EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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User Guidance for Marketing Authorisation Holders (MAHs) for PSUR Repository

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Table of contents

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)	
9.0	19/09/18	Updated to reflect changes implemented in release v1.15.0.0	Asim Qureshi
10.0	25/08/19	General updates, updated to reflect changes implemented in release v1.16.0.0 and addition of section 3.2 on Closing sequences.	Kristiina Puusaari
11.0	09/06/20	General updates and updates to reflect changes implemented in release 1.17.0.0 (e.g. Start of procedure notification and closed procedures).	Kristiina Puusaari
12.0	14/06/22	Updated version 2.0.0.0 with a technical update of the framework with an upgrade from AngularJS to Angular has been done. This technical update does not change any functionality; however, it provides new, different look and feel to the user interface. Additionally, the submission format NeeS has been removed due to mandatory use of eCTD for all procedure types since 1 January 2019 and for non-EU PSURs the sequence number has been moved from the product level to the delivery file level. There are no changes to business rules/other features as a result of this update. **NOTE:** Please note that the screenshots included in this guidance **have not been updated** to reflect the change related to update from AngularJS to Angular. This will be done gradually over time. This user guide reflects the previous look and feel of the system.	Kristiina Puusaari

1. Introduction

This document serves as a simple guide for applicants wishing 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.

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 became mandatory 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 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.

It is now **mandatory** to submit PSURs in **eCTD format**. For more information, please see the eSubmission website.

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 mandatory delivery file is included in the submission** and hence a simplified filenaming convention should be used for submissions to the PSUR Repository. Please see examples of these simplified filenames in Annex 3. **It is important the filename does not contain special characters**.

All eCTD format submissions for Centrally Authorised Products are validated using an automated eCTD technical validation. A technical eCTD validation is also 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.

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

The **submission-unit** is an 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	Not applicable for PSUR submissions – as PSUR/PSUSA procedure doesn't normally contain business validation this attribute cannot be selected for PSUR/PSUSA submissions.
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. **Please note**: Responses cannot be submitted to the PSUR Repository if 'initial' PSUR has not been submitted for the procedure in question.
additional-info	Not applicable for PSUR/PSUSA submissions – This attribute cannot be selected 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 sequences resulting from a PSUSA Procedure are sent via the eSubmission Gateway and the XML delivery file is created using the PSUR Repository industry access, however the closing sequences are not placed in the the PSUR Repository, but are available to the NCAs via the Common Repository.
consolidating	This submission unit type cannot be used for PSUR/PSUSA procedures.
corrigendum	This submission unit type cannot be used for PSUR/PSUSA procedures.

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.

2.1.1. 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.

It is not acceptable to create a single, standalone sequence for PSUR/PSUSA submissions as the PSUR is part of the **product lifecycle** and must be submitted as the next sequence in the product lifecycle.

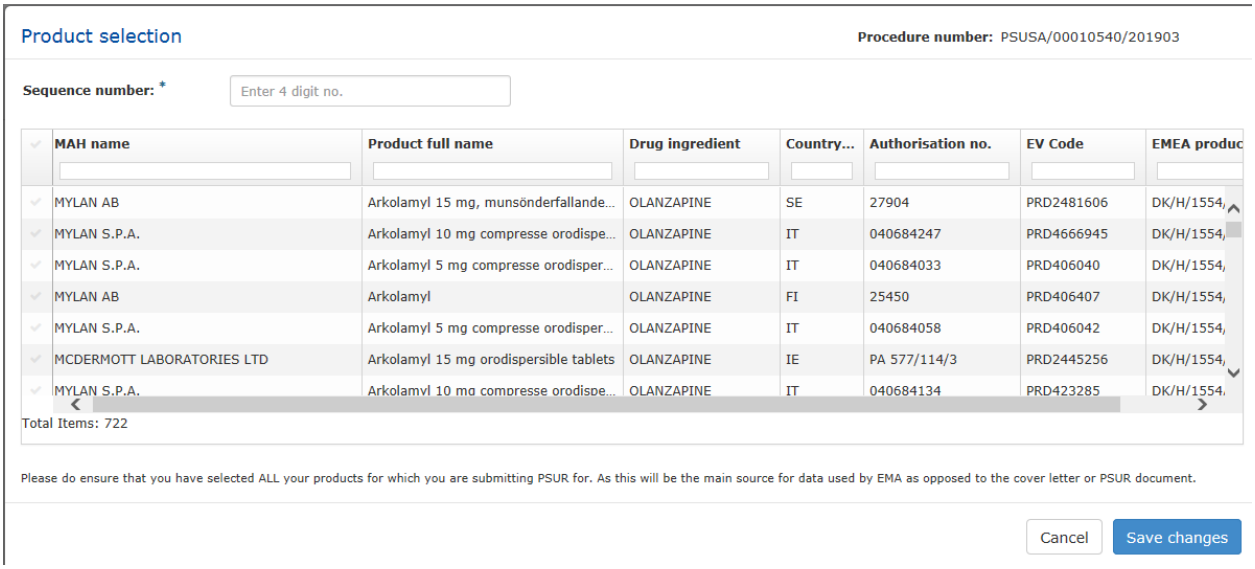
2.1.2. Example 2: MRP/DCP authorisation – comprehensive model (harmonised approach) using eCTD format:

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 **one 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:



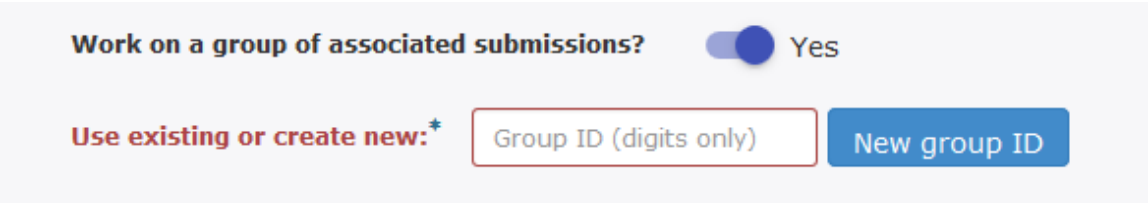
2.1.3. Example 3: MRP/DCP/National authorisation – eCTD format:

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 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.

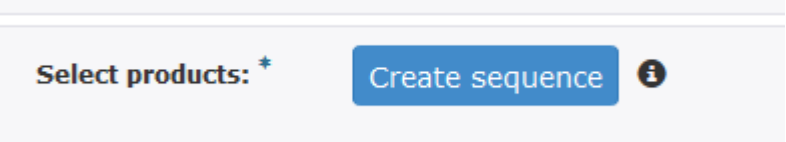
Note: this functionality can, and should, also be used to group together comments/responses relating to multiple products for which a common comments/responses document has been created i.e. the functionality to work on associated submissions should also be used when sending supplemental sequences for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



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

The use of **eCTD is now mandatory** for all European procedures. More information can be found from the eSubmission website.

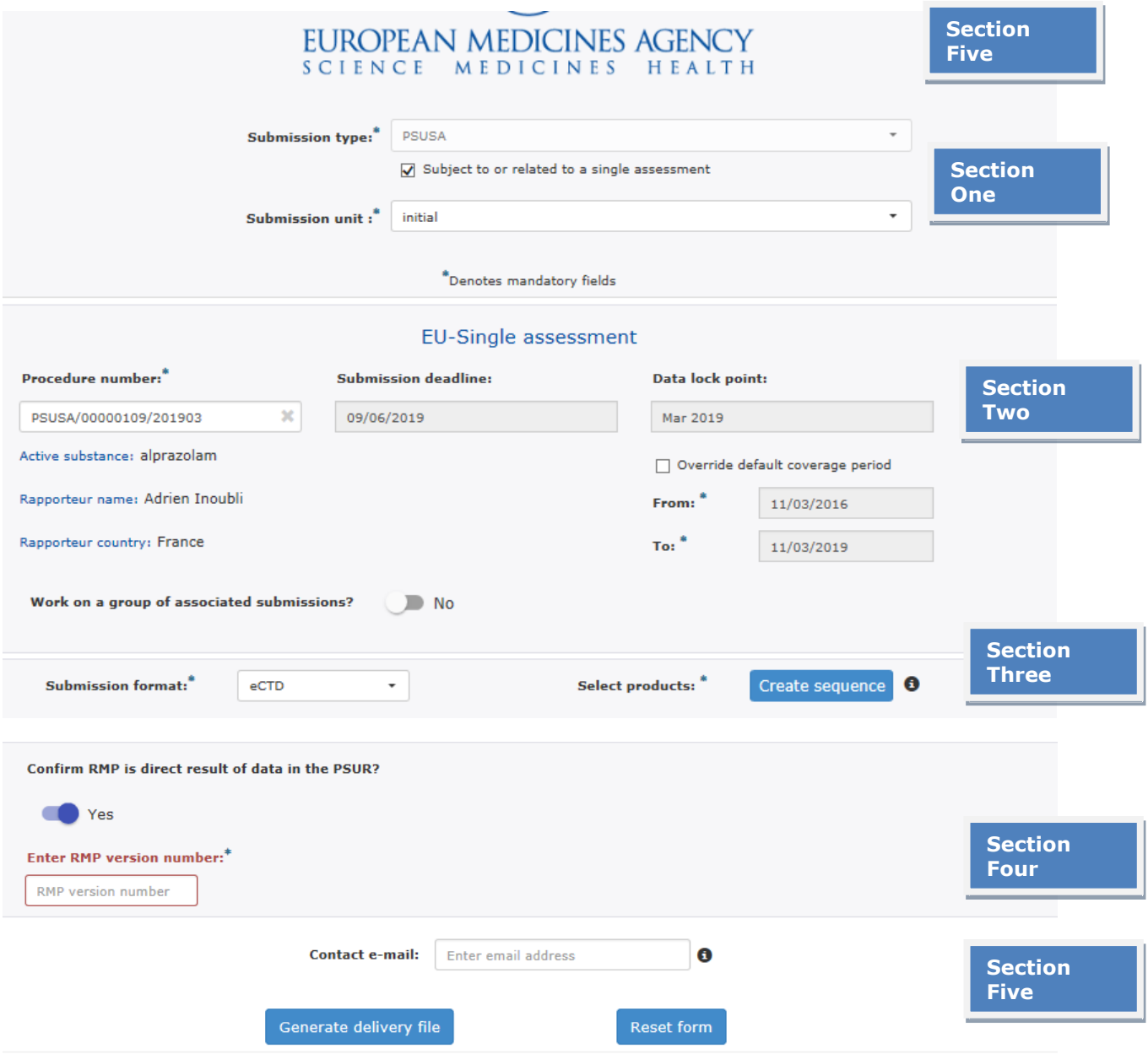
PSUR submission of single, pure NAP (submissions for products not listed in the EURD list and products for which the active substance has been authorised in just one member state)

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 first word must always be "delivery".** It is also very important not to use any special characters in the delivery file name as these may lead to technical failure of the submission. Only latin characters without any umlauts or accents should be used. Dash is not allowed.



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

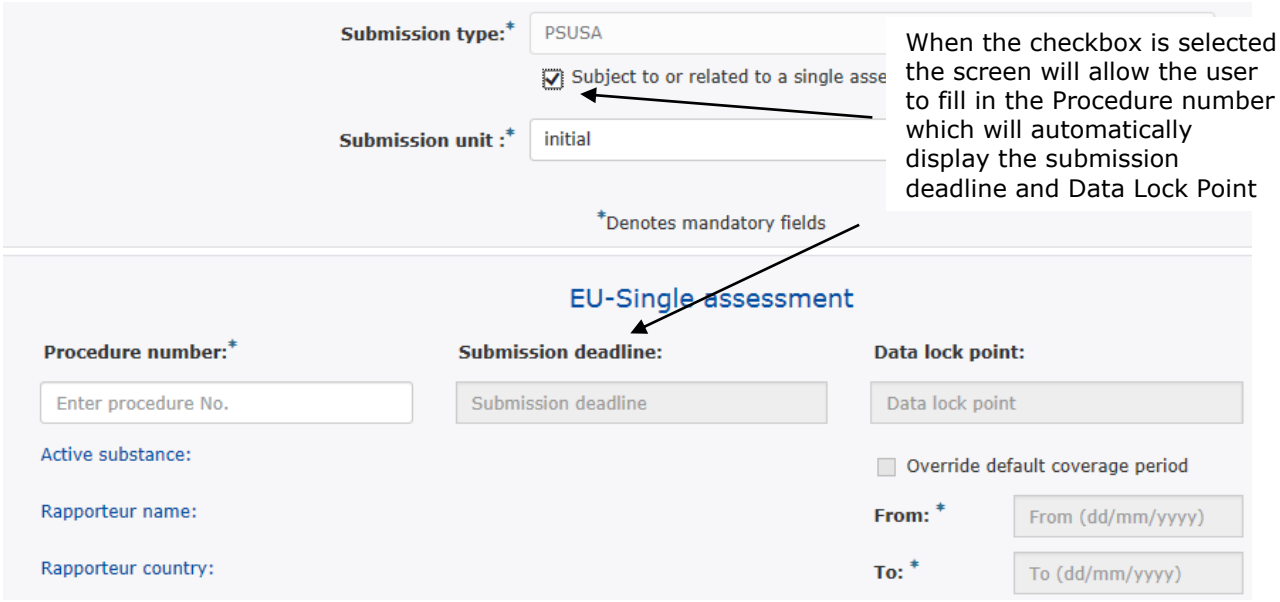
The user will be required to complete all fields in each section.

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 PSUSA submission 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 portal to request for a late submission ID.	Creation of delivery file for any subsequent sequences (responses) after the initial PSUR submission is **not** linked to a submission deadline and **no** late submission ID is required. **Note:** it is important the only submission unit 'initial' is used to send initial PSURs. Initial PSUR submissions sent using other submission units will be excluded from the procedure. **Note:** There is a known issue related to time zones which may cause the submission deadline in the PSUR Repository is shown one day earlier than in the EURD list. In order to avoid issues **please always submit well in advance of the submission deadline**.

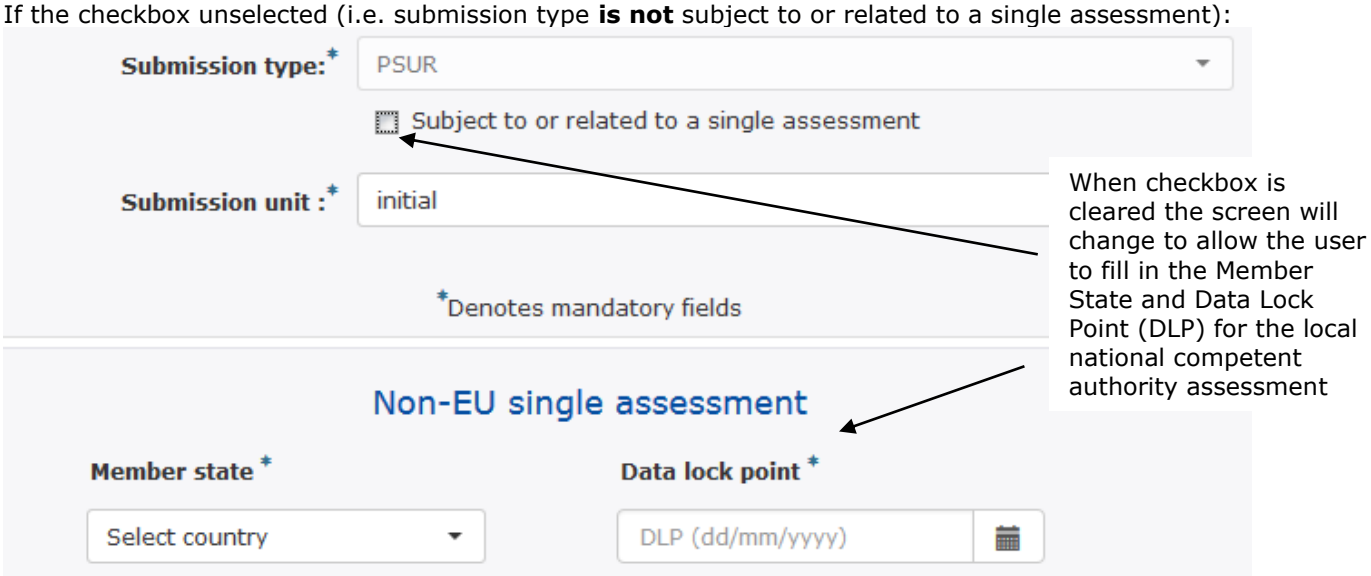
2	Indicate whether the submission is for single assessment.	The checkbox is ticked by default

If the checkbox is selected (i.e. submission type **is** subject to or related to a single assessment):

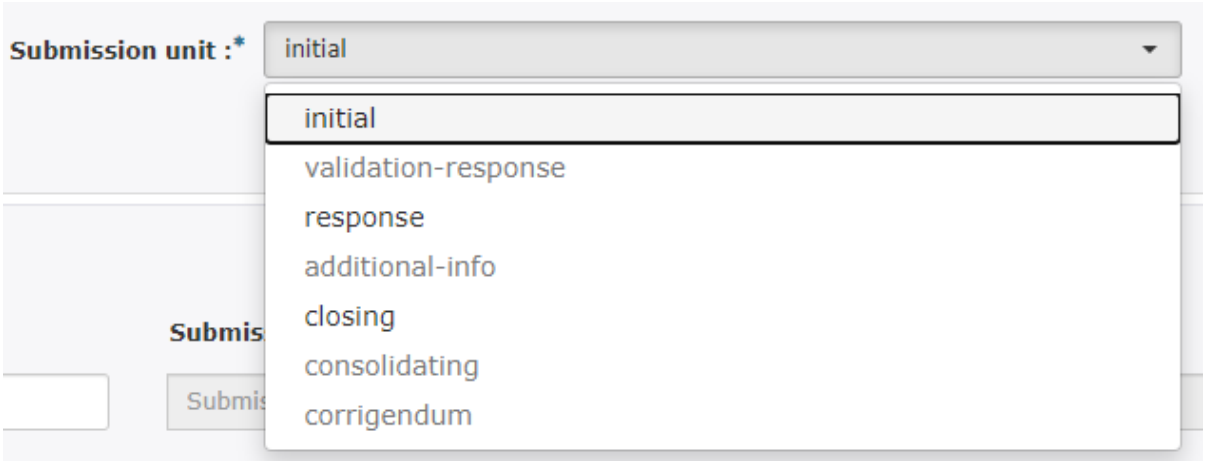
[1] This section will change to display "Non-EU single assessment" if the checkbox in section one is deselected



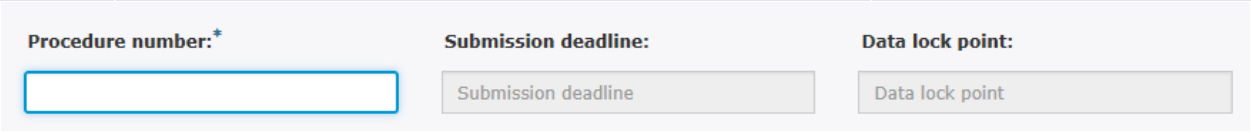
If the checkbox unselected (i.e. submission type **is not** subject to or related to a single assessment):



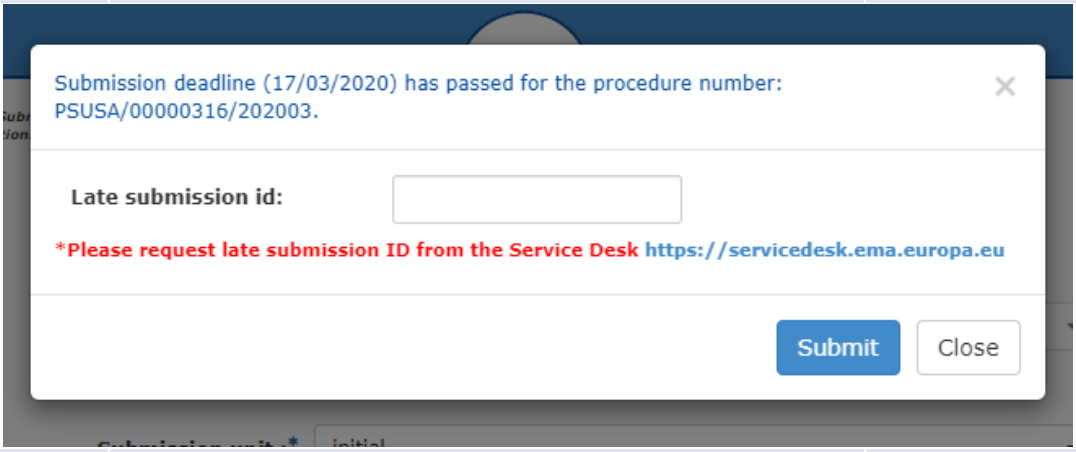
3	Select the relevant Submission unit (initial or response) from the list. The selection is defaulted to 'initial'. If you are submitting responses or comments, submission unit 'responses' should be used. **Please note**: 'response' cannot be selected if an 'initial' PSUR has not been submitted to the PSUR Repository for the given procedure. **Please note**: Once the procedure has been closed i.e. the PRAC outcome has been reached, it is no longer possible to submit any PSURs or responses for the given procedure. If you have **missed the submission deadline**, please always request a Late Submission ID via the EMA Service Desk. Late submissions **must not** be submitted using submission unit 'response'.	Updates to product information following a PSUR Repository should be submitted to the EMA using the eSubmission Gateway.



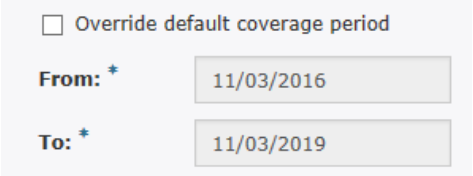
4	Search and select the PSUR procedure number as in EURD list by typing at least 4 characters, for example 2020.	



5	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. Each late submission ID can only be used once. If you have requested multiple late submission IDs please ensure you use the correct id for the corresponding procedure.	

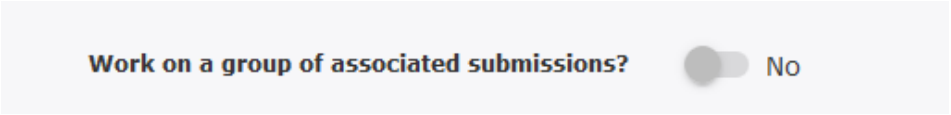


6	It is possible to override the default coverage period for the PSUR by ticking the box. It will then be possible to enter the new date range in the 'from' and 'to' fields.	The latest range date will be the date valid for the next submission for that PSUSA

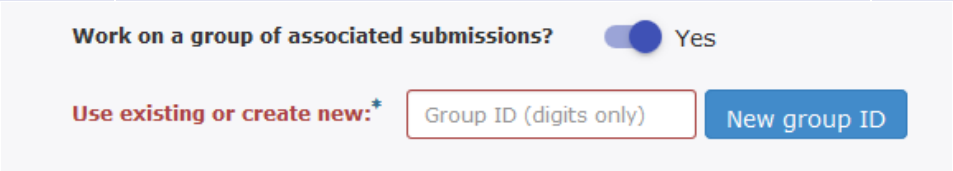


7	Indicate if you want to group together associated submissions i.e. you have created just one single PSUR covering multiple products that have different eCTD	Please note that use of eCTD is now mandatory for all procedure types (CAP,

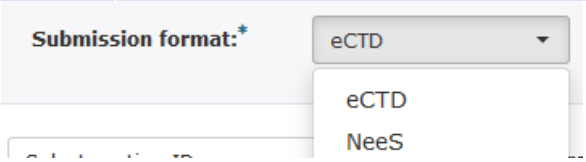
	lifecycles	MRP/DCP, NP). More information is available on the eSubmission website.



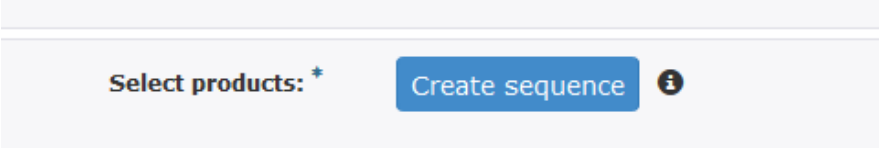
8	Generate a 'New Group ID' or use one you have previously generated and noted down if one of the submissions for associated products has failed	Do not use the same group ID to send a PSUR for products for which a different PSUR document has been prepared. Do not use the same group ID for sending PSURs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



9	The submission format is defaulted to eCTD. For eCTD submissions only one sequence can be added.	Please note that use of eCTD is now mandatory for all procedure types (CAP, MRP/DCP, NP). More information is available on the eSubmission website.

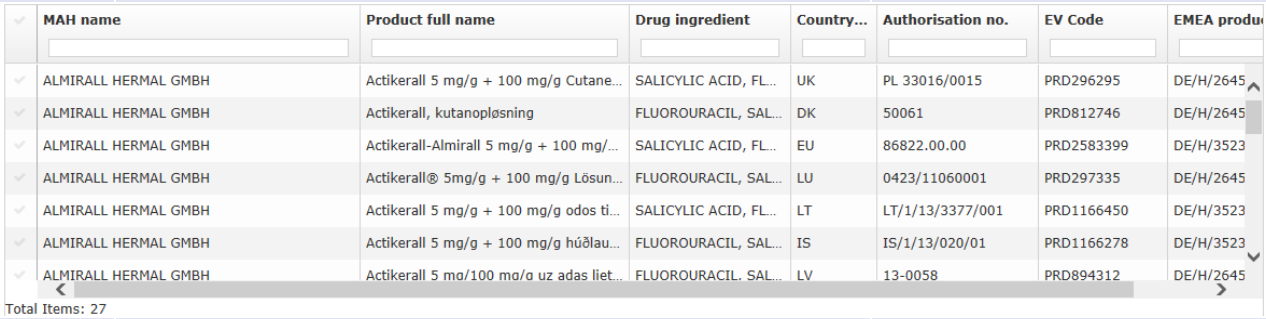


10	Click 'Create sequence' to display the list of products containing the relevant active substance(s) based on the procedure number from the EURD list.	



11	The system will display a list of products that are included in the procedure and that containing the relevant active substance(s) given that the products are correctly entered in the Art. 57 database with the correct legal basis. 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	All different 'generic' products and entries in different languages are displayed on the list. If you are not able to find the product in the list using Latin characters and product is authorised for example in BG, the entry in Art. 57 may be in Bulgarian and you should try to search using the relevant

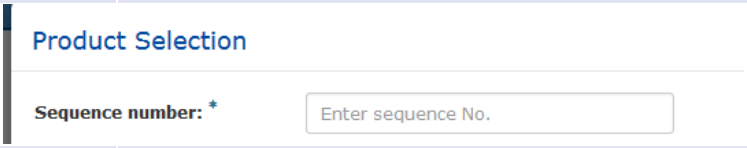
	file are excluded from the procedure. The list can be filtered by the MAH name/product full name, drug ingredient, authorisation country, the authorisation number, the EV code and EMEA/MRP/DCP number.	alphabet. Correct product listing in the delivery file is essential to ensure that the procedure scope is correct. Annex 1 listing the products should **not** be provided.



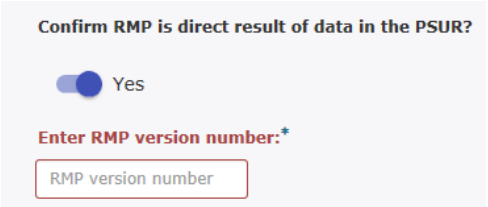
MAH name	Product full name	Drug ingredient	Country...	Authorisation no.	EV Code	EMEA produ
ALMIRALL HERMAL GMBH	Actikerall 5 mg/g + 100 mg/g Cutane...	SALICYLIC ACID, FL...	UK	PL 33016/0015	PRD296295	DE/H/2645
ALMIRALL HERMAL GMBH	Actikerall, kutanopløsning	FLUOROURACIL, SAL...	DK	50061	PRD812746	DE/H/2645
ALMIRALL HERMAL GMBH	Actikerall-Almirall 5 mg/g + 100 mg/...	SALICYLIC ACID, FL...	EU	86822.00.00	PRD2583399	DE/H/3523
ALMIRALL HERMAL GMBH	Actikerall® 5mg/g + 100 mg/g Lösun...	FLUOROURACIL, SAL...	LU	0423/11060001	PRD297335	DE/H/2645
ALMIRALL HERMAL GMBH	Actikerall 5 mg/g + 100 mg/g odos ti...	SALICYLIC ACID, FL...	LT	LT/1/13/3377/001	PRD1166450	DE/H/3523
ALMIRALL HERMAL GMBH	Actikerall 5 mg/g + 100 mg/g húðlau...	FLUOROURACIL, SAL...	IS	IS/1/13/020/01	PRD1166278	DE/H/3523
ALMIRALL HERMAL GMBH	Actikerall 5 mg/100 mg/g uz adas liet...	FLUOROURACIL, SAL...	LV	13-0058	PRD894312	DE/H/2645

Total Items: 27

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

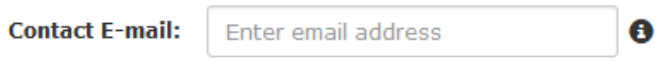


13	Only **one** sequence number can be entered per product selection window.	In eCTD format only single sequence can be added. Please note that use of eCTD is now mandatory, information is available on the eSubmission website.
14	Complete the product selection steps.	
15	For **CAPs included in PSUSA procedures** the MAH should confirm if RMP is direct result of data in the PSUR. If yes, please provide the relevant RMP number.	RMP should be provided **only** in case it is a **direct result** of this PSUSA procedure

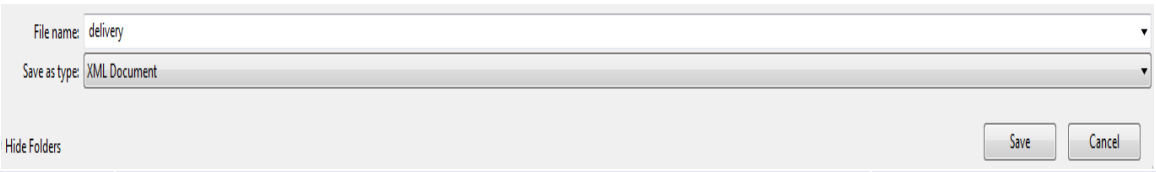


13	Enter email address of the person who is the responsible contact for the PSUSA procedure. All relevant correspondence will be sent to this email address. Please note that this email address is also used for new **Start of procedure'** notification sent to the MAHs (implemented in v1.17.0.0 in June 2020).	New automated Start of Procedure notification including the procedure timetable is sent to the MAH(s) who have submitted PSUR for the given procedure. The email address used for this notification is the one

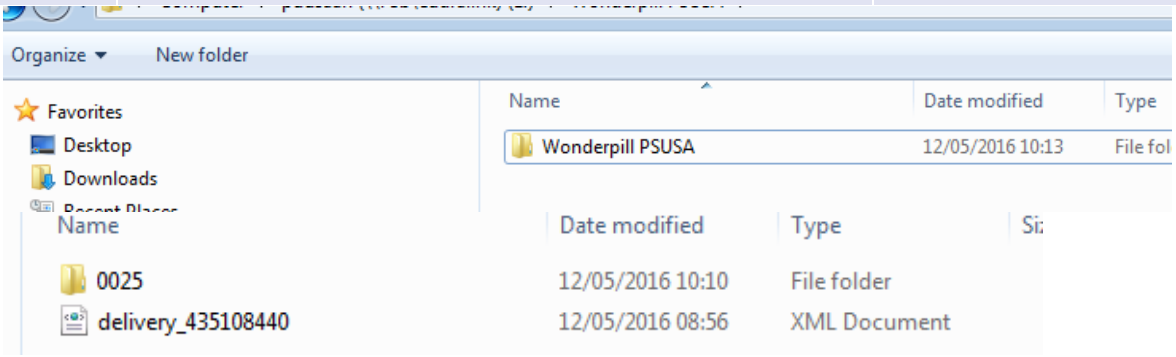
		provided in the XML delivery file.



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"** as the first word. It is very important not to use any special characters in the delivery file name as these may lead to technical failure of the submission.



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" as the first word. 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 PSUR Repository 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.

If you are unable to find your product(s) from the list, please check the Art. 57 entry first confirming that the **correct legal base has been entered** as more often than not, the reason why products do not appear in the product selection is because they are incorrectly entered in the Art. 57 database (XEVMPD). In particular, the legal basis is either left empty, or is incorrect, or the products(s) may be out of scope of the procedure (i.e. the procedure does not include the following legal basis: Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC.) As a result, these products would be filtered out of the product selection in the PSUR Repository as this list is taken directly from the Art 57 database.

Example for Centrally Authorised Product (CAP):

EMEA procedure number (i.e. "Agency Product Number" as published on the Agency's webpage) must be specified in the field MRP/DCP/EMEA number (AP.12.7) when the "Authorisation Procedure" (AP.12.2)" is entered as "EU authorisation procedures - Centralised Procedure (1)". The format of the EMEA procedure number should be EMEA six digit procedure number (i.e. EMEA/H/C/123456) of a specific CAP as found on the EMA website.

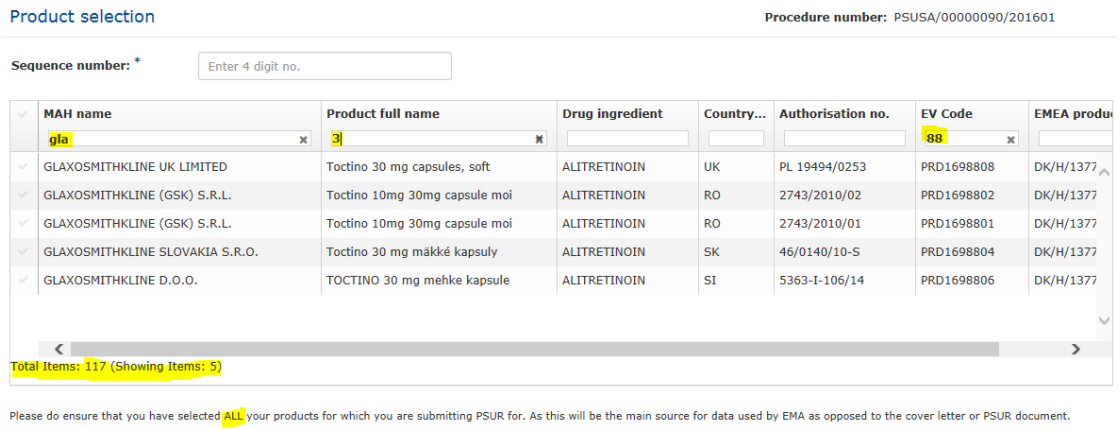
EXAMPLE
AMP authorised in the centralised procedure with EU number: EU/1/23/4569/789 and EMEA number: EMEA/H/C/123456 should be entered in the corresponding fields as follows:
Authorisation Procedure" (AP.12.2) = EU authorisation procedures - Centralised Procedure
"Authorisation Number" (AP.12.4) = EU/1/23/4569/789
"MRP/DCP/EMEA Number" (AP.12.7) = EMEA/H/C/123456
"EU Number" (AP.12.8) = EU/1/23/4569/789

Description	Name/Value	
Type	Authorised	
Is EMA Owned		
Operation Type	Insert	
New Owner ID		
MAH		Field is Mandatory
QPPV		
Master File Location		
PhV enquiry email		
PhV enquiry Phone		
Sender Local Code		
Info Date		
Authorisation Country Code		Field is Mandatory
Authorisation Procedure		Field is Mandatory
Authorisation Status		
Authorisation Number		Field must have a specified value
Authorisation/Renewal Date		
MRP/DCP/EMEA Number		
EU Number		
Legal Basis		
Orphan Drug		
Additional Monitoring		
Invalidated Date		Field must have a specified value
Full Presentation Name		Field is Mandatory
Product Short Name		Field is Mandatory Optional
Product INN/Common Name		Field is Mandatory Optional
Product Company Name		Field must have a specified value
Product Strength Name		
Product Form Name		
Package Description		
Comment		
	Medicinal Product Types (-)	
	Authorised Pharmaceutical For...	
	Pharmaceutical Products (-)	Section is Mandatory
	Drug ATCs (-)	Section is Mandatory
	Drug Indications (-)	
	Previous EV Codes (-)	
	Product Attachments (-)	

Please also refer to Chapter 3.II of the XEVPRM user guidance of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency: https://www.ema.europa.eu/en/human-regulatory/post-authorisation/data-medicines-iso-idmp-standards/reporting-requirements-authorised-medicines/guidance-documents

Once you have confirmed that the missing products are entered correctly and that the legal basis for these products is within the scope of the procedure, please wait for an overnight refresh. If the products still do not appear on the list in the PSUR Repository the following day, please raise a ticket using the EMA Service desk

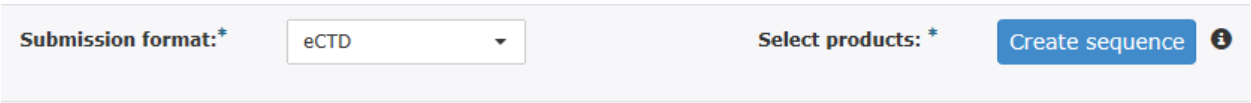
As all products relevant to the procedure are listed and the list can contain hundreds of products/presentations. You can filter the results to narrow down the list and find the specific products/presentations that you wish to include in the delivery file. Any part of the MAH name, product full name, authorisation number(s), the EV code 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

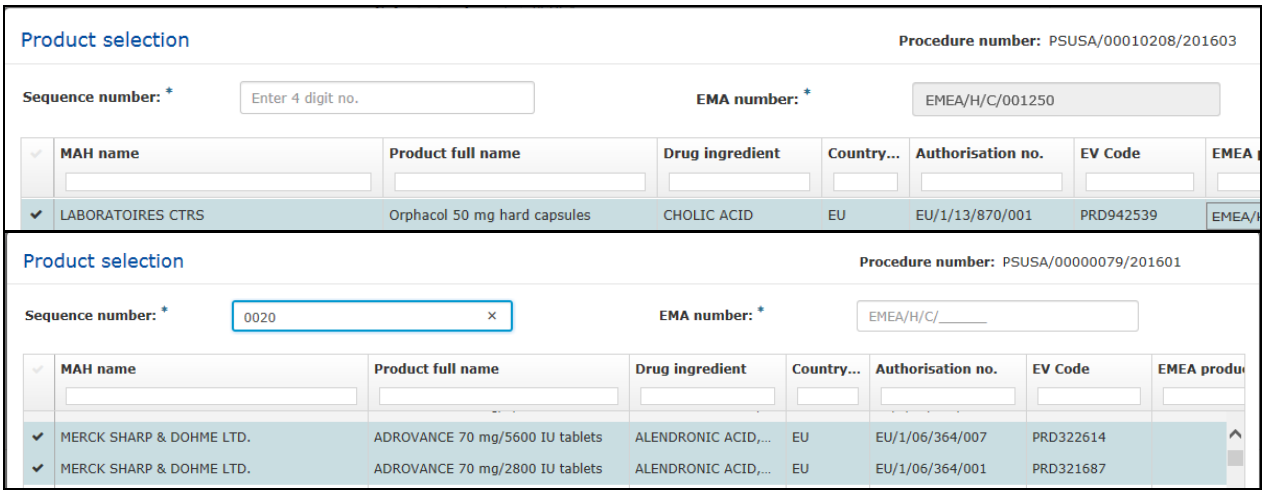
Screen extract 1 – Product selection



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 -

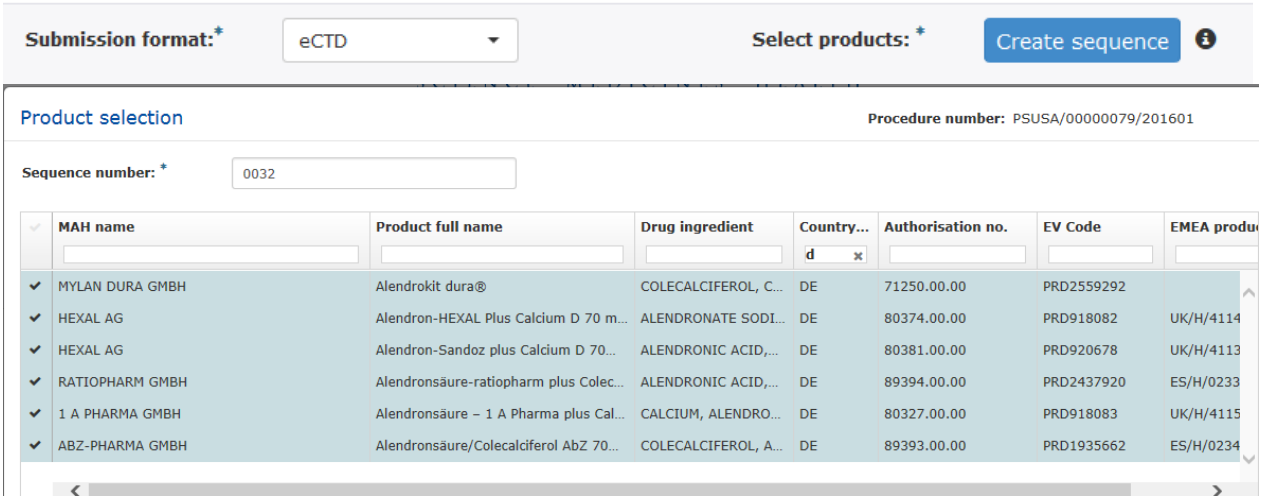


3.1.3. Scenario 2: The submission relates to MRP/DCP products with harmonised, comprehensive lifecycle in eCTD format

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	Screen

Step	Description	Notes
	the PSUR/responses being submitted. You can select all the products by 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

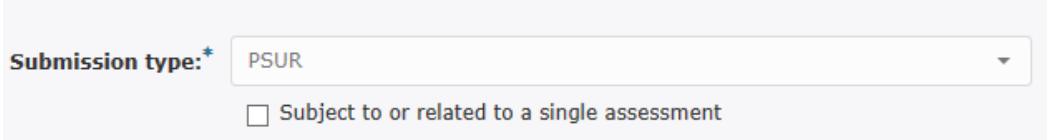


3.1.4. Scenario 4: The submission relates to a pure, single NAP submission outside the EU single assessment

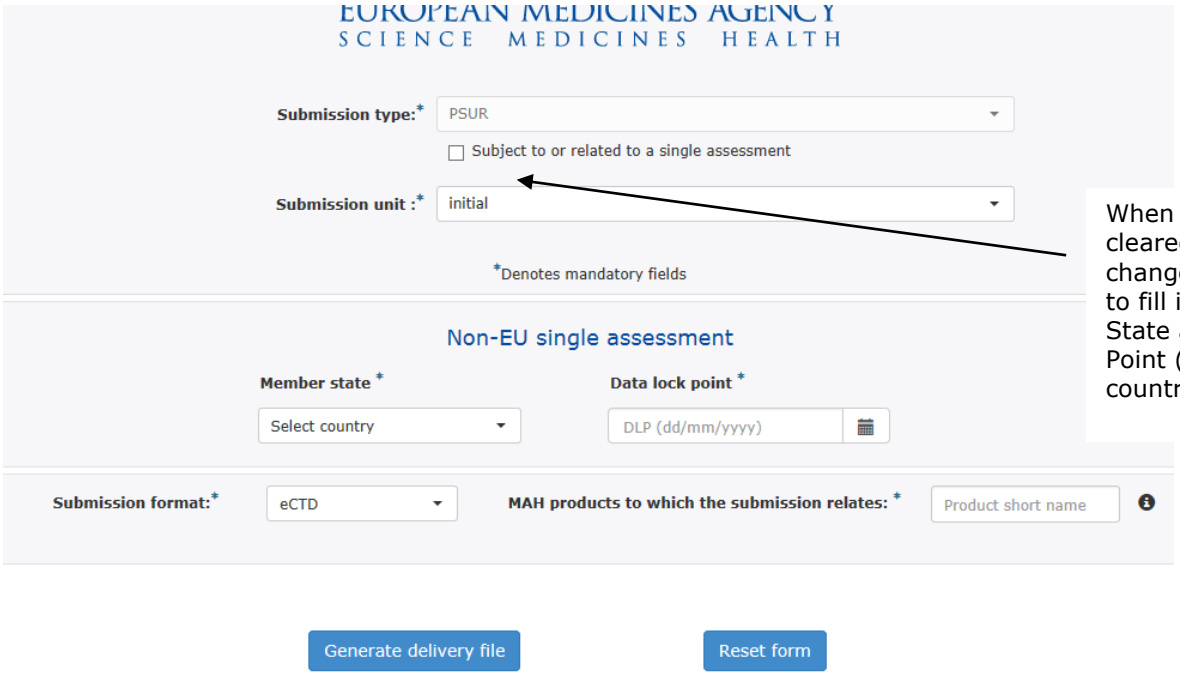
PSURs for products for which the active substance is not in the EURD list, should be sent using the 'Non-EU single assessment mode. The current functionality of the PSUR repository does not allow selection of multiple member states for PSURs not governed the EURD list. This functionality will be further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

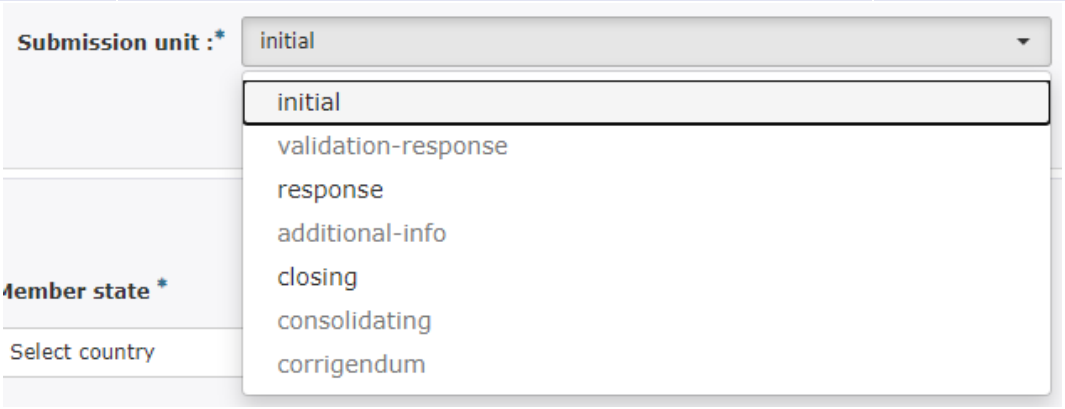


2	Ensure you untick the checkbox to reflect that the submission is for single assessment.	The checkbox is ticked by default

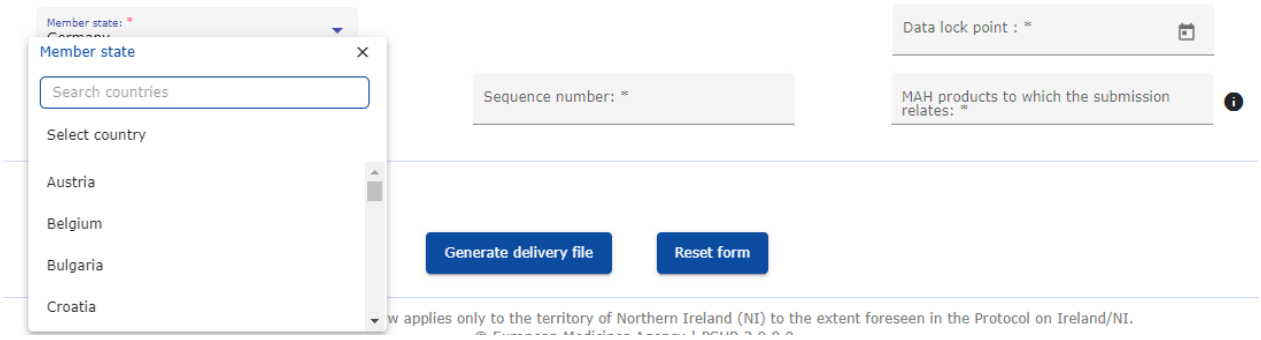


When checkbox is cleared the screen will change to allow the user to fill in the Member State and Data Lock Point (DLP) for the local country's assessment

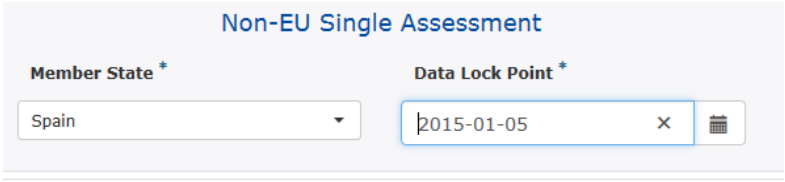
3	Select the Submission unit from the list. The selection is defaulted to 'initial'. If you are submitting responses or comments, submission unit 'responses' should be used.	



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.

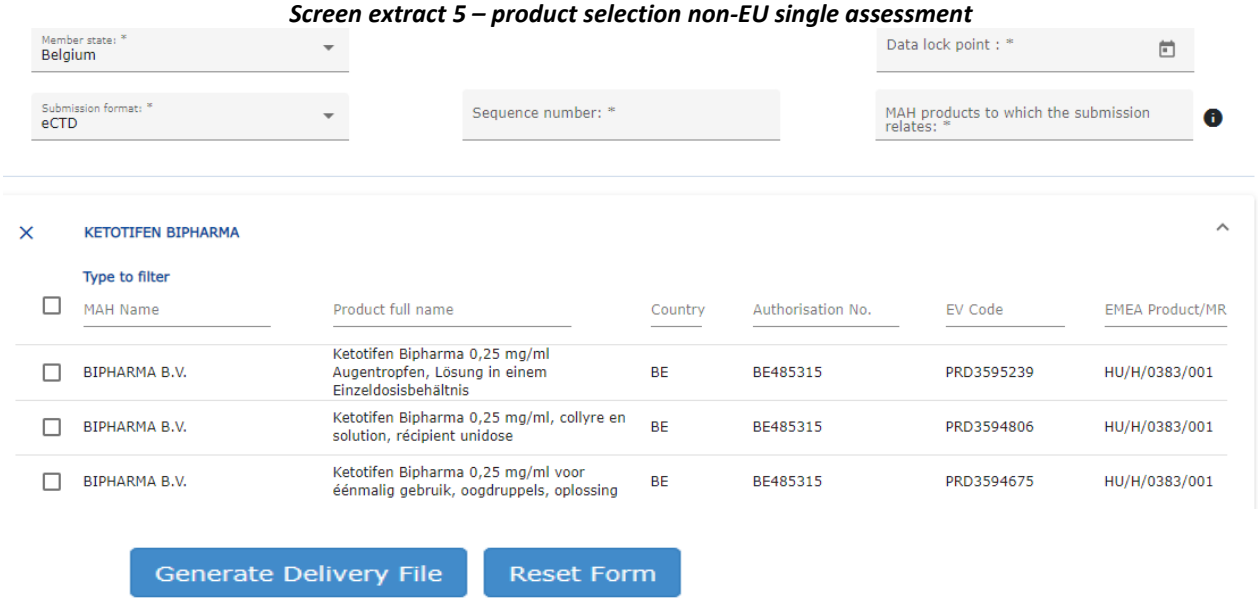


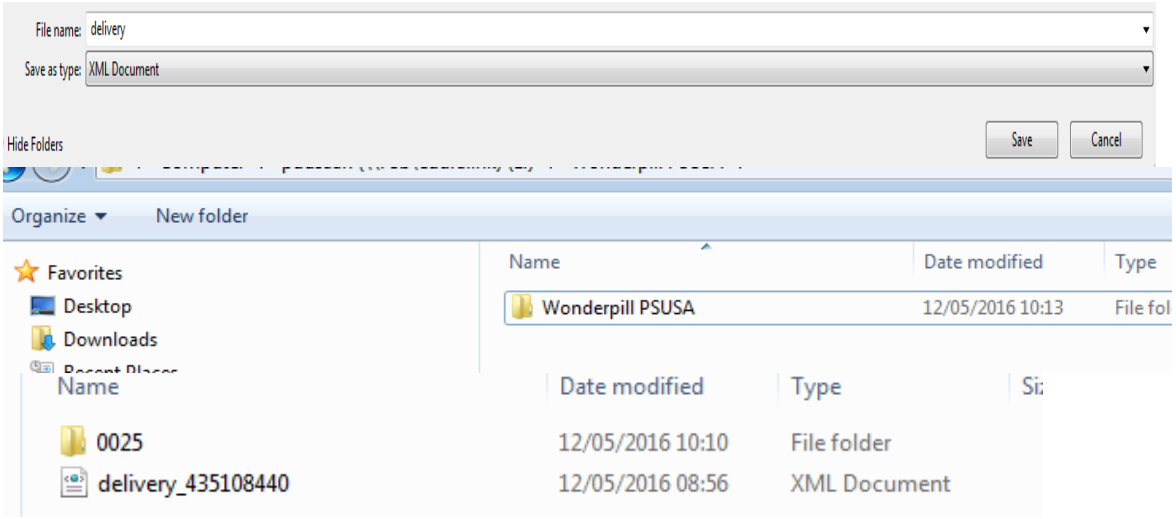
5	Select the PSUR data lock point from the calendar window	



6	The submission format is defaulted to eCTD.	
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 locally.	The delivery file may be renamed however it must always contain word **"delivery"** as the first word. No special characters or dashes are allowed in the delivery file name.
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" as the first word. The file must be placed in the top level of your ZIP package.

Screen extract 5 – product selection non-EU single assessment





3.2. *Closing sequence*

Occasionally, when the PSUSA procedure results in changes in Annexes or the product information a closing sequence needs to be submitted to the EMA to bring the product lifecycle up to date.
The closing sequences are submitted using eSubmission Gateway and the delivery files are created using the PSUSA repository industry user interface. The closing sequences are available for the NCAs via the Common Repository only.

Step	Description	Notes
1	Select the Submission unit 'closing' from the list. The selection is defaulted to 'initial'	
2	Search and select the PSUR procedure number as in EURD list by typing at least 4 characters, for example 2020	
3	Click 'Create sequence button' to access the product selection window	
4	Enter the relevant sequence number	
5	Full list of products included in the procedure is displayed. Filter the list of products to select presentations for which you are submitting the Closing sequence for. Select the relevant products as usual.	
6	Enter email address of the person who is responsible contact for the procedure	

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 previously used mailboxes

which should no longer be used. All technical queries concerning 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 raise a change request using the Service Desk portal.

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.