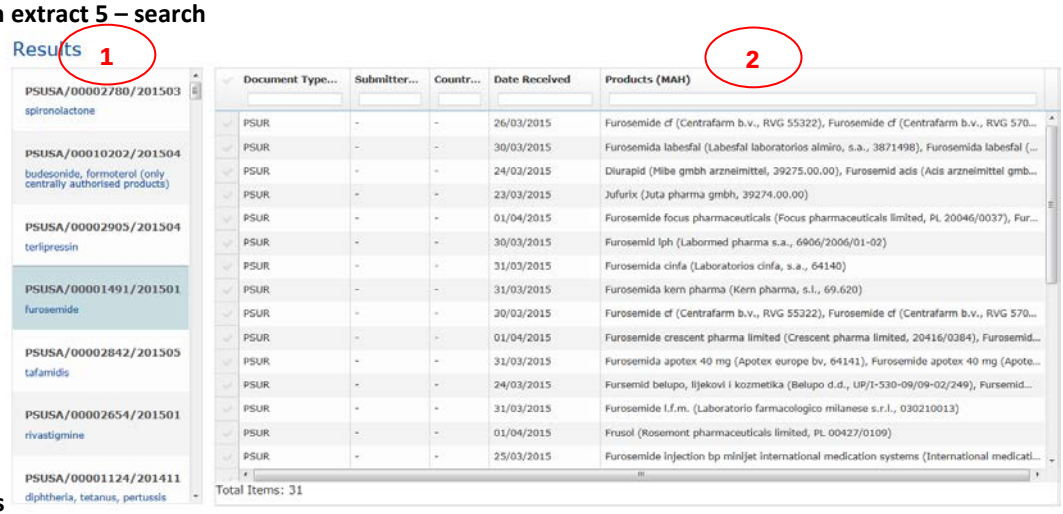
4.	To perform a new search with new criteria press 'reset'. If you wish to change only some parameters you do not need clear the search, just change the relevant selections and click search.	

4.3. Search results

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

1. 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.
2. 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 will be introduced inline with the changes to the eCTD EU M1. These changes will be introduced in the next version of the system planned for release around the time of the new specification entering into force. More information on the eCTD EU M1 can be found from the eSubmission website.

Screen extract 5 – search results



4.3.1. 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.

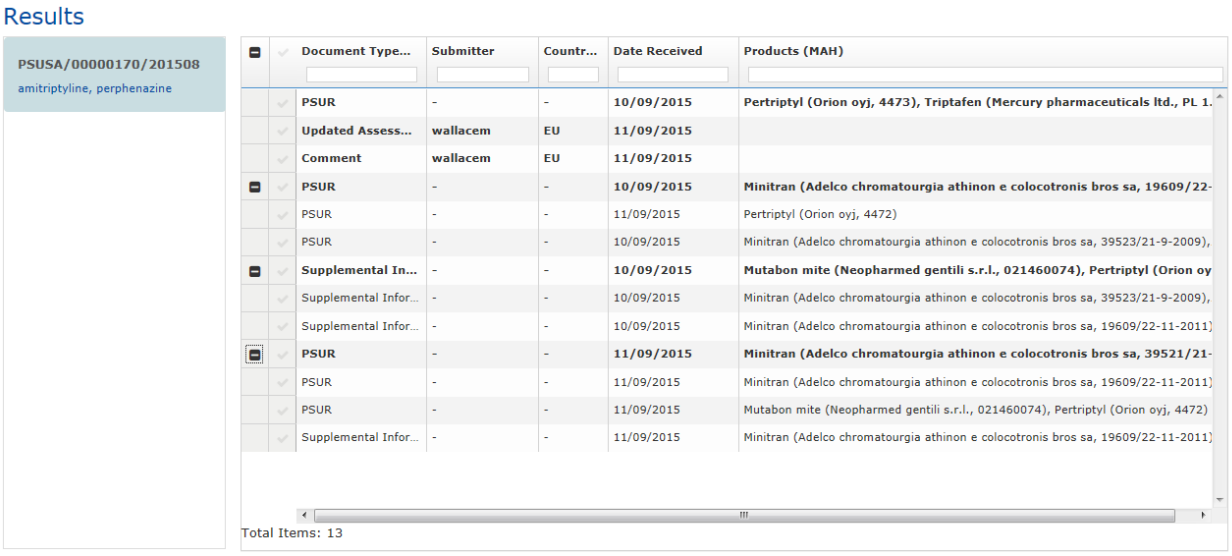
The deduplication functionality is designed to be used for those procedures for which there are multiple different products submitted in eCTD or mixed eCTD and NeeS formats where the MAH has prepared a single PSUR document but due to eCTD rules must submit the PSUR multiple times as a part of each products 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.

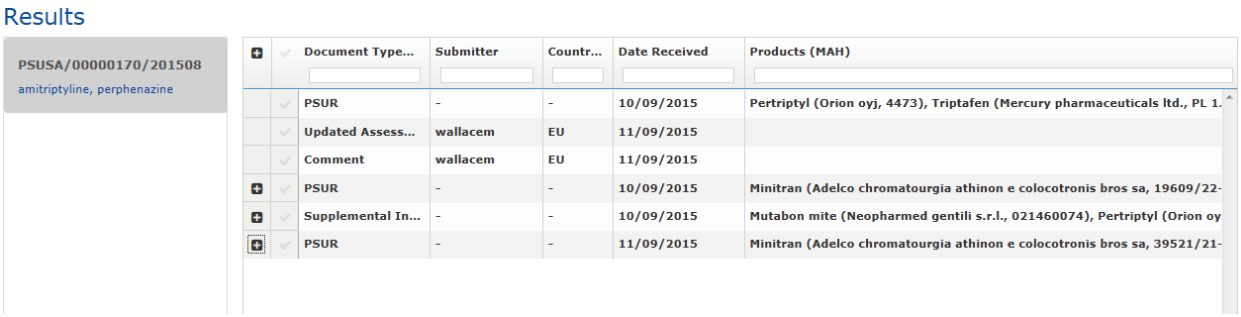
The search results are shown as submitted initially – i.e. no deduplication is shown in the initial search view – the new minus ⊟ and plus ⊞ buttons can be used to hide and show the full list of documents.

Screen extract 6 – example of deduplication

Full results



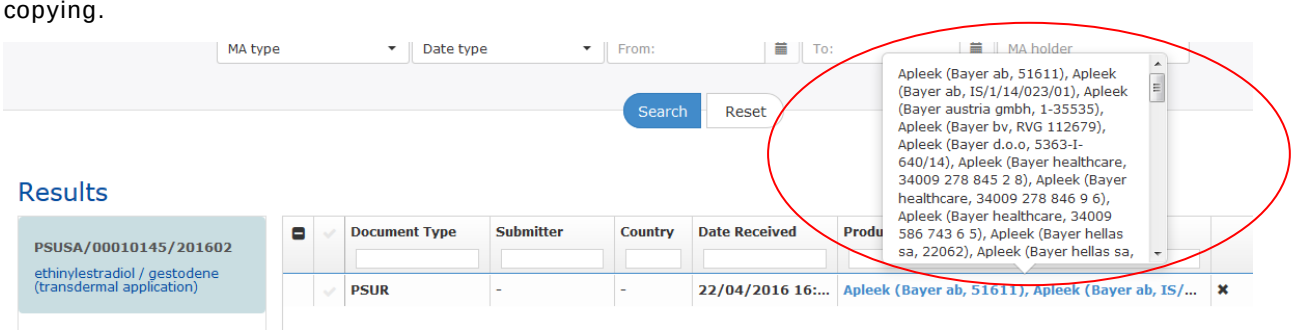
Deduplicated results



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.



4.4.1. Sort

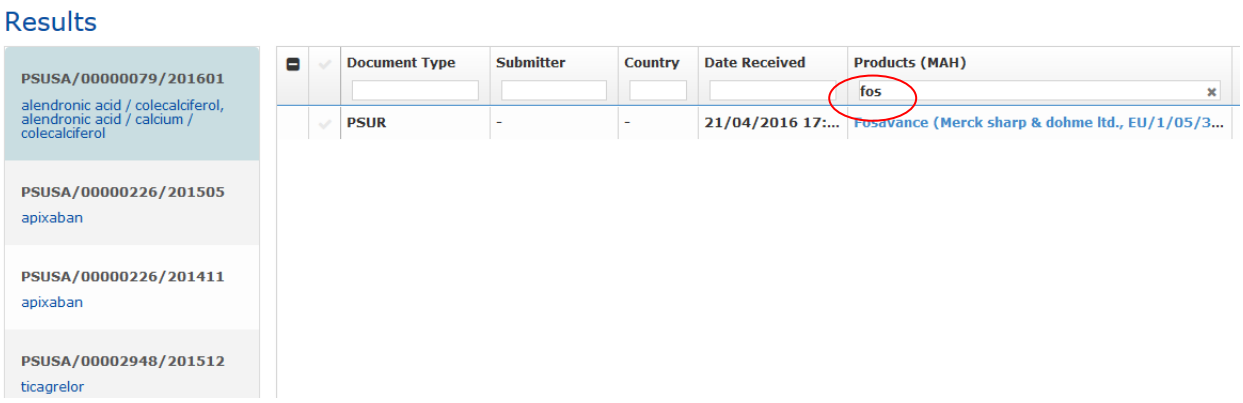
To sort by a column simply click the name of the column e.g. Date Received, shown in the screenshot above and choose the sort order.

4.4.2. Filter results

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

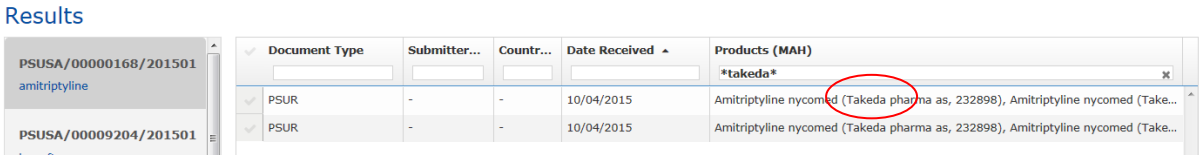
Basic filtering can be performed by simply typing in the text you want filter by. The system will immediately begin to filter results for records that match letters you are typing. For example, the screenshot below shows the results filtered by the records that begin with "fos". The filtering function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

Screen extract 7 – example of basic filtering



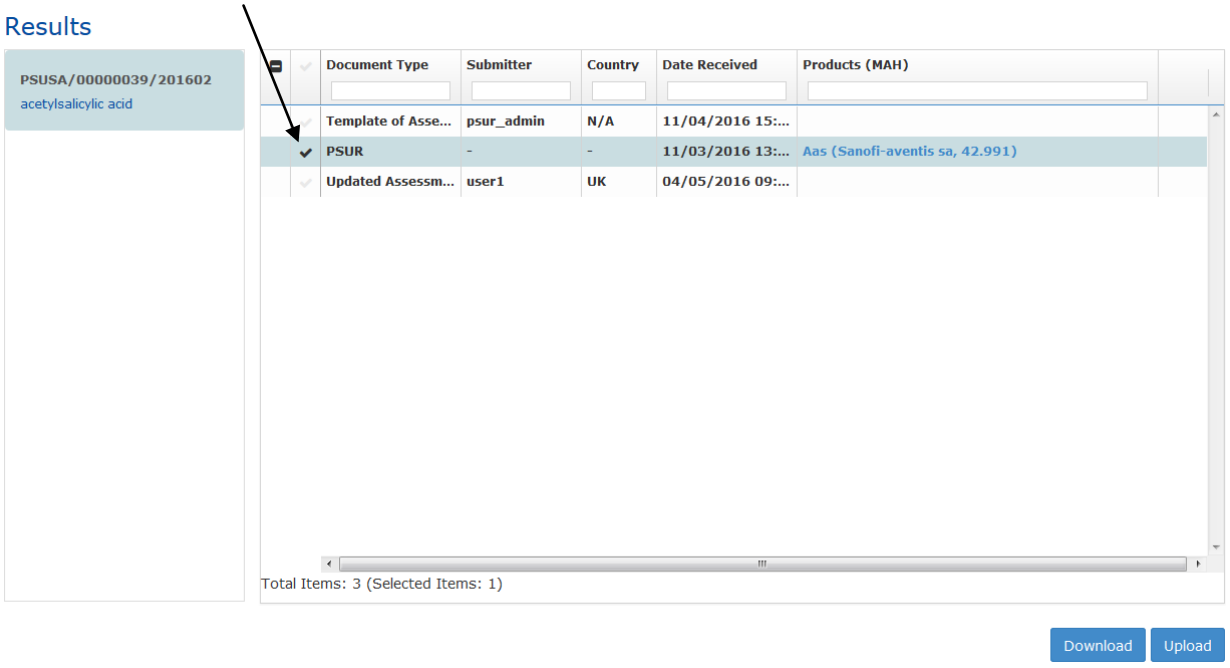
The system allows the use of the asterisk (*) to facilitate partial matches of text. The text you want to search for must be enclosed with asterisks on either side, e.g. *takeda*

Screen extract 8 – example of wildcard filtering

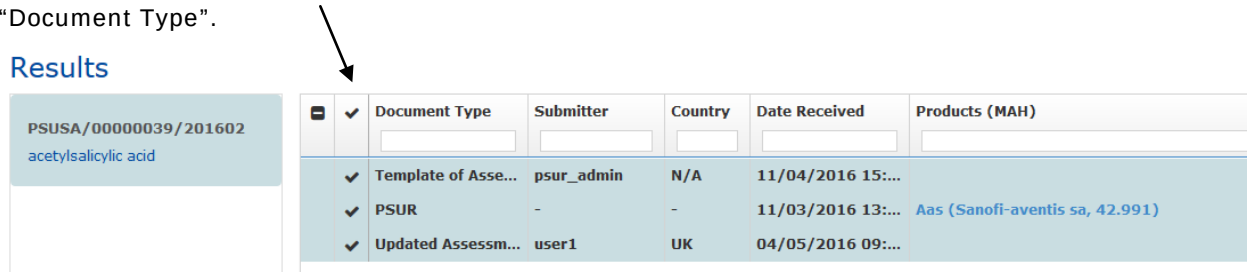


4.5. Downloading documents

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



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



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.

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 supplementary information is available in the PSUR repository. It is now possible to upload an assessment report and/or comments for procedures for which only the supplementary information has been received.

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

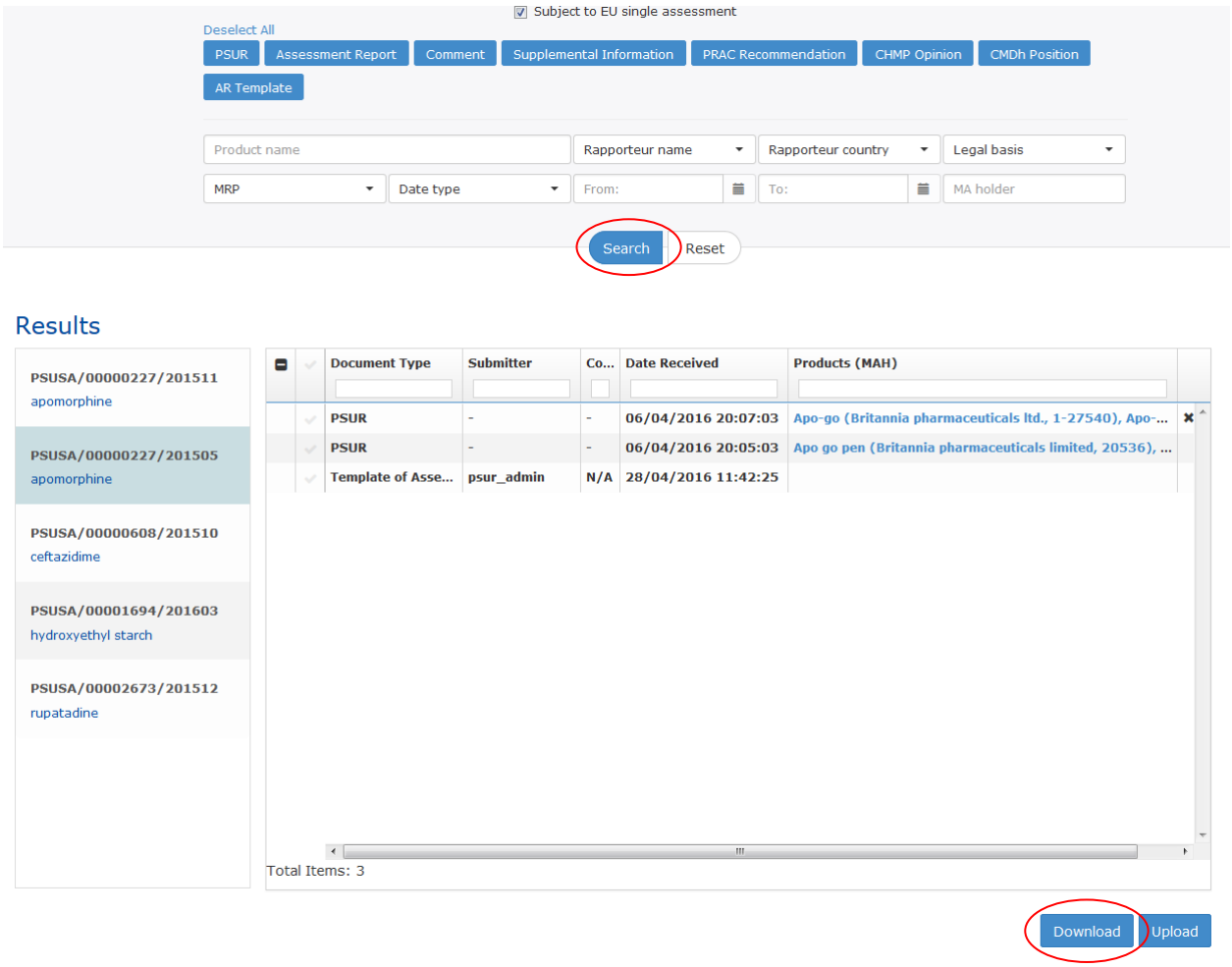
It is recommended that the Assessment Reports and comments are provided in **word** format to enable easier reviewing and processing of these documents. The ARs and comments should **not** be uploaded in PDF format.

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

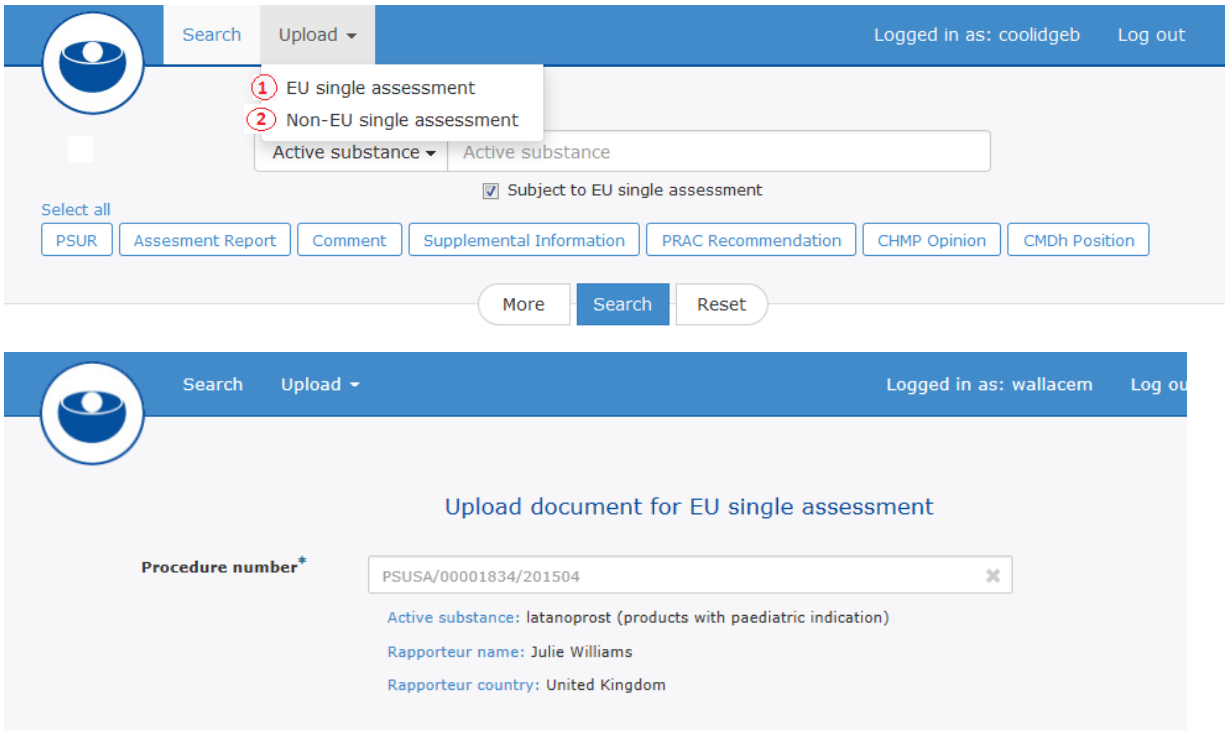
- Via dedicated 'Upload' screen
- Via 'Upload' button in the search screen

5.1. Uploading documents for EU single assessment procedure

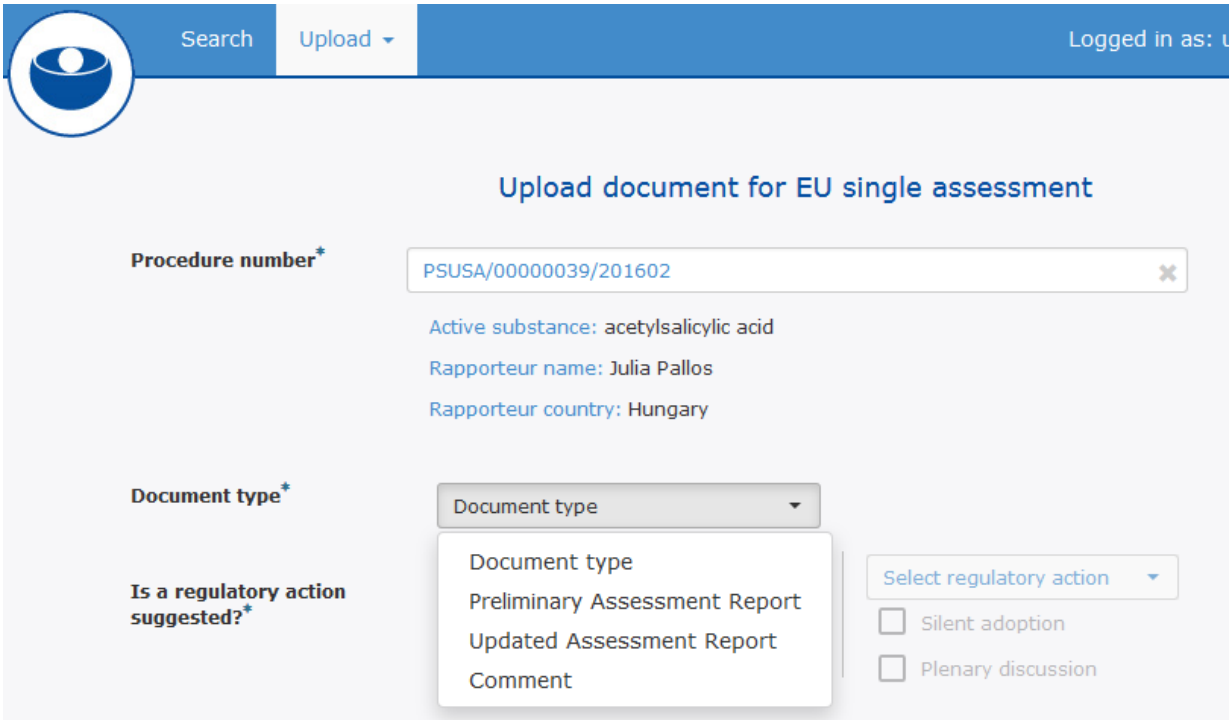
Screen extract 9 – upload directly from the search screen



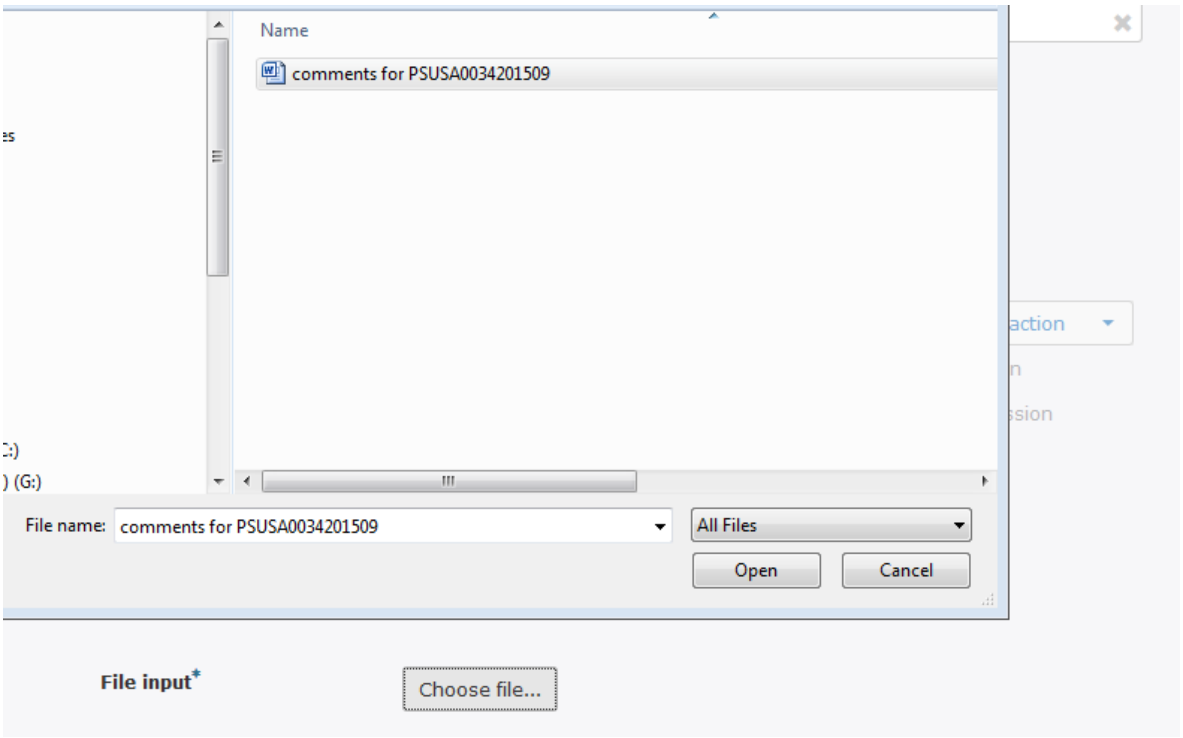
Screen extract 10 – Upload via dedicated upload screen



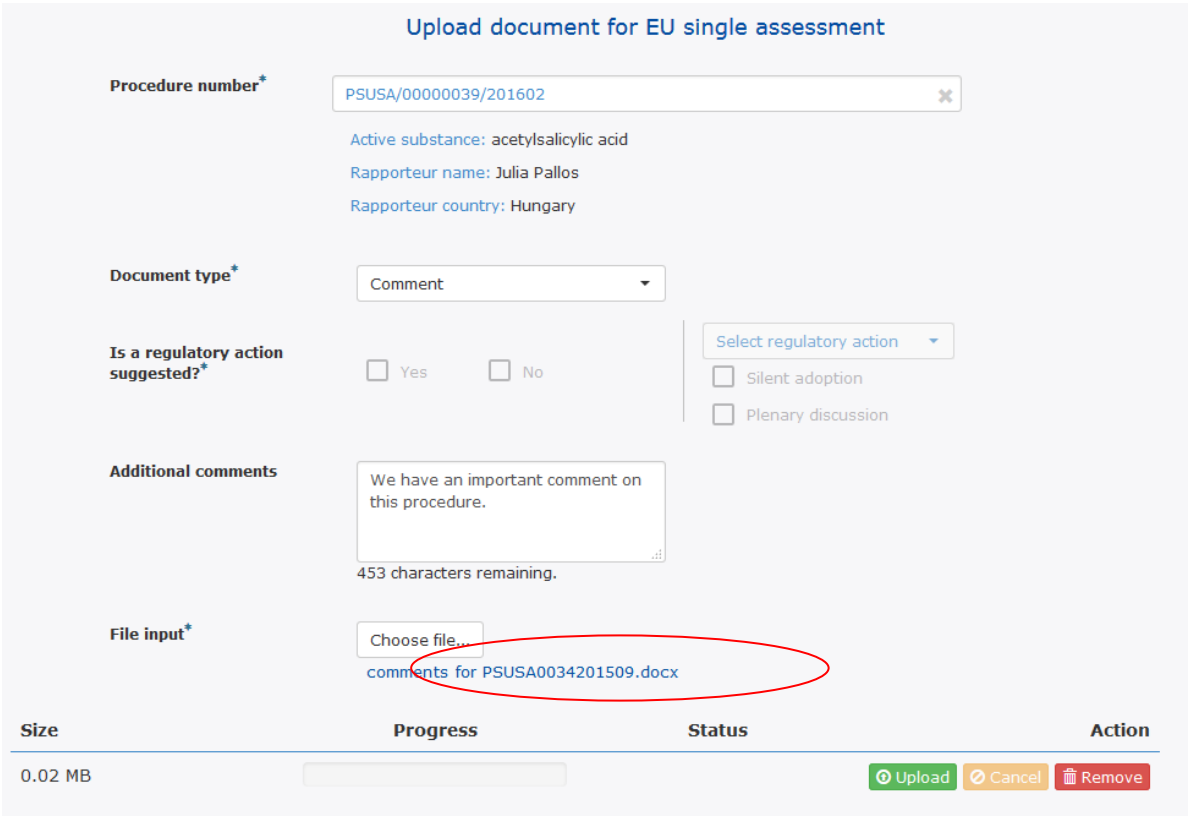
Screen extract 11 - Upload details and document type



Screen extract 12 - Browse for file to upload



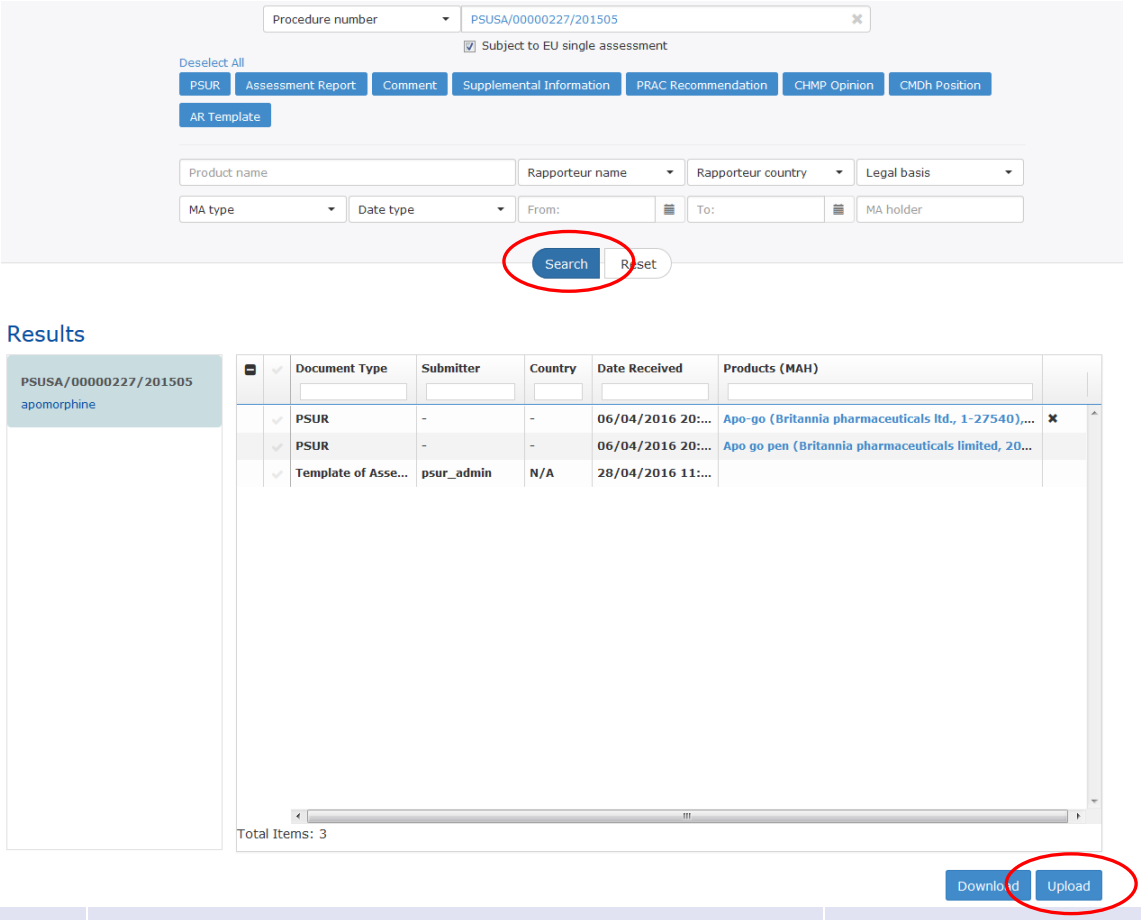
Screen extract 13 - Document to be uploaded



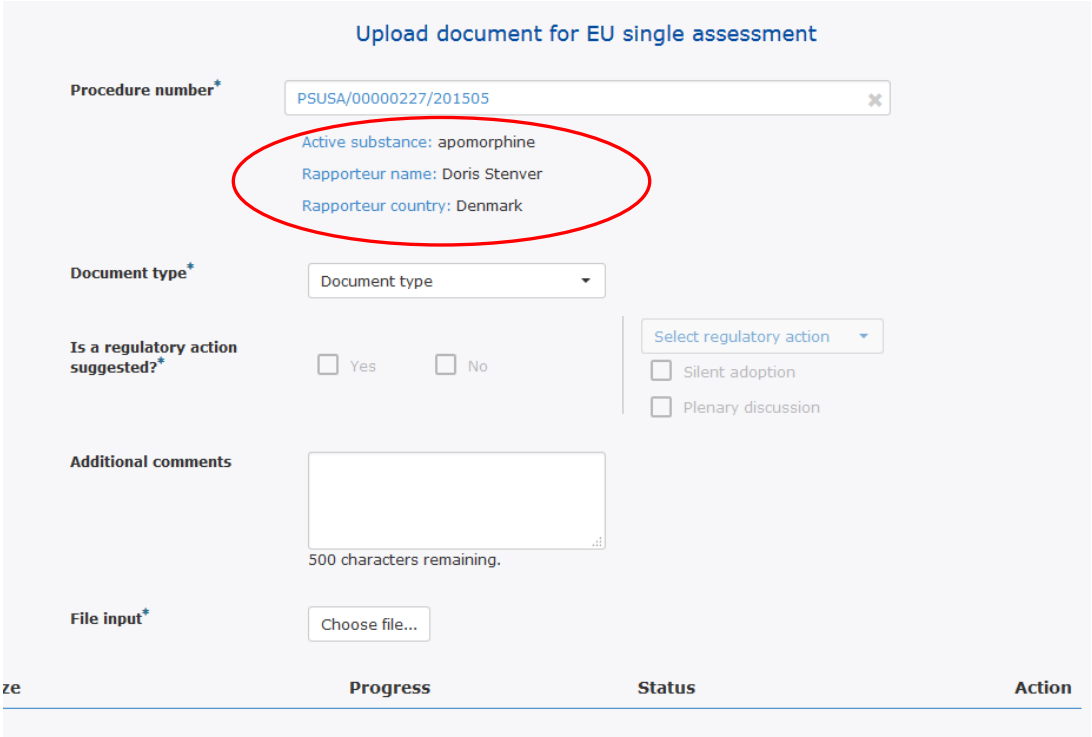
5.2. Detailed instructions for uploading documents for EU single assessment procedure

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

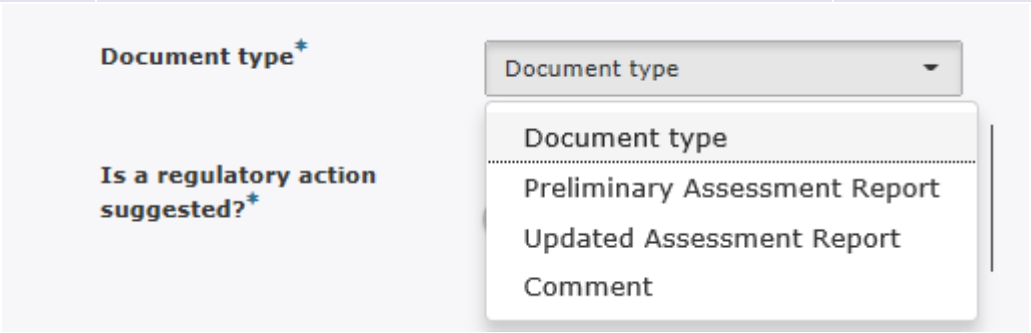
Step	Description	Notes
1.	Perform a search following instructions in section 3. and once you have found the required procedure proceed to upload. There is no need to select the documents (by ticking one or more PSURs on the list – it does not matter if all or just one of the received PSURs have been selected – the upload will be for the procedure level). Click the 'Upload' button next to 'Download' button to access the upload screen.	1. Select "EU single assessment" if you have a PSUSA number. 2. Select non-EU to upload a document for a local assessment procedure.



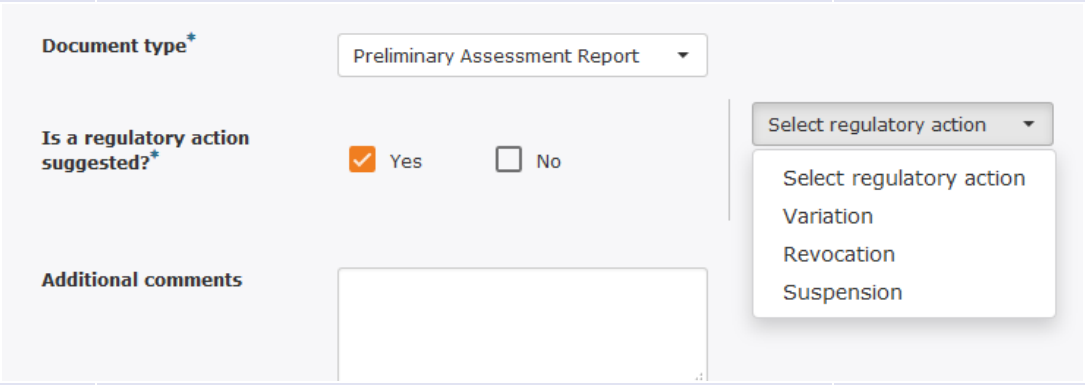
2.	The procedure number, active substance, Rapporteur and country are prepopulated as per the selection in the search screen Check the details displayed are correct	



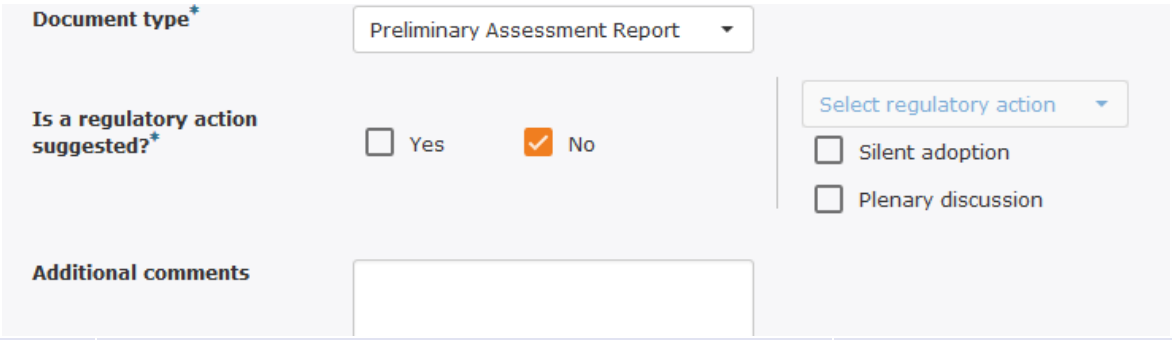
3.	Select the document type It is not possible to upload UAR or comments if the PAR has not uploaded.	Assessment Reports should only be uploaded by the **Rapporteur/Lead Member state**.



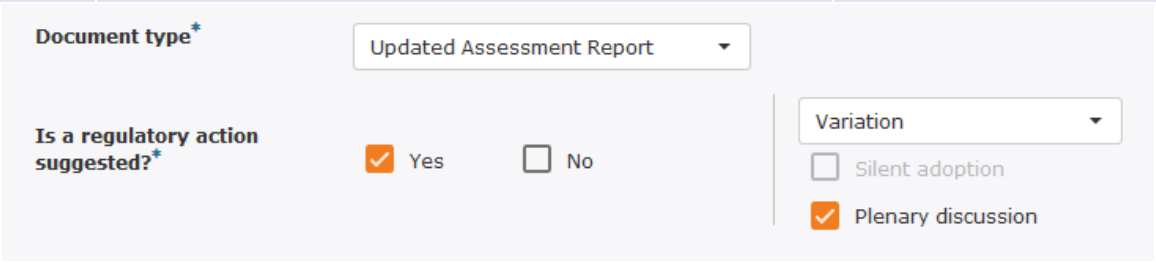
4.	If **Preliminary Assessment Report** is selected, it is possible to indicate if a 'regulatory action' is suggested. The possible regulatory actions to be selected from the dropdown menu are; • Variation • Revocation and • Suspension It is possible to add 'additional comments. The comments are visible in the notification only.	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.
5.	Indicate if Regulatory action is suggested by ticking the relevant 'yes or no' button and select the required regulatory action.	Regulatory actions available depend on the document selected.



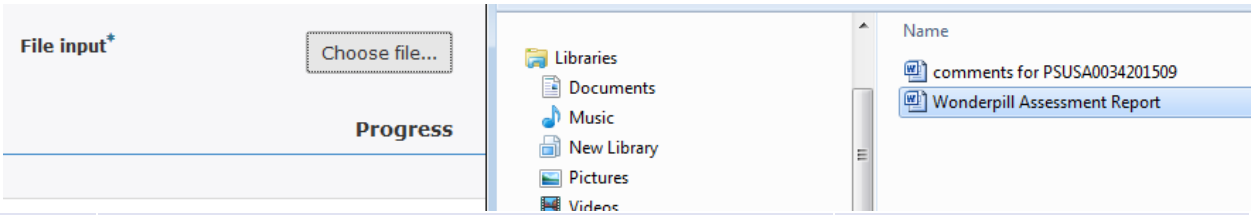
6.	If no regulatory action is suggested, it is possible to indicate if a silent adoption or plenary discussion is foreseen. It is possible to add 'additional comments'. The comments are visible in the notification only.	



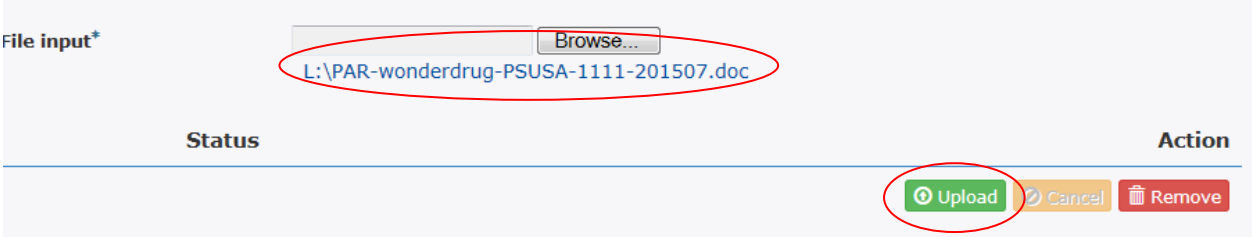
7.	If **Updated Assessment Report** is selected, it is possible to indicate if a 'regulatory action' is suggested. The possible regulatory actions to be selected from the dropdown menu are; • Variation • Revocation and • Suspension All the regulatory actions may be suggested for 'plenary discussion' 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.	



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.	



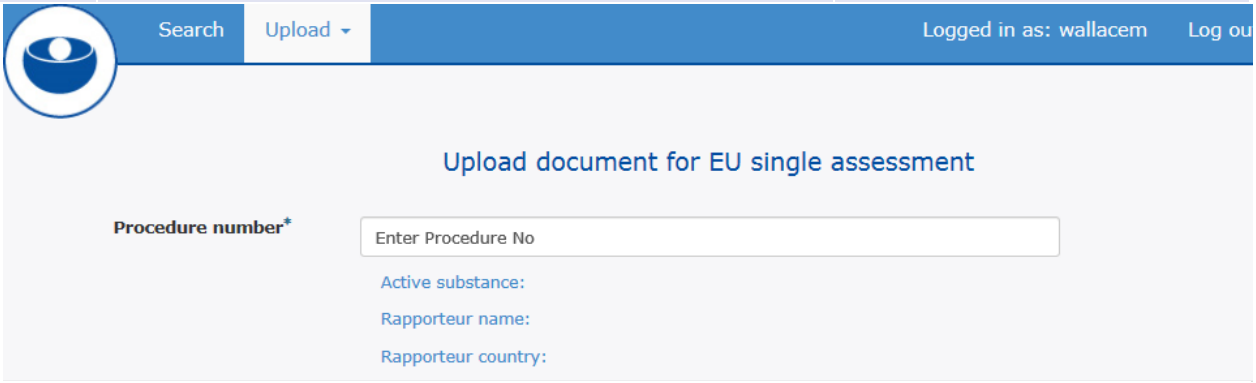
11.	Click the “upload” button to make the document available in the repository. (Screen extract 8 - Document to be uploaded).	To choose another file, before the upload is done, click the “Remove” and then “Choose file” button.



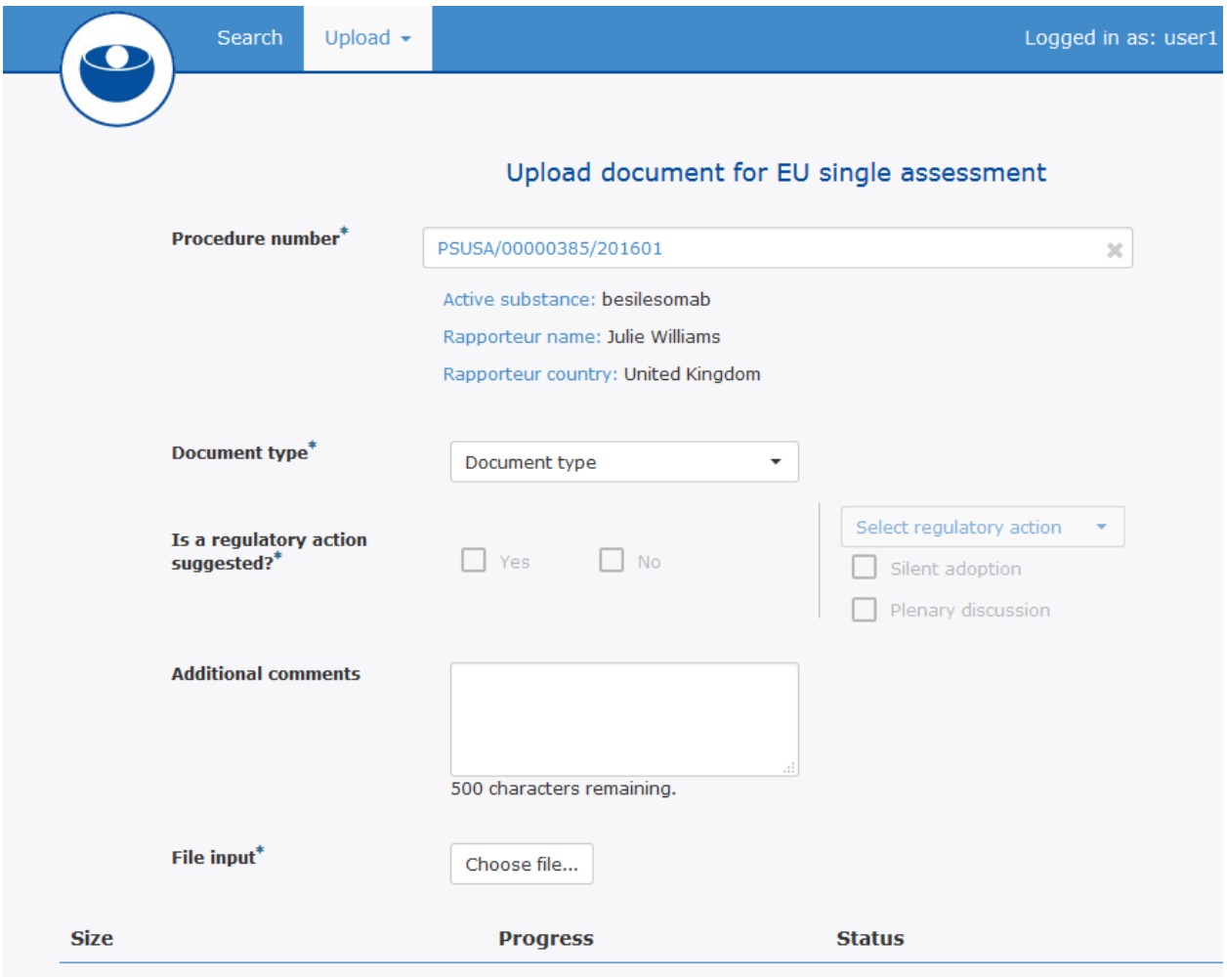
12.	The system will display a message to indicate the success or failure of the upload.	In cases of failure, please check the details and try again or contact EMA.

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.



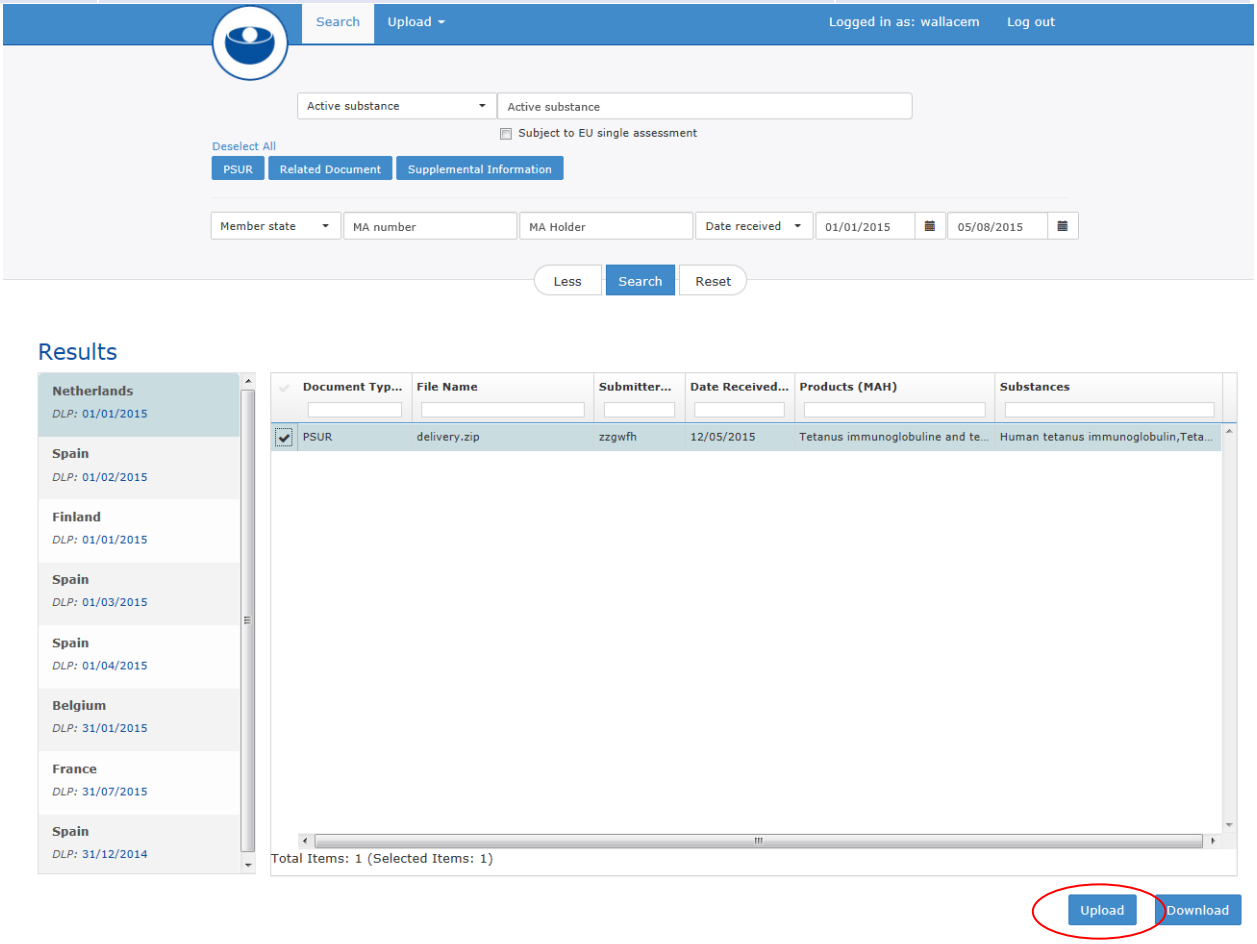
2.	Active substance, Rapporteur name and country are displayed for visual confirmation. Check the details displayed are correct and continue from step 3 of section 4.2.1.	

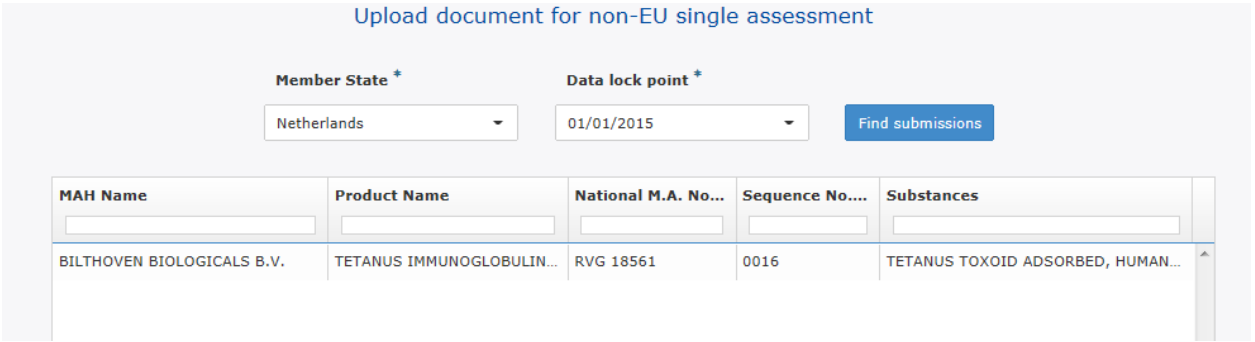

Search
Upload
Logged in as: user1
Upload document for EU single assessment
Procedure number*
PSUSA/00000385/201601
Active substance: besilesomab
Rapporteur name: Julie Williams
Rapporteur country: United Kingdom
Document type*
Document type
Is a regulatory action suggested?*
Yes
No
Select regulatory action
Silent adoption
Plenary discussion
Additional comments
500 characters remaining.
File input*
Choose file...
Size
Progress
Status

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

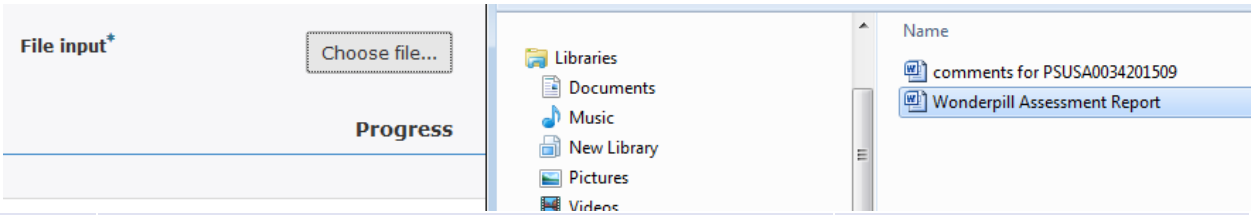
5.3.1. Detailed instructions for uploading documents for non-EU assessment procedure (local assessment procedure) from search screen

1.	For **Non-EU Single assessement** 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.	

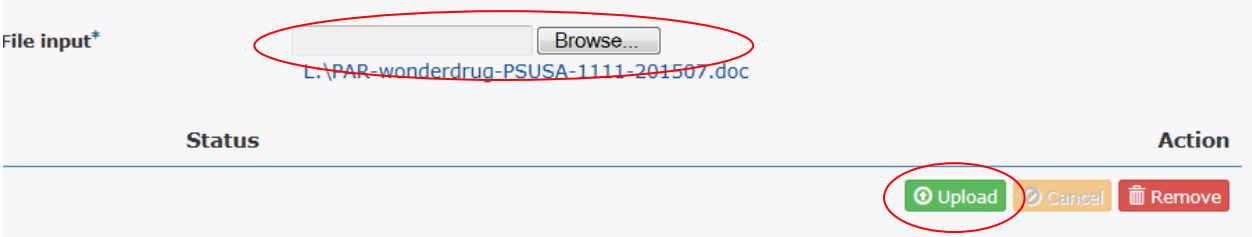




2.	Browse to select the document and check that the correct file has been selected.	



3.	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.

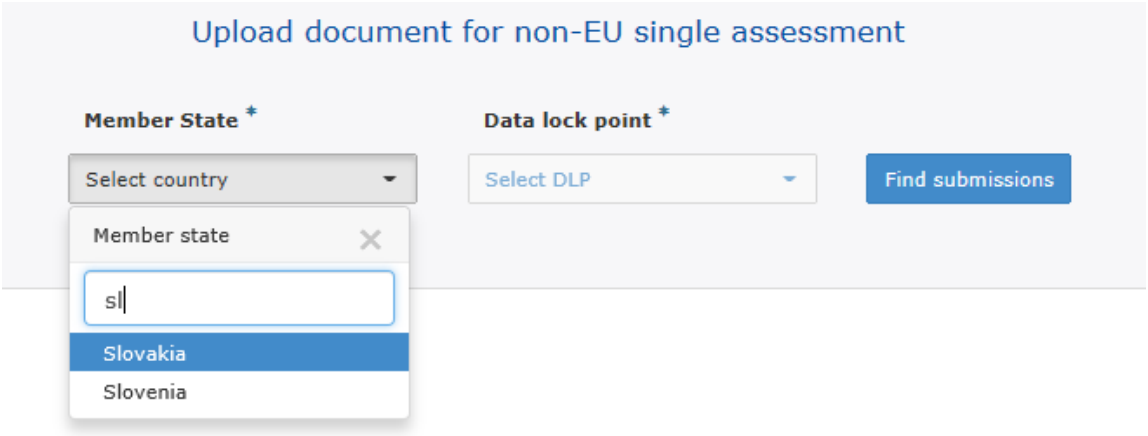


4.	The system will display a message to indicate the success or failure of the upload.	In cases of failure, please check the details and try again or contact EMA.

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

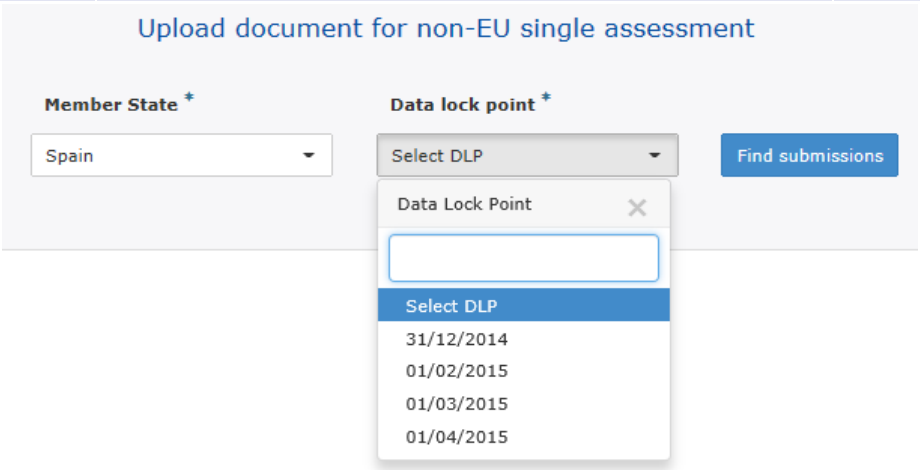
Step	Description	Notes
1.	Select ‘Upload’ from the top of the screen to navigate to the Upload page and select ‘Non-EU single assessment’.	

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

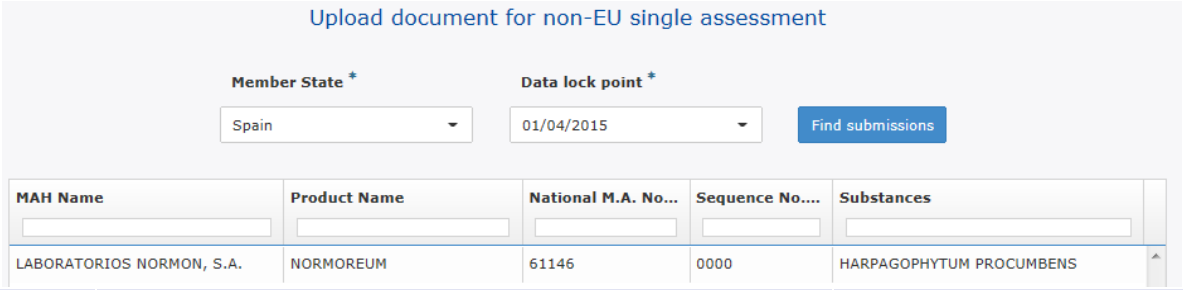


3.	Select the correct Data lock point for the procedure for which you wish to upload the assessment report and click	

	‘Find submissions’.	



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



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

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

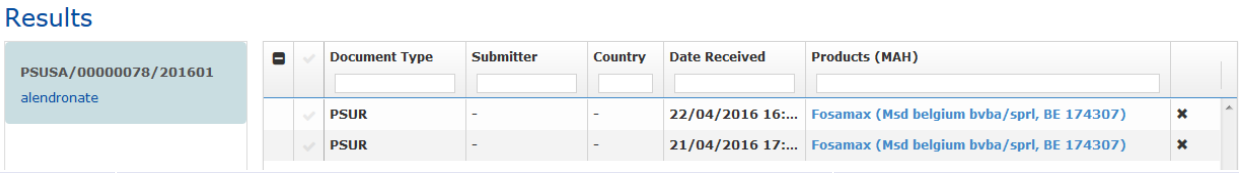
A full eCTD technical validation is run upon receipt of PSUR and supplemental information submissions to the PSUR Repository for Centrally Authorised Products. The EMA does not have the full product lifecycle for products authorised under Mutual Recognition, Decentralised and the National processes and 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.

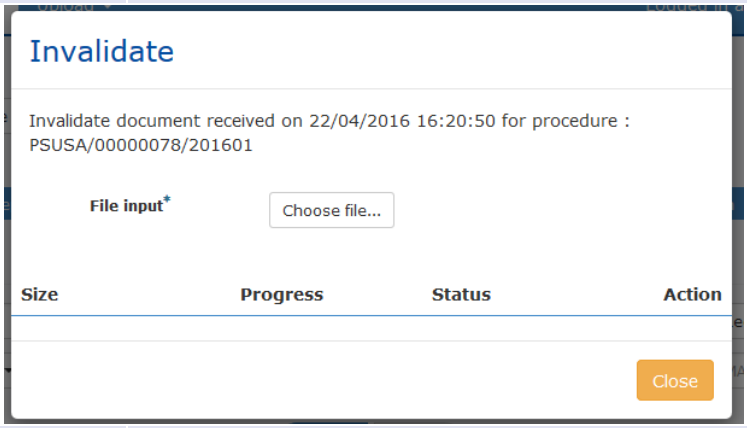
It may happen that after closer investigation and discussion between the relevant NCA and the MAH it is deemed that the PSUR submission is in fact valid and the invalidation issue was caused by an issue in a previous submission, the NCA can ‘revoke’ the invalidation. Once this revocation is performed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

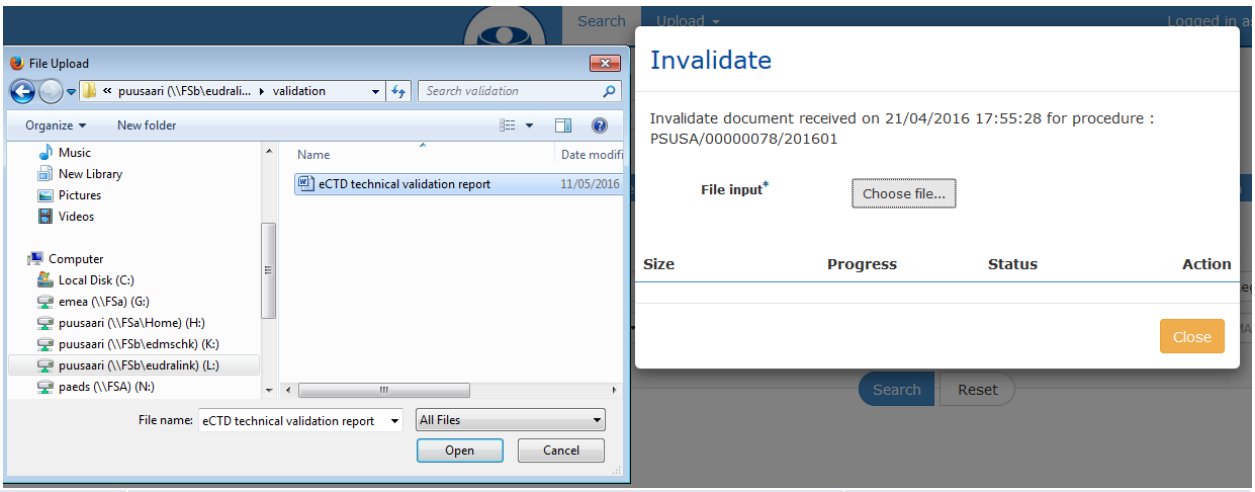
Step	Description	Notes
1.	Search for the procedure / submission as described in section 3. of this document. The submissions that can be invalidated by your NCA are indicated with an **X** in the right hand column of the search results.	Only the NCA who has the product in the market in their member state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



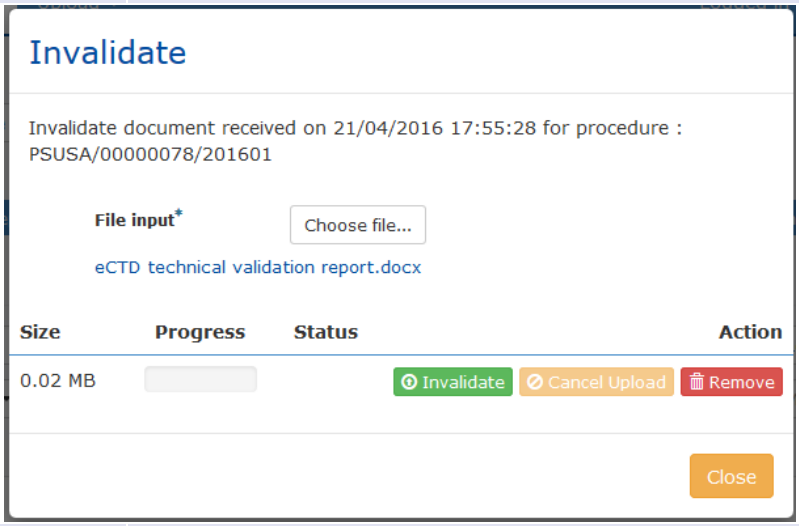
2.	Click the **X** in the last column to perform the invalidation.	Ensure you have the technical eCTD validation report from your eCTD validation tool in hand before performing this action.
3.	A pop up window will open that gives the date when the submission was received and the procedure number for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



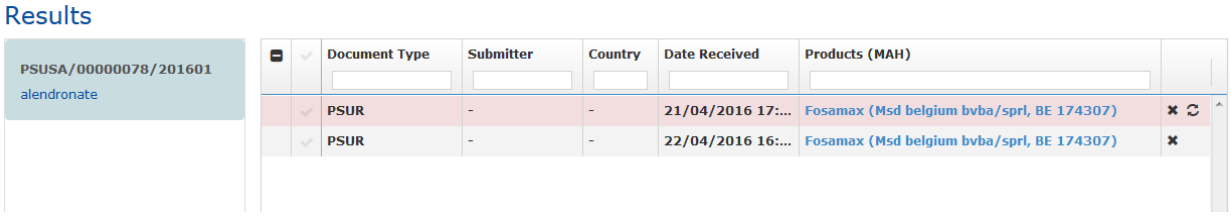
4.	Click 'choose file' button to upload the technical eCTD validation report from your validation tool.	



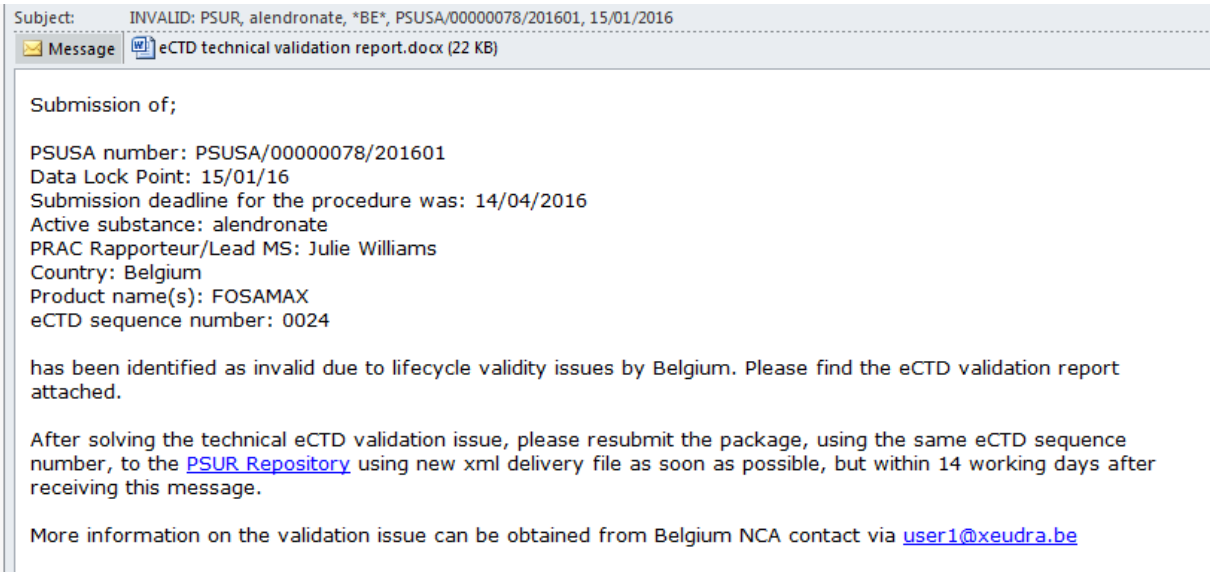
5.	Check that you have uploaded the correct document i.e. the technical validation report and click 'invalidate' button	



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



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.

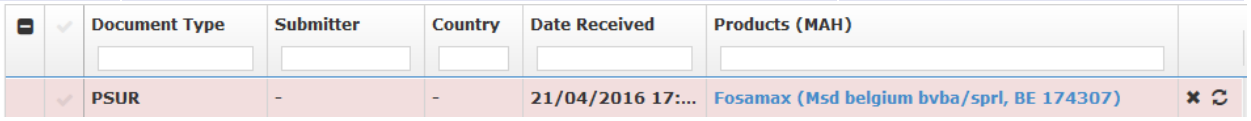
After solving the technical eCTD validation issue, please resubmit the package, using the same eCTD sequence number, to the PSUR Repository using new xml delivery file as soon as possible, but within 14 working days after receiving this message.

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 information submission to the PSUR repository using the same sequence number.	

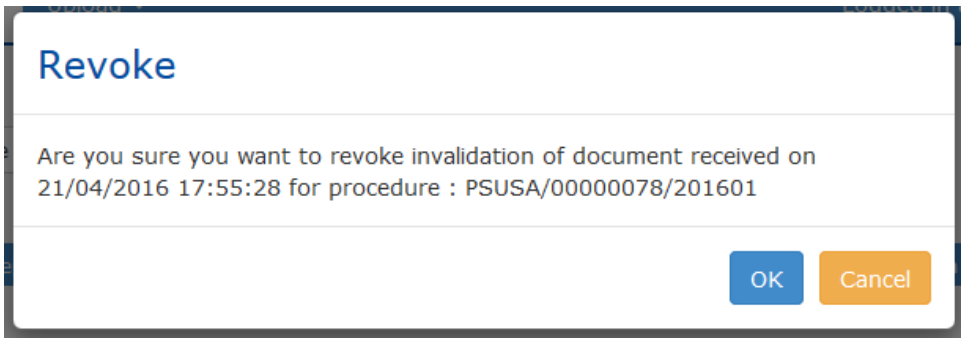
6.2. Detailed instructions how to revoke the invalidation eCTD submission in PSUR repository

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.



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

	Click the in the last column to perform the revoking of the invalidation. A pop up window will open that gives the date when the submission was received and the procedure number for visual confirmation.	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.

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. The notification contains a list of products that have been submitted for that particular procedure. The notification also contains a link to the PSUR repository which opens the relevant procedure in question.

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 acetylsalicylic acid, *HU*, PSUSA/00000039/201602, 01/02/2016

PSUR-REPO-XCOMP@ema.europa.eu

Sent: Mon 02/05/2016 00:15

To: Reddy Sasidhar V; esubUAT@ext.ema.europa.eu; esubUAT_Finland@ext.ema.europa.eu; esubUAT_Netherlands@ext.ema.euro
esubUAT_France@ext.ema.europa.eu; esubUAT_Germany@ext.ema.europa.eu; esubUAT_Spain@ext.ema.europa.eu; esubUAT
esubUAT_Croatia@ext.ema.europa.eu; esubUAT_Italy@ext.ema.europa.eu; esubUAT_Poland@ext.ema.europa.eu; esubUAT_(
esubUAT_Luxembourg@ext.ema.europa.eu; esubUAT_Latvia@ext.ema.europa.eu; esubUAT_Romania@ext.ema.europa.eu; esu

Message product.xlsx (36 KB)

Supplemental information has been received on 22/04/2016 and is ready for your review.

Active substance: diclofenac (topical formulations)
PRAC Rapporteur/Lead MS: Doris Stenver
Country: Denmark

List of products: please see attached excel sheet

You can download the document, using the following link https://psur-repo-xcomp.eudra.org/psur-ui?url=app/search/PSUSA_00010342_201509/supplinfo

7.1.2. PSUR start of procedure notification – no PSURs received

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.

PSUR nalmefene, *DE*, PSUSA/00010120/201602, 24/02/2016

PSUR-REPO-XCOMP@ema.europa.eu

Sent: Thu 05/05/2016 00:15

To: Reddy Sasidhar V; esubUAT@ext.ema.europa.eu; esubUAT_Finland@ext.ema.euro
esubUAT_Iceland@ext.ema.europa.eu; esubUAT_Croatia@ext.ema.europa.eu; esu
esubUAT_Romania@ext.ema.europa.eu; esubUAT_Slovakia@ext.ema.europa.eu; e
esubUAT_UnitedKingdom@ext.ema.europa.eu; esubUAT_Estonia@ext.ema.europa.eu

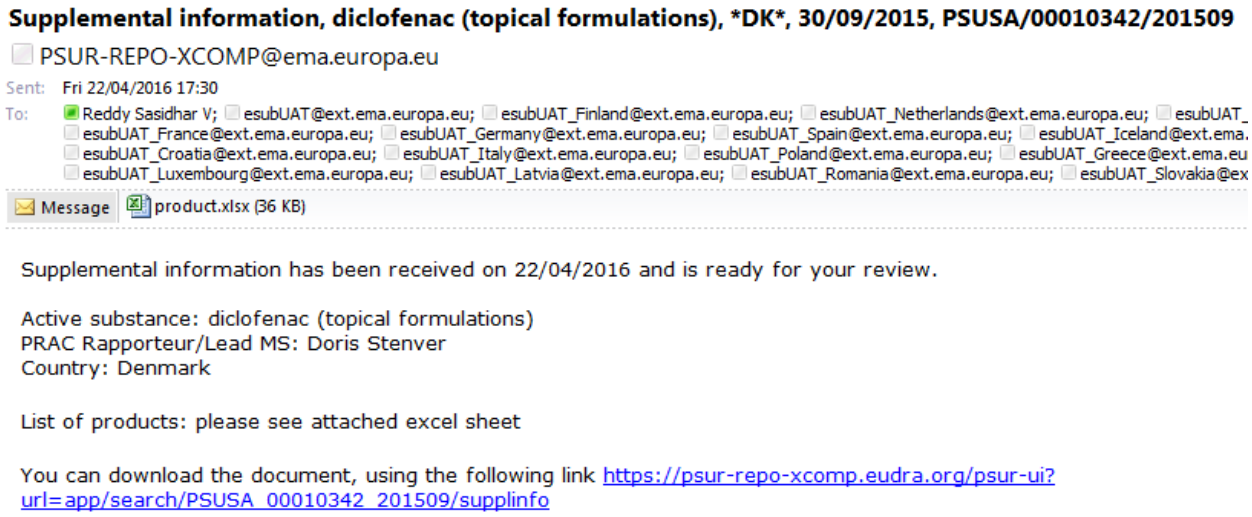
PSUSA number: PSUSA/00010120/201602
Data Lock Point: 24/02/16 00:00
Submission deadline for the procedure was 04/05/2016

Active substance: nalmefene
PRAC Rapporteur/Lead MS: Martin Huber
Country: Germany

No PSUR submissions have been recorded for this PSUSA

7.1.3. Supplemental information submission notification

When **supplemental information** is submitted a notification is now sent to all NCAs.



Supplemental information, diclofenac (topical formulations), *DK*, 30/09/2015, PSUSA/00010342/201509

PSUR-REPO-XCOMP@ema.europa.eu

Sent: Fri 22/04/2016 17:30

To: Reddy Sasidhar V; esubUAT@ext.ema.europa.eu; esubUAT_Finland@ext.ema.europa.eu; esubUAT_Netherlands@ext.ema.europa.eu; esubUAT_
esubUAT_France@ext.ema.europa.eu; esubUAT_Germany@ext.ema.europa.eu; esubUAT_Spain@ext.ema.europa.eu; esubUAT_Iceland@ext.ema.
esubUAT_Croatia@ext.ema.europa.eu; esubUAT_Italy@ext.ema.europa.eu; esubUAT_Poland@ext.ema.europa.eu; esubUAT_Greece@ext.ema.eu
esubUAT_Luxembourg@ext.ema.europa.eu; esubUAT_Latvia@ext.ema.europa.eu; esubUAT_Romania@ext.ema.europa.eu; esubUAT_Slovakia@ex

Message product.xlsx (36 KB)

Supplemental information has been received on 22/04/2016 and is ready for your review.

Active substance: diclofenac (topical formulations)
PRAC Rapporteur/Lead MS: Doris Stenver
Country: Denmark

List of products: please see attached excel sheet

You can download the document, using the following link https://psur-repo-xcomp.eudra.org/psur-ui?url=app/search/PSUSA_00010342_201509/supplinfo

7.1.4. 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.

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 incompliance 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

7.1.5. 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

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.

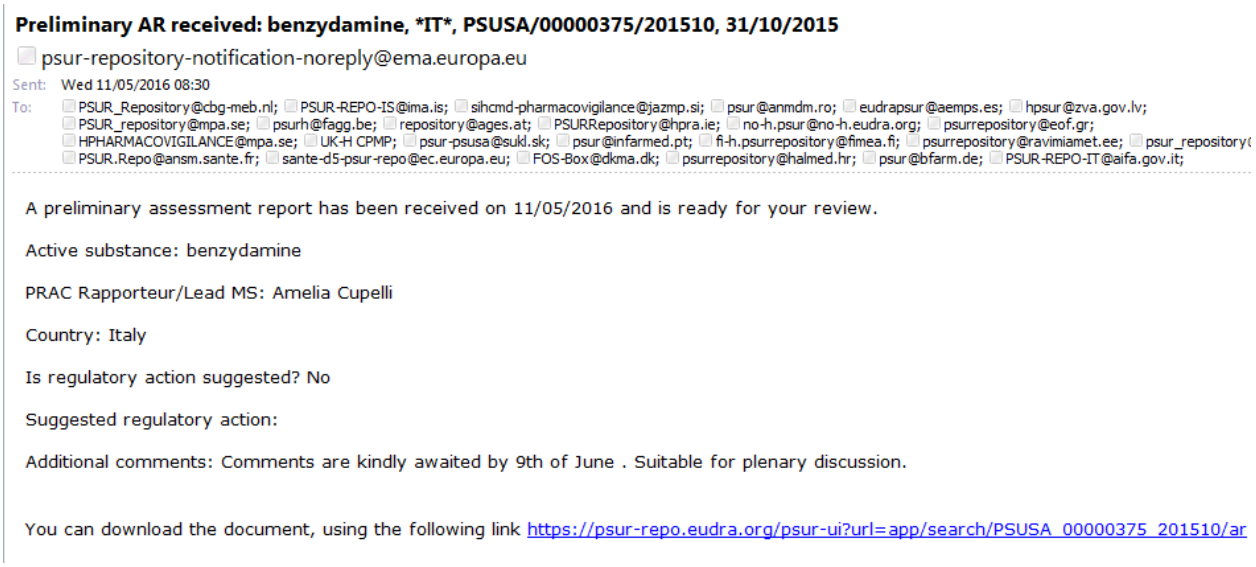
To upload your assessment report please log in to the PSUR Repository with your login credentials. https://psur-repo.eudra.org/psur-ui/

Yours sincerely,

Hesse Iris
Iris.Hesse@ema.europa.eu

7.1.6. 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; eudrapsur@aemps.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@ravimiamet.ee; psur_repository(PSUR.Repo@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

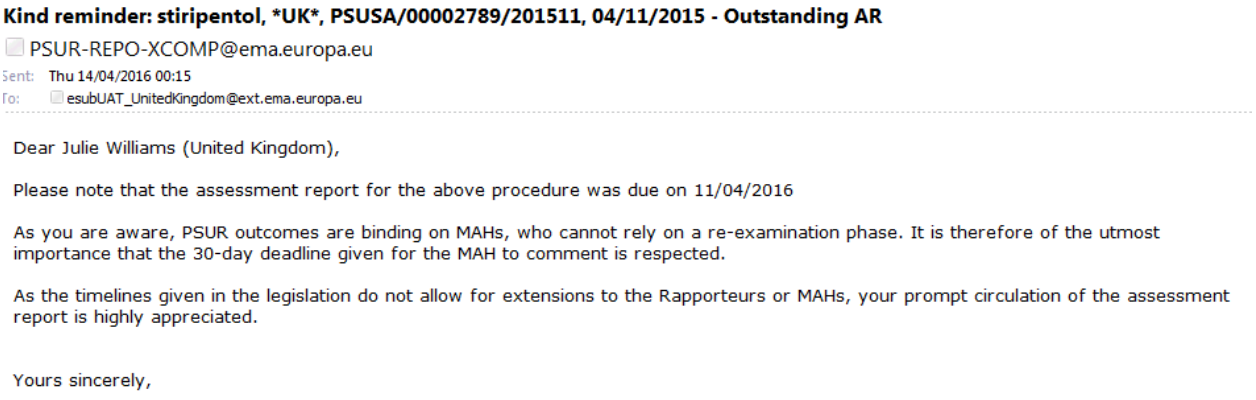
Suggested regulatory action:

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

7.1.7. 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.



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

To: 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,

7.1.8. 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: deferasirox, *FR*, PSUSA/00000939/201510, 31/10/2015

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

Sent: Tue 10/05/2016 17:50

To: PSUR_Repository@cbg-meb.nl; PSUR-REPO-IS@ima.is; sihcmd-pharmacovigilance@jazmp.si; psur@anmdm.ro; eudrapsur@aemps.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@ravimiamet.ee; psur_repository@ PSUR.Repo@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;

An updated assessment report has been received on 10/05/2016 and is ready for your review.

Active substance: deferasirox

PRAC Rapporteur/Lead MS: Corinne Féchant

Country: France

Is regulatory action suggested? No

Suggested regulatory action:

Plenary discussion: No

Silent adoption: No

Additional comments:

You can download the document, using the following link https://psur-repo.eudra.org/psur-ui?url=app/search/PSUSA_00000939_201510/ar

7.1.9. 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

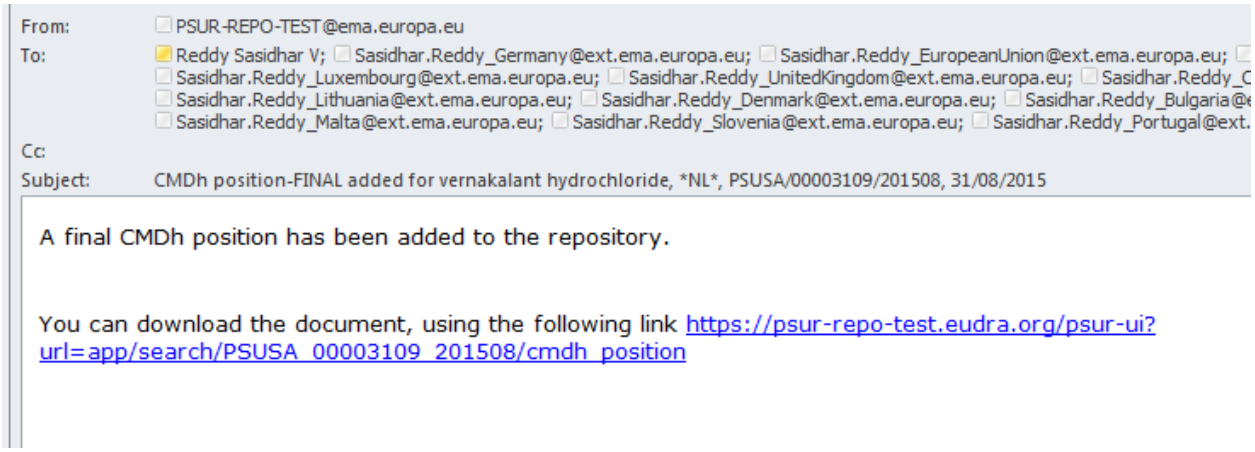
Commenting country: PT

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

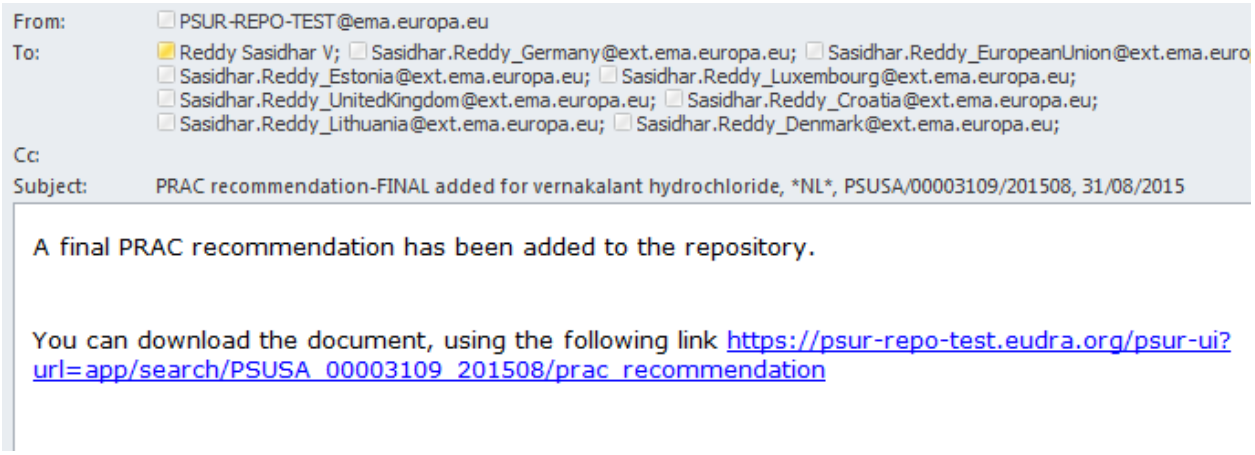
7.1.10. CMDh position notification

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



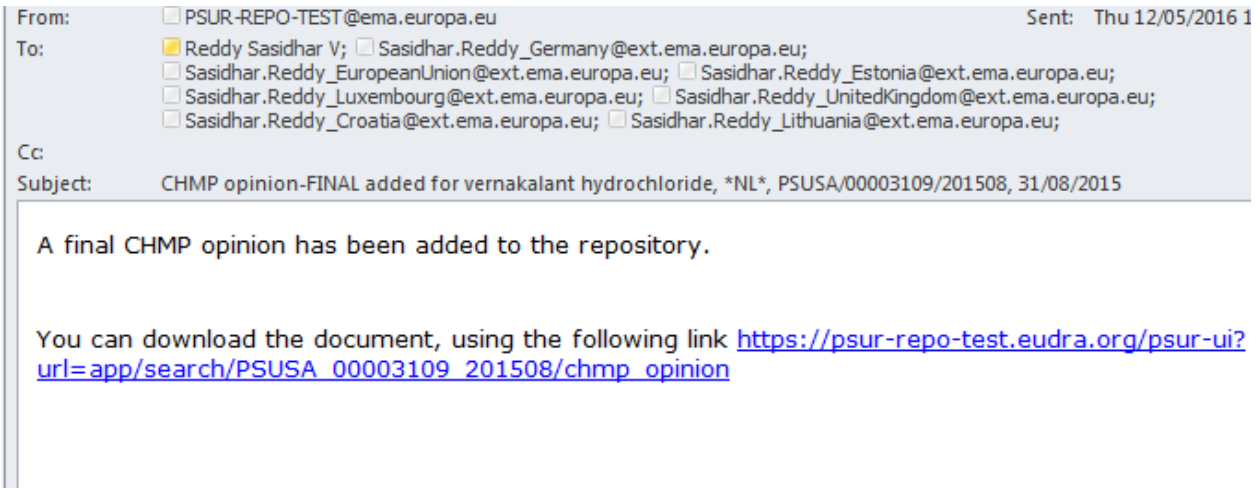
7.1.11. PRAC recommendation notification

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



7.1.12. CHMP opinion notification

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

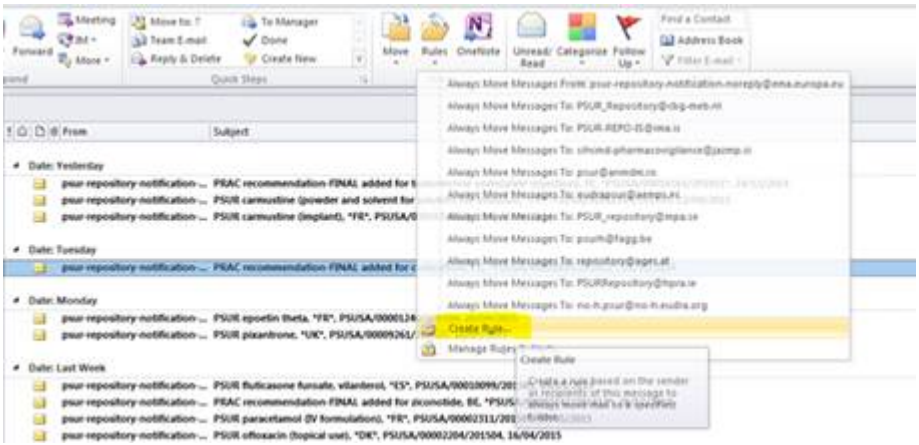


8. Filtering and auto-forwarding notifications

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:

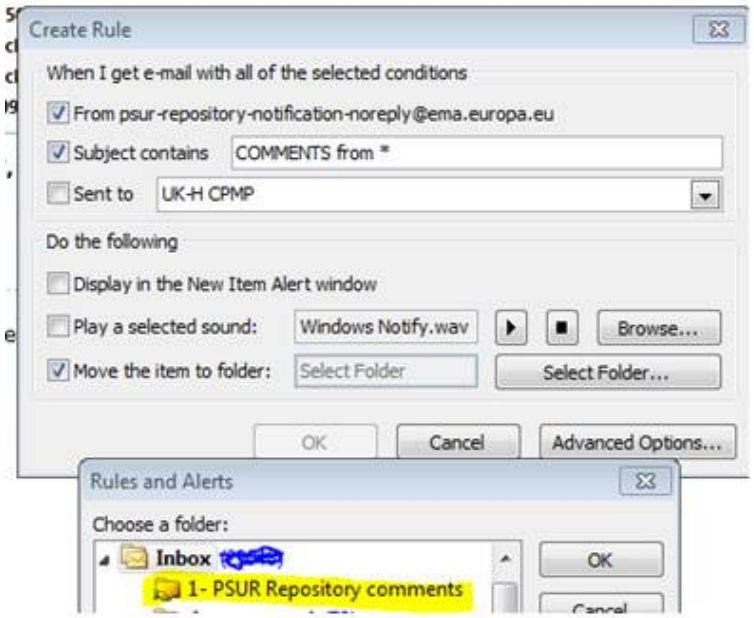


Once the **Create Rule** dialog box appears continue with the following steps:

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 **File**tab).

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 the following mailboxes

(gatewaysupport@ema.europa.eu, eCTD@ema.europa.eu and PSURrepository@ema.europa.eu).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 psurrepository@ema.europa.eu mailbox to submit your change 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.