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User Guidance for Marketing Authorisation Holders (MAHs) 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
1.1, 1.2	05/11/14	Added "Create delivery file" screens and annotation	Wasif Sabir
1.3	06/11/14	Added section on eSubmissions and restrictions around submission formats	Wasif Sabir
1.4	07/11/14	Reviewed and updated with additional comments on eCTD and NeeS restrictions. Also added note regarding file naming convention not required for PSUR and Supplemental Info submissions.	Wasif Sabir, Kristiina Puusaari
1.7	11/11/14	Added the correct EMA routing ID and URL for create delivery file	Wasif Sabir
2.0	17/04/15	Updated	
2.1	05/06/15	Updated to add information on how to submit MRP/DCP submissions in eCTD format	Kristiina Puusaari
3.0	06/08/15	Update information in line with release 01.03 e.g. fixing issues with product selection, multiple eCTD submissions for the same procedure	Kristiina Puusaari
4.0	12/10/15	Update information in line with release 01.04 e.g. complete change in the product selection functionality due to implementation of solution which links the procedure number and the products, use of indicator for 'grouped submissions' and inclusion of contact person email address in xml delivery file	Kristiina Puusaari
5.0	14/05/16	Update information in line with release 01.06 e.g. introduction of 'late submission ID' concept, automated provision of EMA product number for centrally authorised products and automated recognition of senders and receivers routing IDs. Unique identifier as a part of the delivery file name when saved and the ability to rename the delivery file. Automated messages to MAHs with request to resubmit if eCTD sequence is found to have lifecycle validity issues upon receipt by the relevant national competent authority.	Kristiina Puusaari
6.0	13/06/16	Updated to reflect mandatory use of the PSUR Repository	Kristiina Puusaari
7.0	22/07/16	Updated in line with the revised EU M1 Specification v3.0 and v3.0.1	Kristiina Puusaari
8.0	20/02/17	Updated to include additional information on non-EU PSUR submissions and to clarify how to place the	Kristiina Puusaari

Version	Date	Changes applied	Author
		delivery file in the submission package. Updated with information on inclusion of RMP in PSUSA submission (CAPs only)	

1. Introduction

This document serves as a simple guide for applicants to submit PSUR documents. It highlights the restrictions and conventions that users need to be aware of when generating submission and delivery files.

It also describes the existing constraints and workaround solutions to enable submissions to the repository.

The document assumes prior knowledge of the eSubmission gateway processes and will therefore focuses on the process of creating delivery files to be included in the submissions.

Formal communication regarding the changes to the PSUR submission process will be presented via the eSubmission website.

1.1. 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 further 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 study protocols and reports **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 for centrally authorised products are available to the NCAs via the Common Repository. For more information on the PASS 107 submissions please see EMA regulatory Post-Authorisation Guidance.

2. The submission Process

The MAHs are required to include a delivery file in the submission package. The use of the PSUR Repository is mandatory since 13th June 2016 and the submission of PSURs directly to National Competent Authorities is no longer accepted.

PSURs can be submitted in eCTD format (mandatory for all CAP submission) or NeeS format.

At a high level, submission to the PSUR repository is a two-step process:

1. Create a delivery file for your submission by navigating to create delivery file screen. See Create delivery file screen section.
2. Add the delivery file to the top-level folder of your document package and submit this document package via eSubmissions Gateway / Web Client. See eSubmission Gateway website for detailed guidance on how to register and use the gateway.

Note: The **filenaming conventions** for PSUR submissions **are not validated when a delivery file is included in the submission** and hence a simplified filenaming convention may be used for submissions to the PSUR Repository. Please see examples of these simplified filenames in Annex 3.

All eCTD format submissions for Centrally Authorised Products are run through an automated eCTD technical validation. A technical eCTD validation is done for all other eCTD format PSUR submissions however, as EMA does not hold the full product lifecycle for products authorised via Mutual Recognition Procedure, Decentralised Procedure or National authorisation procedures, a full lifecycle validation cannot be done at the time of the submission. This full lifecycle validation may be done by the receiving National Competent Authorities. If the NCAs detect lifecycle issues in the submissions in the PSUR Repository, they may trigger 'invalidation' of the submission. When performing the 'invalidation' in the PSUR Repository the NCA will need to provide a technical eCTD validation report. The Repository will send an automated email to the relevant MAH, with the validation report attached. This email is sent to the email address provided on the delivery file by the MAH at the time of the submission. The MAH should correct the issue in the submission sequence. If there are any questions or queries regarding the invalidation, the MAH should contact the relevant NCA directly. If it is confirmed that the submission has lifecycle issues and there is a need to resubmit but the submission deadline has already passed for this procedure, the MAH should contact EMA to request a late submission id and they can then proceed to resubmit. The submission should have the **same** eCTD sequence number as the invalid sequence.

If the MAH has any questions regarding the validation, they should contact the relevant NCA who triggered the invalidation. If the validation issue is found to be due to a different reason for example issue in a previous sequence, the NCA can trigger 'revocation' of the invalidation and an automated message will be sent to the MAH informing that they do not need to take any action and that the resubmission is not required.

2.1. Introduction of attribute 'submission unit' in eCTD EU Module 1

The **submission-unit** is a new attribute introduced in the EU Module 1 Specification v.3.0.

The following submission unit values may be used:

initial	Initial submission to start any regulatory activity – should be used for all **new** PSUR/PSUSA submissions
validation-response	For rectifying business validation issues – as PSUR procedure doesn't normally contain business validation this attribute should be used rarely.
response	Submission unit type that contains the response to any kind of question*, out-standing information requested by the agency * Use this unit for responses to Lists of Questions and Lists of Outstanding Issues, Requests for Supplementary Information, etc.
additional-info	Other additional information (could include, for example, missing files) and should only be used, if validation-response or response is not suitable – should be used only in exceptional cases for PSUR/PSUSA submissions.
closing	Submission unit type that provides the final documents in the centralised procedure following the decision of the European Commission – Closing sequence should not be sent to the PSUR Repository.

consolidating	This submission unit type should also be used when consolidating the dossier in as a result of withdrawing or rejecting a single regulatory activity (not in case of the withdrawal of the entire application/marketing authorisation).
corrigendum	Correction to the published annexes in the centralised procedure (usually shortly after approval)
reformat	Intended to support the reformatting of an existing submission application from any format to eCTD, i.e. a baseline eCTD submission containing no content change and which will not be subject to review (see example below). This type will always be used together with the submission type 'none' In the exceptional case of reformatting the application no regulatory activity (submission type) is allowed. Therefore, 'none' must be stated. The submission unit will identify the sub-activity related to the product. In the submission description some information can be provided to e.g. highlight specific modules being reformatted. The delivery file user interface will show value 'none' as reformat/baseline for usability reasons. The eCTD envelope should contain value 'none' for submission type and 'reformat' for submission unit.

2.2. PSUR submission for product lifecycle maintained using Electronic Common Technical Document (eCTD) format including examples of workaround solutions and constraints

There are a range of possible scenarios in which eCTD format could be used spanning across different marketing authorisation types. The following examples expand on the particularities of each possible combination in order for applicants to fully understand the submission requirements in each case.

2.2.1. Example 1: Duplicate CAP/NAP – eCTD format:

A PSUR covers centrally or nationally authorised **duplicate** products; product A and product B which are both managed using their own, **separate** eCTD product lifecycles. A separate submission is required for **each product** to ensure continuity of the eCTD lifecycles. **A separate delivery file needs to be created and attached for each submission**. The submissions should be linked together using the 'group of associated submissions' if a single PSUR document has been created for both products.

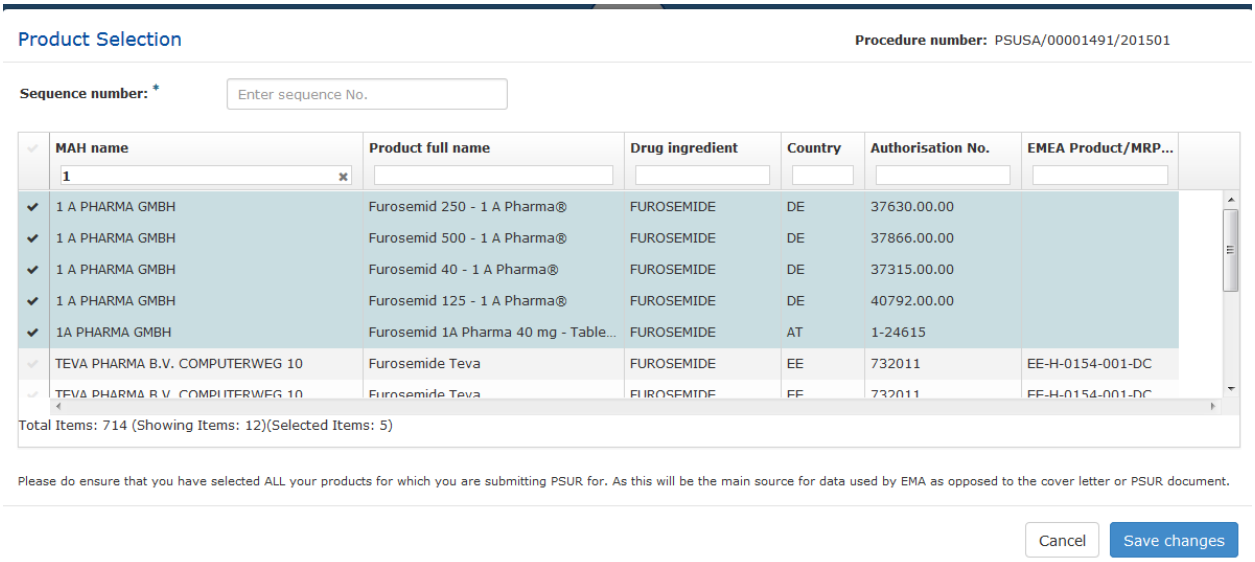
2.2.2. Example 2: MRP/DCP authorisation – comprehensive model (harmonised approach) using eCTD format:

A PSUR covers multiple products authorised via MRP/DCP procedure managed using a single harmonised eCTD lifecycle, this is also known as the 'Comprehensive model' which includes all strengths in all member states (MS) i.e. where the **same sequence number** is used for mutual submissions.

You can select one or **multiple** products from the list of product included in the procedure and create a single xml delivery file covering **all different products with the harmonised lifecycle** and just o**ne single submission** can be made.

It is important to note that the products must have harmonised lifecycle. This option cannot be used for products that have different eCTD lifecycles.

See example:



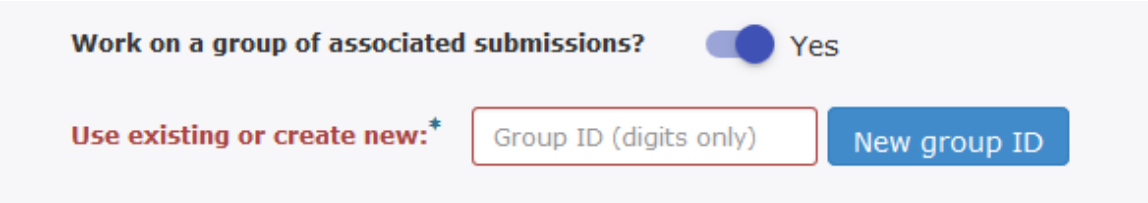
2.2.3. Example 3: MRP/DCP/National authorisation – eCTD format:

If you have prepared just one PSUR document covering multiple different products with separate individual lifecycles (not the comprehensive model) you will need to prepare an xml delivery file for each package. You can now indicate that these submissions are associated to each other by selecting 'yes' from 'work on a group of associated submissions' toggle button. The functionality to allow the association of different submissions with same PSUR content will allow 'deduplication' of PSURs by assessors at the member states during the review of the PSURs. You will have an option to generate a new 'Group ID' or use previously generated group ID in case one of the submissions which contain the same PSUR has failed. These packages should be sent to the PSUR repository using the eSubmission Gateway/Web Client.

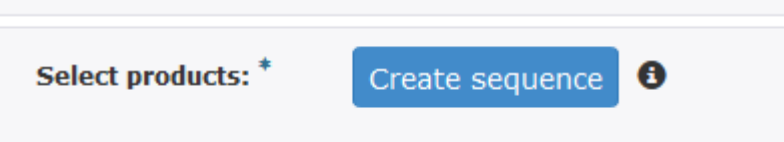
Note: this functionality can, and should, also be used to group together comments/responses relating to multiple products for which a common comments/responses document has been created i.e. the functionality to work on associated submissions should also be used when sending supplemental sequences for example 'responses'.

It is very important **not** to use the same group ID for submissions that contain **different PSURs** or to **mix PSURs and responses** as this functionality allows the 'Deduplication' of packages on the NCA side.

Work on a group of associated submissions:



Select 'create sequence' to create an xml delivery file for each package



2.3. PSUR submission for product lifecycle maintained using Non-eCTD Electronic Submission (NeeS) format

Due to the different nature of co-existing electronic formats, products maintained in NeeS format do not share the same level of constraints as those maintained in eCTD. In light of this, product lifecycles that are maintained in NeeS format allow the same submission to be used for multiple products. In the case of MAH having created a single PSUR for multiple products only one submission needs to be prepared and one delivery file can be created listing all products. See section 3.1.3. below for detailed instructions on how to create xml delivery file in this scenario.

2.4. PSUR containing a mixture of products maintained using eCTD and NeeS formats

When a PSUR contains multiple products that are maintained in different electronic formats it is **not** possible to combine the submission for these products and each will need to be submitted with different, relevant delivery file. A solution to enable sending of 'multiple zip packages at once is currently under investigation by the EMA. For example, a PSUR contains the following products:

Product name	Lifecycle format	Sequence number	Authorisation procedure
Product A	eCTD	Next eCTD lifecycle sequence number	CAP
Product B	eCTD	Next eCTD lifecycle sequence number	CAP
Product C	NeeS	Indicate the relevant sequence number in the delivery file. This should be the next sequential number in the product lifecycle or 0000.	NAP
Product D	NeeS	Indicate the relevant sequence number in the delivery file. This should be the next sequential number in the product lifecycle or 0000.	NAP
Product E	eCTD	Next eCTD lifecycle sequence number	NAP (MRP)
Product F	eCTD	Next eCTD lifecycle sequence number	NAP (MRP)

Product name	Lifecycle format	Sequence number	Authorisation procedure
Product G	eCTD	Next eCTD lifecycle sequence number	NAP (non-harmonised eCTD lifecycle)

In this example 5 delivery files need to be created and five separate submissions must be made:

- One for each eCTD lifecycle for CAP Products A and B.
- One for the two NeeS Products C and D. If a single submission is made for products C and D, it is very important to indicate the relevant sequence numbers for each product/presentation in the xml delivery file.
- **Note**: Due to a defect at the system the sequence number of the package attached should be the first product as listed in the delivery file xml. Due to the defect this is not the first sequence added to the delivery file when creating delivery file. Please open the delivery xml to check that the submission package corresponds with the first 'sequence number' listed on the xml. The EMA is currently working on fixing this issue.
- The receiving NCAs can rename the submission package as necessary when adding the sequence as a part of the product NeeS lifecycle. This can be mentioned in the submission cover letter to alert the NCA to rename the package upon upload to their review tool.
- One for the two eCTD Products E and F with harmonised eCTD lifecycle.
- One for eCTD lifecycle for product G which does not have same harmonised lifecycle.

See section 3.1.2.

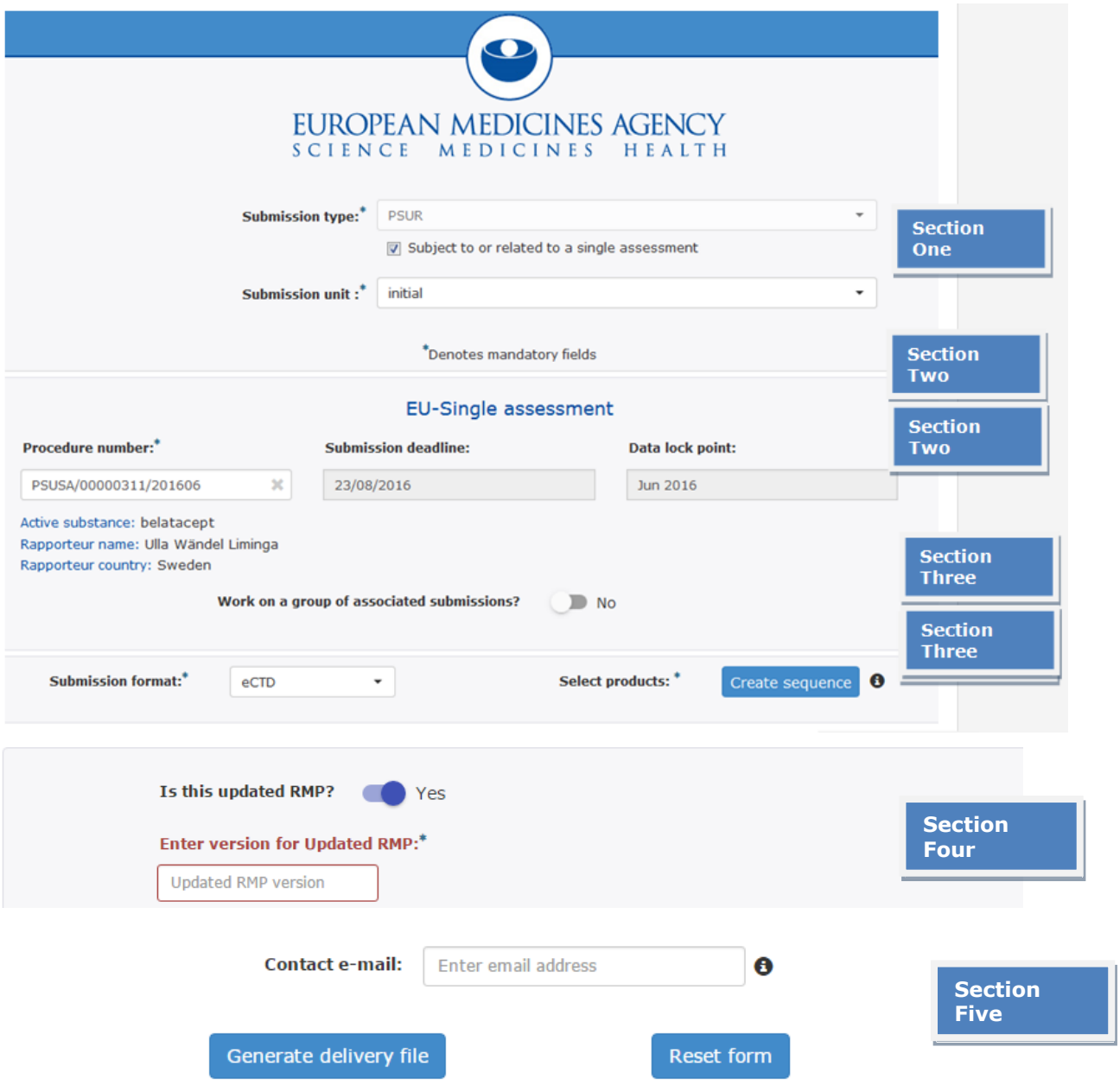
2.5. PSUR submission of single, pure NAP (submissions for products not listed in the EURD list and products for which the active substance has been authorised in just one member state)

At a high level the process is exactly the same as for PSURs included in an EU PSUR Single Assessment, see above.

The rules for product selection are the same; please see sections 2.1-2.3 below.

3. Create delivery file screen

Each delivery file that is generated will have a unique name consisting of word 'delivery' with a number, for example 'delivery_435108440'. The delivery file may be renamed and there are no restrictions on the number of characters to be included. **If the delivery file is renamed it is important to note that it must always contain word "delivery".**



The screen is divided into five sections:

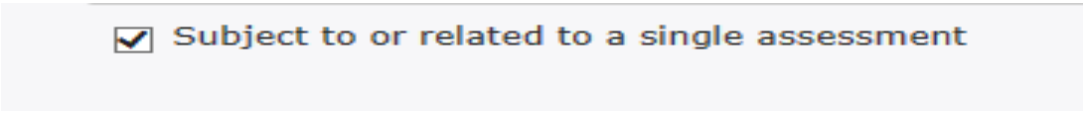
Section 1: Regulatory activity with submission type and submission unit and type of assessment
Section 2: Details of the assessment procedure[1]
Section 3: Product selection
Section 4: Information on Updated RMP (CAP only)
Section 5: MAH contact email address

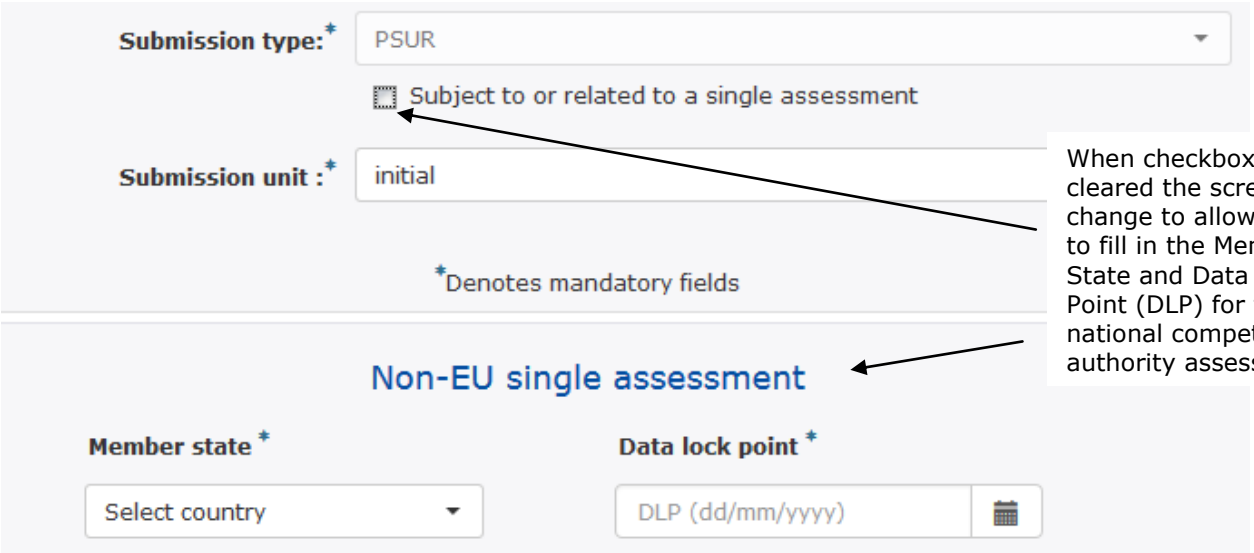
The user will be required to complete all fields in each section.

[1] This section will change to display "Non-EU single assessment" if the checkbox in section one is deselected

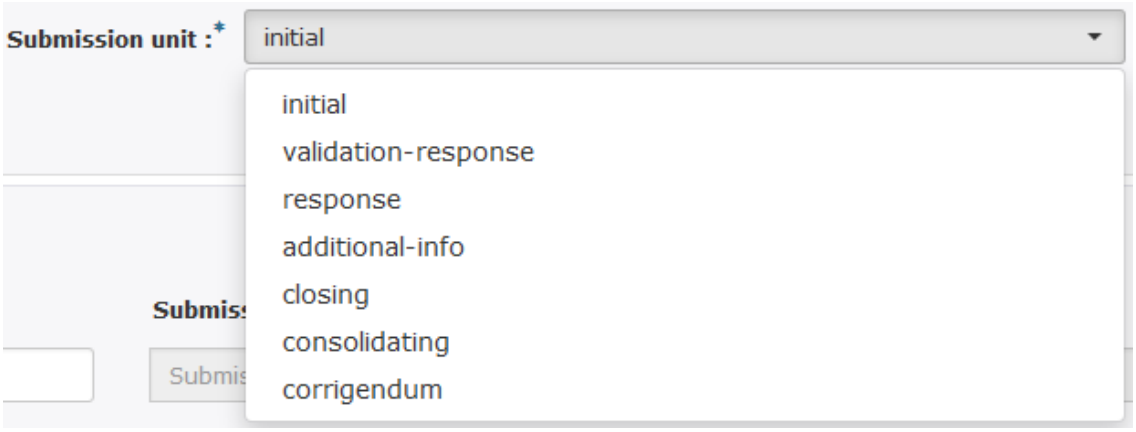
Step	Description	Notes
1	Submission type for PSURs included in the PSUR Single Assessment is always PSUSA (as per the EU Module 1 specification). Submission type for non EU Single Assessment PSURs is PSUR. The ability to create the delivery file for a PSUSAsubmission is linked to the submission deadline published on the EURD list. If the submission deadline for your procedure has already passed, please contact EMA as soon as possible via the EMA service desk portalto request for a late submission ID.	Creation of delivery file for any subsequent sequences (responses, additional information etc) after the initial PSUR submission is **not** linked to a submission deadline and **no** late submission ID is required.

2	Indicate whether the submission is for single assessment.	The checkbox is ticked by default

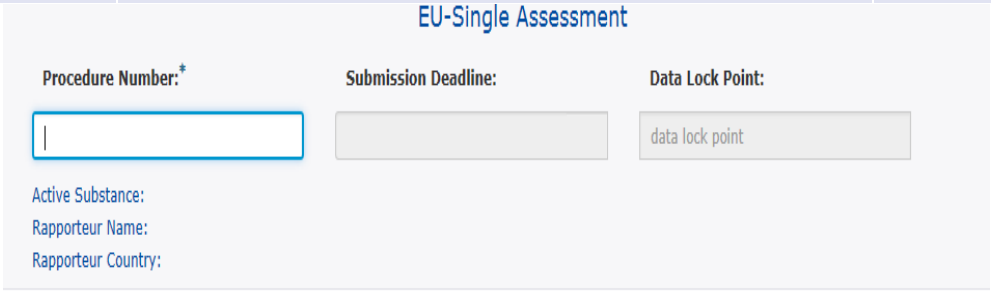




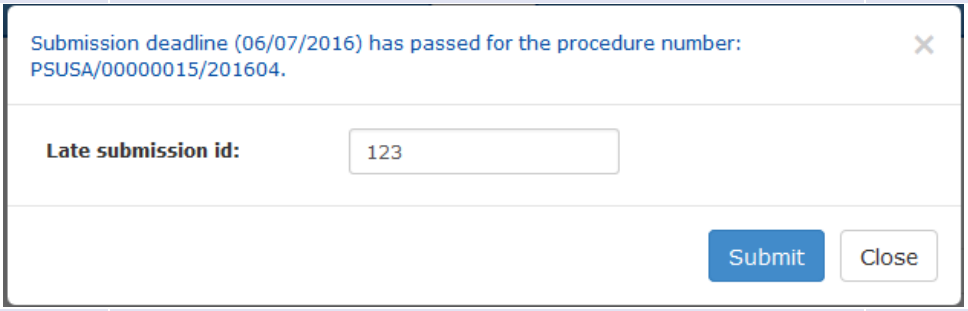
3	Select the Submission unit from the list. The selection is defaulted to 'initial'. If you are submitting responses or comments, submission unit 'responses' should be used.	



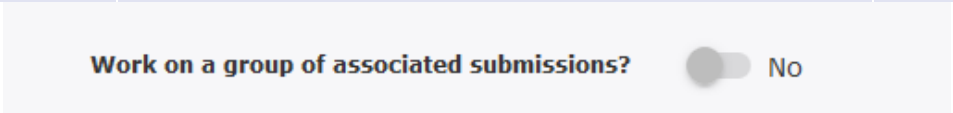
4	Search and select the PSUR procedure number as in EURD list by typing at least 4 characters, for example 2016.	



4	For late submission, enter the late submission ID provided by EMA in the 'late submission ID' pop up window. The late submission ID is linked to the procedure it was created for and cannot be used for other procedures. If you have requested multiple late submission IDs please ensure you use the correct id for the corresponding procedure.	

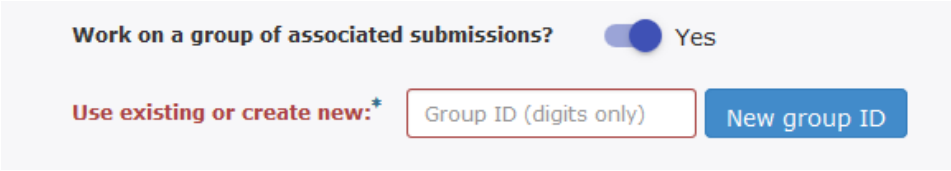


5	Indicate if you want to group together associated submissions i.e. you have created just one single PSUR covering multiple products that have different eCTD or mixed eCTD and NeeS lifecycles	

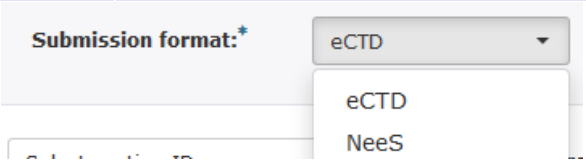


6	Generate a 'New Group ID' or use one you have previously generated and noted down if one of the submissions for associated products has failed	Do not use the same group ID to send a PSUR for products for which a different PSUR document has been prepared.

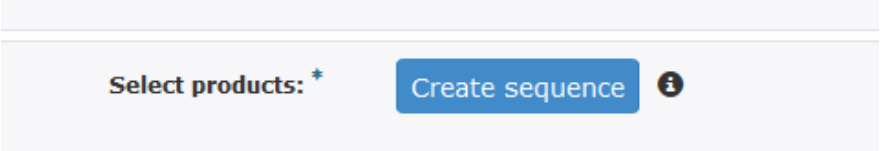
		Do not use the same group ID for sending PSURs and responses.



7	Select the submission format (eCTD or NeeS).	For eCTD submissions only one sequence can be added. For NeeS submissions multiple sequences can be added by repeating the product selection step as many times as required.



8	Click 'Create sequence' to display the list of products containing the relevant active substance(s) based on the procedure number from the EURD list.	

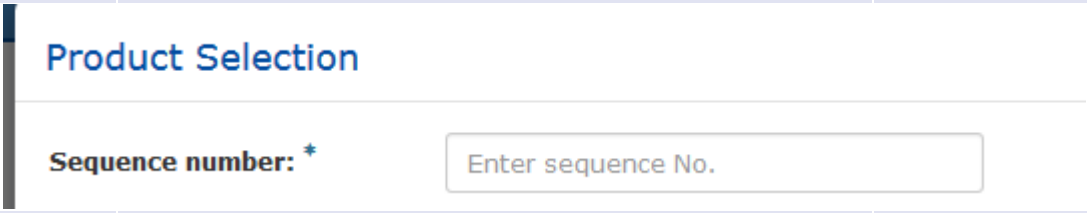


9	The system will display a list of **all** products containing the relevant active substance(s). The products are presented with all presentations, strengths and formulations. **Important**: Ensure you select all relevant presentations from the list, the products selected in the delivery note form the scope of the procedure and products/presentations that are not included in the delivery file are not considered as a part of the procedure. The list can be filtered by the MAH name/product full name, drug ingredient, authorisation country, the authorisation number and EMEA/MRP/DCP number.	All different 'generic' products and different language products are also displayed on the list. Correct product listing in the delivery file is essential to ensure that the procedure scope is correct. Annex 1 listing the products should **not** be provided.

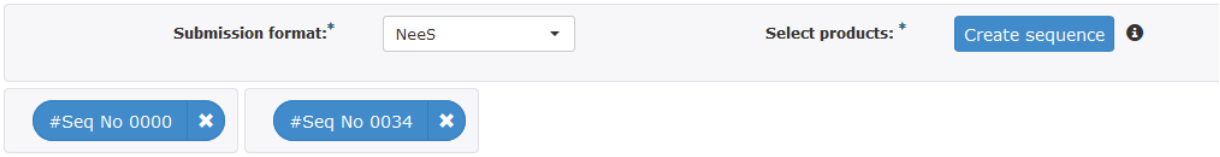
MAH name	Product full name	Drug ingredient	Country	Authorisation
SANOFI-AVENTIS SA	SEGURIL 250 MG SOLUCION INYECT...	FUROSEMIDE	ES	56508
SANOFI-AVENTIS SA	SEGURIL 20 MG SOLUCION INYECTA...	FUROSEMIDE	ES	39968
TAKEDA OY	Vesix® 40 mg -tabletti	FUROSEMIDE	FI	7988
TAKEDA OY	Vesix® Special 500 mg -tabletti	FUROSEMIDE	FI	7989
ACTAVIS EAD	Фурантрил 40 mg таблетки	FUROSEMIDE	BG	20000377
SOPHARMA AD	Фуроземид Софарма 40 mg таблет...	FUROSEMIDE	BG	20010702
SOPHARMA AD	Фуроземид Софарма 10 mg/ml инж...	FUROSEMIDE	BG	20010605

Total Items: 714

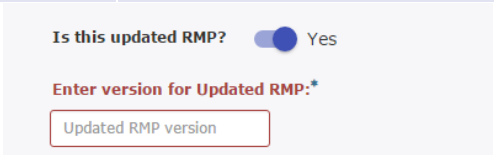
10	Enter the submission sequence number on the top of the product selection window.	



11	Only **one** sequence number can be entered per product selection window. If NeeS products have multiple different sequence numbers but just single PSUR document, multiple sequences can be added to a single delivery file by repeating 'create sequence step'.	



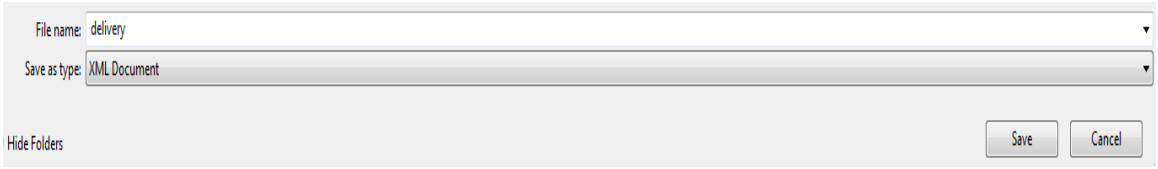
12	Complete the product selection steps.	See 0
13	For **CAPs included in PSUSA procedures** it is now possible to indicate that the submission includes an updated RMP. Please provide the relevant RMP number.	RMP should be provided only in case it is a direct result of this PSUSA procedure



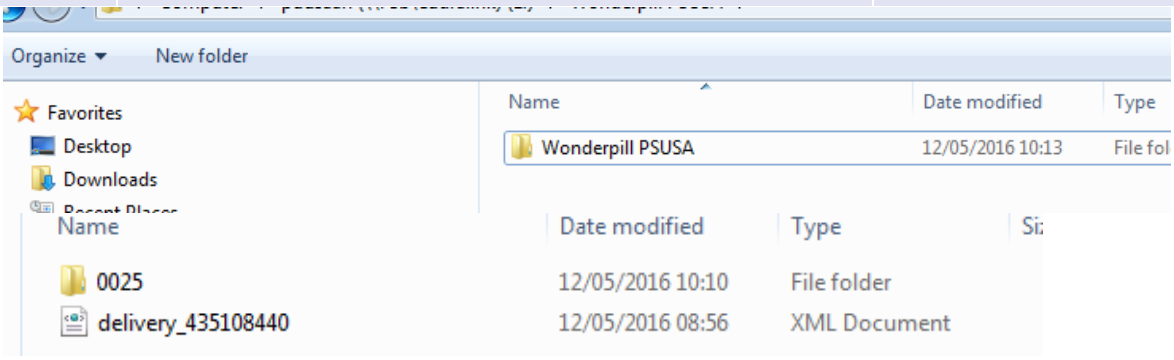
13	Enter email address of the person who is the responsible contact for the PSUSA procedure. All relevant correspondence will be sent to this email address.	

14	Click "Generate Delivery File" and save the file to your local machine.	The delivery file may be renamed however it must always contain word

		"delivery".



15	Add the delivery file to the submission ZIP file package on the root level i.e. the same level with the submission sequence folder and submit via the eSubmissions gateway.	The delivery file name must contain word "delivery". The file must be placed in the top level of your ZIP package.



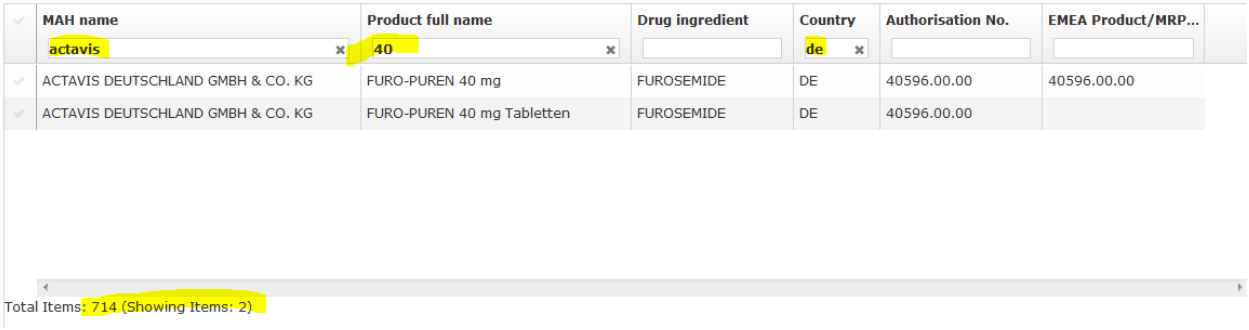
3.1. Product Selection

Product selection is the process of identifying the products which are relevant to a particular PSUR procedure in the MAH user interface. The product selection scenarios described below apply to both EU and non-EU single assessment.

3.1.1. Filtering authorised product listing

Once you have entered the relevant PSUSA procedure number the system will display a full list of authorised products that relate to that particular PSUSA procedure. The prerequisite for the availability of products in the product selection screen is that all relevant products have been correctly entered in the Extended Medicinal Product Dictionary (XEVMPD), also known as Art. 57 database. Products are only shown in the user interface if the correct legal basis for the product is reflected in Art. 57 as according to the EURD list, some procedures do not require submissions for products authorised under Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC as amended.

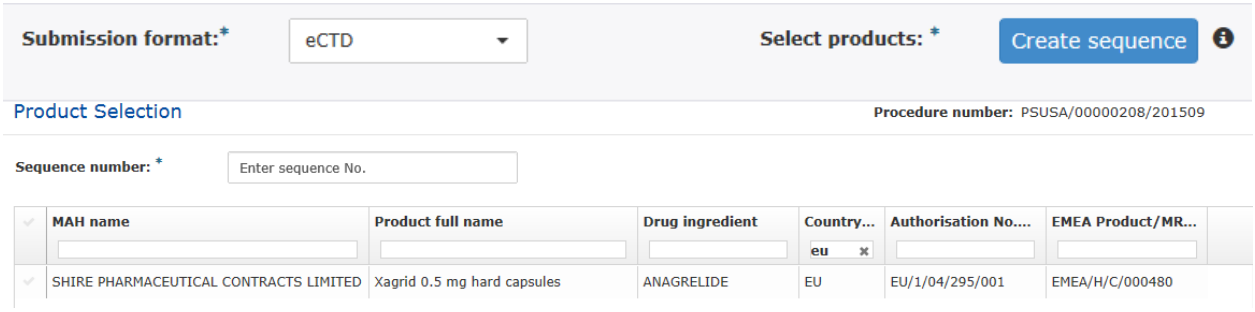
As all products relevant to the procedure are listed and hence the list can contain hundreds of products/presentations you can filter the results to narrow down the list and find the specific items that are interested in. Any part of the MAH name, product full name, authorisation number(s) and/or procedure numbers can be searched. It is very important to select **all relevant products and presentations,** using this functionality as the evaluation process relies on the accurate information provided by the MAH in this step.



3.1.2. Scenario 1: The submission relates to a centrally authorised product (CAP) which will always require eCTD submission format or a Nationally Authorised or MRP/DCP product in eCTD format which does not have a harmonised lifecycle

Step	Description	Notes
1	Select submission format from the dropdown list – eCTD –	Screen extract 1
2	Click 'Create sequence button' to access the product selection window	Screen extract 1
3	Full list of products included in the procedure is displayed. Filter the list of products to select presentations for which you are submitting the PSUR for	Screen extract 1

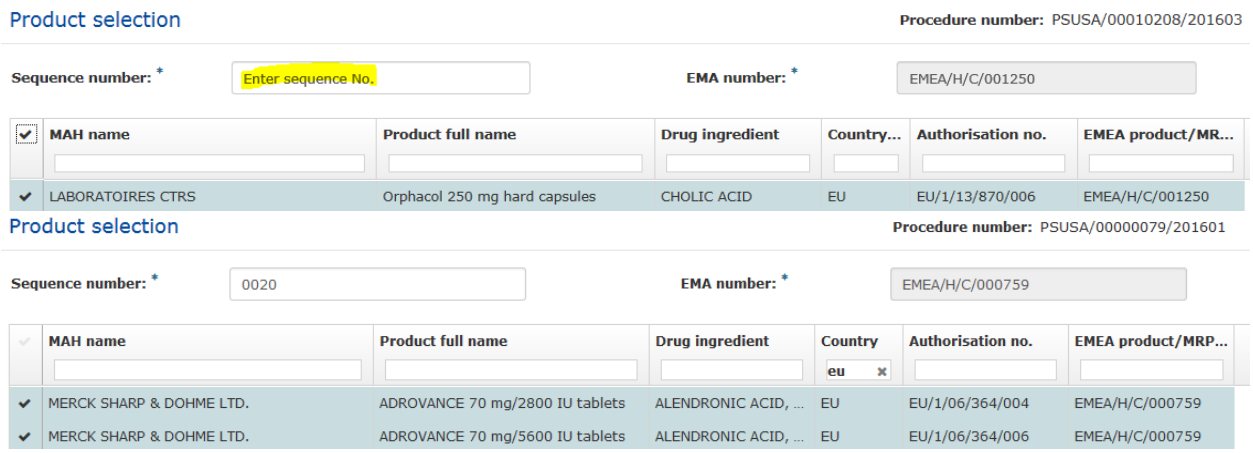
Screen extract 1 – Product selection



5	Provide the sequence number. For eCTD submissions this is the next available sequence number in the product lifecycle.	Screen extract 2
7	Select all relevant 'products/presentations/strengths' that are listed in the PSUR document being submitted. You can select all the	Screen extract 2

	'products/presentations/strengths' by clicking beside the column header "MAH Name" or you can select individual products by clicking on the corresponding rows. **For eCTD submissions for CAPs and NAPs that do not have harmonised lifecycle, only one product (with all its presentations) can be selected.** It is **not** possible to add NeeS submissions as part of the eCTD delivery file and a separate delivery file and separate submission must be prepared. For those eCTD products that share a harmonised single lifecycle see scenario 2.	

Screen extract 2 -

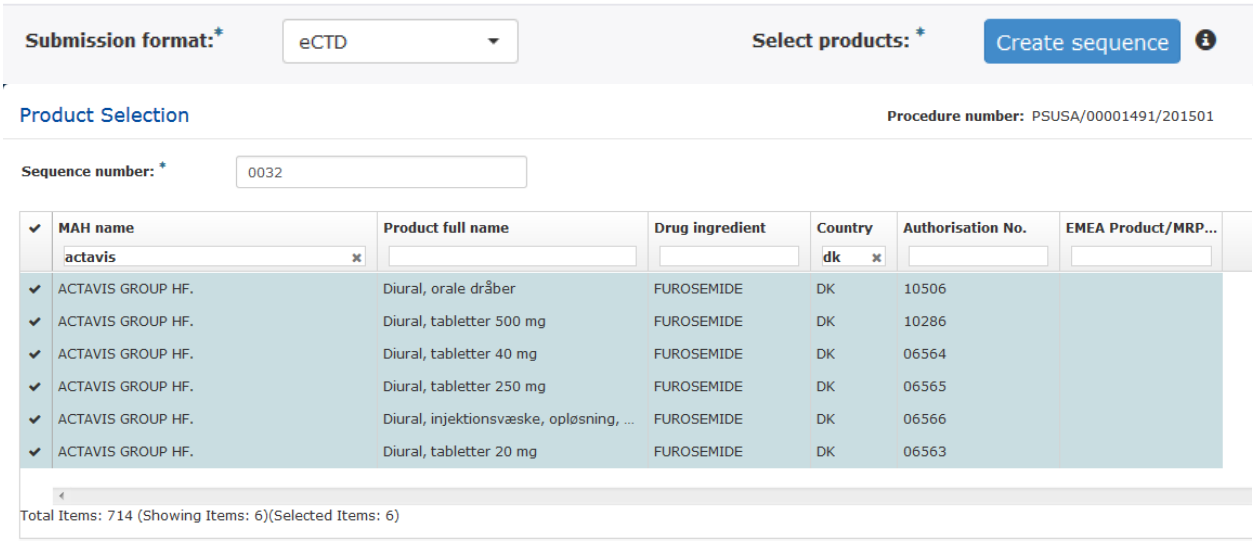


3.1.3. Scenario 2: The submission relates to MRP/DCP products with harmonised, comprehensive lifecycle in eCTD format

Step	Description	Notes
1.	Select submission format from the dropdown list – eCTD.	Screen extract 3
2.	and Click 'Create sequence button' to access the product selection window.	Screen extract 3
3.	Provide the single sequence number at the package level. The submission can only contain one zip file that is shared between the products. It is not possible to send a package that contains one delivery file for multiple different zips that are sent together. (See screen extract below).	Screen extract 3
4.	Full list of products included in the procedure is displayed. Filter the list of products to select one or more of the products/presentations/strengths that are listed in the PSUR document being submitted. You can select all the products by clicking beside the column header "MAH Name" or you can select individual products/presentations/strengths by clicking on the corresponding rows for which you are submitting the PSUR for.	Screen extract 3
5.	Select one or more of the products/presentations strengths that are listed in the PSUR/responses being submitted. You can select all the products by	Screen

Step	Description	Notes
	clicking beside the column header "MAH Name" or you can select individual products/strengths by clicking on the corresponding rows.	extract 3

Screen extract 3 - Add multiple products

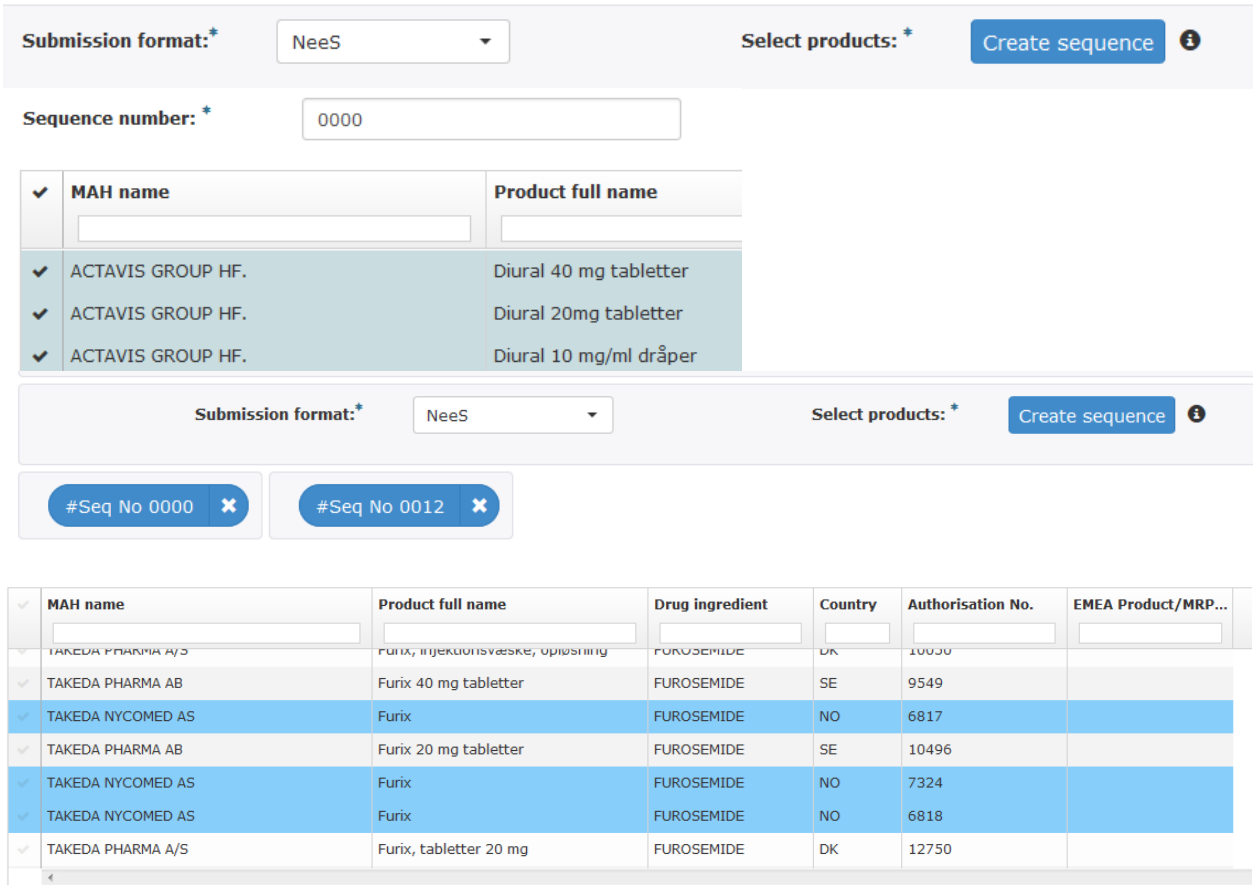


3.1.4. Scenario 2: The submission relates to nationally authorised product (NAP) and requires NeeS submission format

Step	Description	Notes
1.	Select submission format from the dropdown list – NeeS.	Screen extract 4
2.	Click 'Create sequence' to display the full list products included in the procedure.	Screen extract 4
3.	Provide the sequence number. As the NeeS submission sequence number is not linked to the submission envelope, this information is requested for the use of the NCAs who can use the sequence number relevant for each product when uploading submissions to their review systems. The submission can only contain one zip file that is shared between the products. If a single submission is provided covering multiple products in NeeS format, the submission sequence package should correspond with the first sequence number mentioned on the xml delivery file and the receiving NCAs can rename the package upon receipt according to the relevant sequence number indicated in the delivery file for each product. It is not possible to send a package that contains one delivery file for multiple different zips that are sent together. (See screen extract below).	Screen extract 4
4.	Full list of products included in the procedure is displayed. Filter the list of	Screen

Step	Description	Notes
	products to select one or more of the products/presentations/strengths that are listed in the PSUR document being submitted. You can select all the products by clicking beside the column header "MAH Name" or you can select individual products/presentations/strengths by clicking on the corresponding rows for which you are submitting the PSUR for.	extract 4
5.	Click 'save changes' to add selected products to a sequence. The product selection window will be closed and sequence is displayed in the screen with the sequence number visible. You can view and modify (add/delete products/presentations) this sequence by clicking to it. You can delete the whole sequence by clicking the button next to the sequence number.	Screen extract 4
6.	Repeat steps 2 to 6 above until you have the list of products/presentations that match the content of your PSUR/responses document. Please note that the same product/presentation/strength cannot be selected for different sequences. The products already selected are highlighted in blue to indicate that they have already been selected for another sequence.	Screen extract 4

Screen extract 4 - Add multiple products



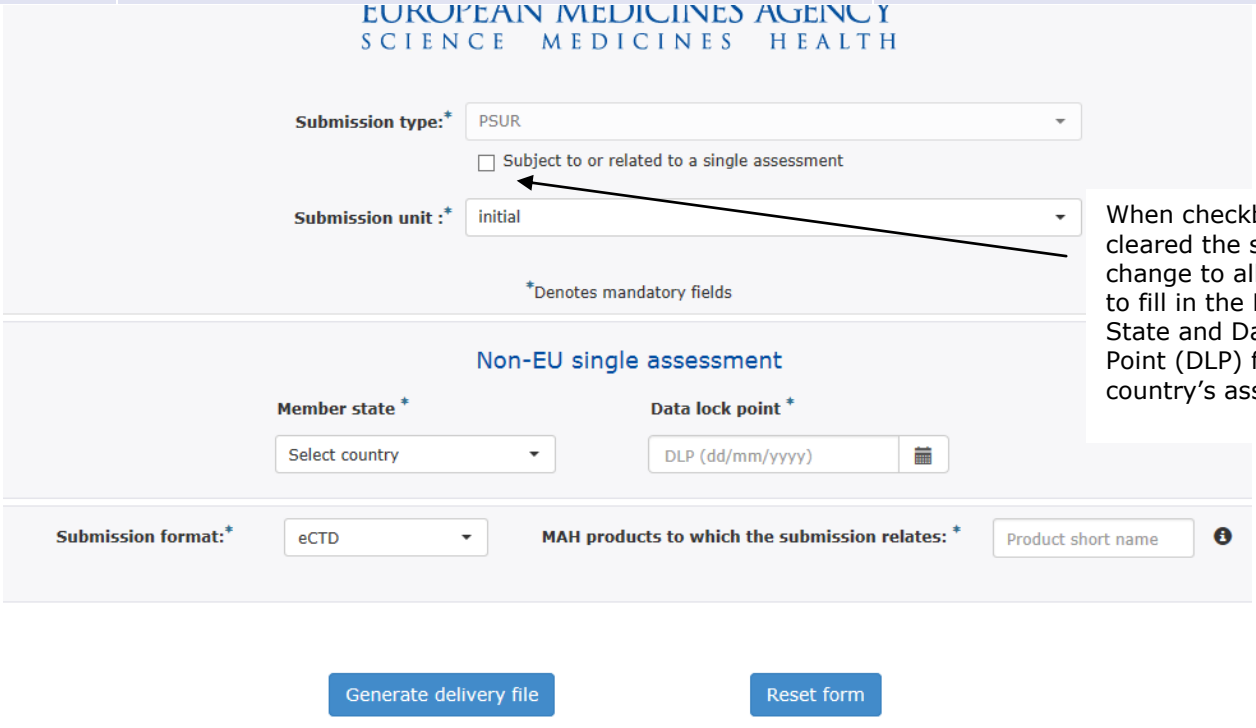
3.1.5. Scenario 3: The submission relates to a pure, single NAP submission outside the EU single assessment

PSURs for products for which the active substance is not in the EURD list, should be sent using the 'Non-EU single assessment mode. The current functionality of the PSUR repository does not allow selection of multiple member states for PSURs not governed the EURD list. This functionality will be further developed to allow selection of multiple member states in a future release.

For these types of submissions, when the product has harmonised lifecycle, as a workaround solution, please select the Reference Member State as the 'Member State' in the XML delivery file and submit the PSUR using the non-EU functionality. The PSUR Repository will send a notification to the selected NCA only. The RMS should inform the CMS' that the submission is available in the PSUR Repository.

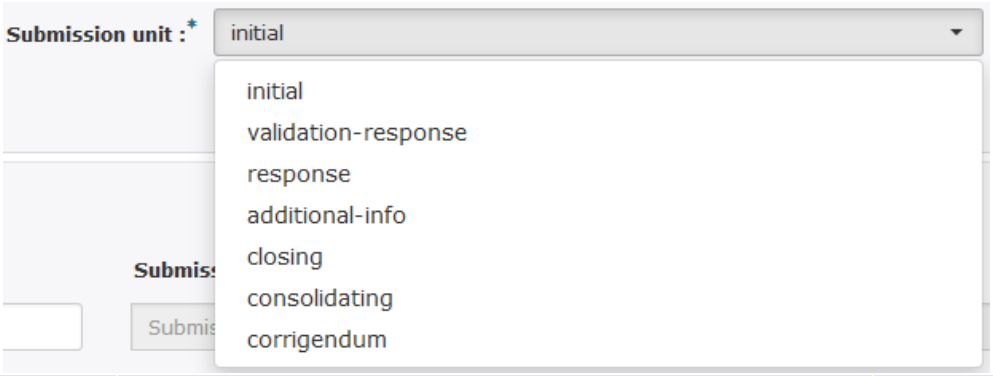
Step	Description	Notes
1	Submission type for PSURs outside EU Single Assessment is always PSUR (as per the EU Module 1 specification).	

2	Ensure you untick the checkbox to reflect that the submission is for single assessment.	The checkbox is ticked by default

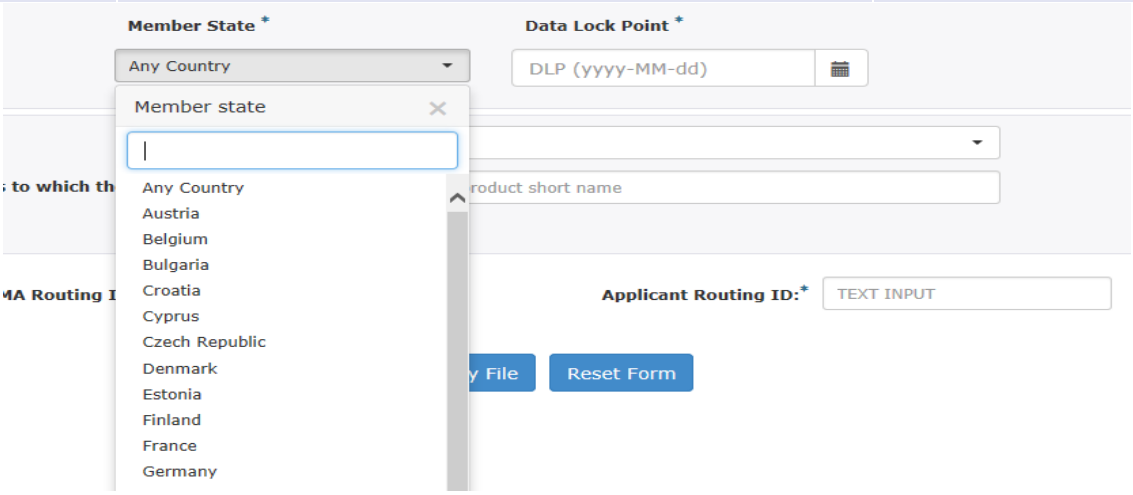


When checkbox is cleared the screen will change to allow the user to fill in the Member State and Data Lock Point (DLP) for the local country's assessment

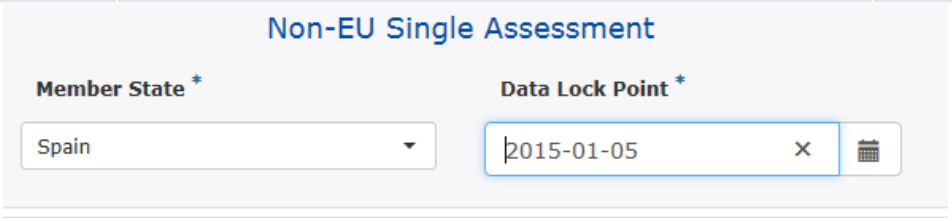
3	Select the Submission unit from the list. The selection is defaulted to 'initial'. If you are submitting responses or comments, submission unit 'responses' should be used.	



4	Select the Member state where product is authorised by typing the name or from the list.	Dropdown menu which can be filtered by typing in the search box.



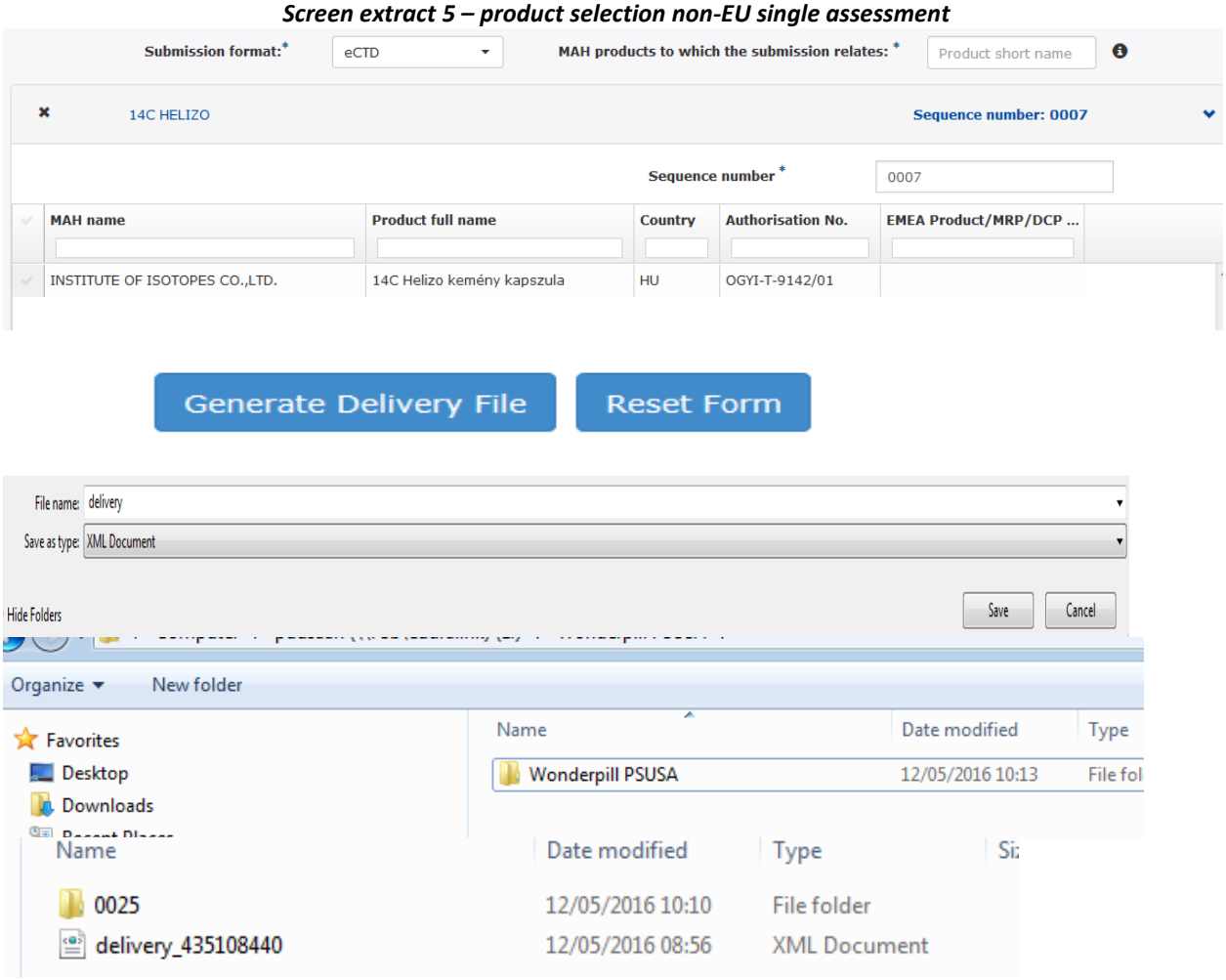
5	Select the PSUR data lock point from the calendar window	



6	Select submission format from the dropdown list – eCTD or NeeS.	
7	Type in some characters from the product short name for which you are submitting, e.g. **Wonderpill.**	
8	Select the relevant product short name.	
9	Click on the product name shown. This will expand a list of the products at the presentation level. You can filter the list the same way as for PSUR Single Assessment. The list can be hidden by clicking the name of the product again. (See screen extract below).	Screen extract 5
9	Click "Generate Delivery File" and save the file to your local	The delivery file may be renamed however it must

	machine.	always contain word **"delivery".**
10	Add the delivery file to the submission ZIP file package on the root level i.e. the same level with the submission sequence folder and submit via the eSubmissions gateway.	The delivery file name must contain word "delivery". The file must be placed in the top level of your ZIP package.

Screen extract 5 – product selection non-EU single assessment



4. 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 eSubmission 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.