

# Fit for PSUR Repository IT guidance and Live Demo

DI Georg Neuwirther  
Head of IT – AGES MEA  
30. Mai 2016

# Status / Overview



- The use of the PSUR Repository will become mandatory from 13<sup>th</sup> June 2016.
  - XML-delivery **must be added** to the PSUR submission
  - previously required filenaming conventions are no longer required; however these can still be used
  - the filenames are no longer validated/checked and do not cause rejection/failure of submission.
- Submission with "Delivery File file" can be sent to the PSUR repository via
  - the eSubmission Gateway
  - or the Web Client

# Links



- General information [EMA]
  - [http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q\\_and\\_a/q\\_and\\_a\\_detail\\_000041.jsp](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp)
- Technical Information PSUR
  - [http://esubmission.ema.europa.eu/psur/psur\\_repository.html](http://esubmission.ema.europa.eu/psur/psur_repository.html)
- Creation Tool for Delivery File
  - <https://psur-repo.ema.europa.eu/psur-ui/prepare/submission.html>
- EMA Gateway und Web-Frontend
  - <http://esubmission.ema.europa.eu/esubmission.html>
- EMA Helpdesk
  - <https://servicedesk.ema.europa.eu>
  - [https://eudralink.ema.europa.eu/ema\\_service\\_desk\\_portal\\_for\\_external\\_users.pdf](https://eudralink.ema.europa.eu/ema_service_desk_portal_for_external_users.pdf)

# Timetable by EMA



MAH webinar for PSUR Repository v 01.06	Industry	17 May 16	Webinar	09:00-10:30
New functionalities of v 01.06 & Mandatory use	Industry	24 May 16	Open Q&A session	14:00-15:30
Mandatory use of PSUR Repository	Industry	13-Jun-16	Webinar (Short presentation and Q&A)	09:00-10:30

# Soft guidelines for filenaming no validation anymore!



EUROPEAN MEDICINES AGENCY

## How to name the zip package

- File names **will not be validated** for **PSUR repository** submissions.
- Submission **metadata is provided via XML delivery file**, however package should have a **meaningful** name (for archiving purposes)
- Suggested file name examples:
  - **CAPs**: HC000999\_Wonderpill\_0020.zip
  - **NAPs included in PSUSA**: Companyname\_00000000\_YYYYMM\_0020.zip
  - **Single, pure NAP**: MemberState\_YYYYMM\_ActiveSubstance\_0020.zip
  - The 8 digit unique (PSUSA) number shown as 00000000 in the above examples and the -YYYYMM- format Data Lock Point, can be found in the published EURD list)
  - Folders inside the zip containing submissions (e.g. Sequence 0001, 0002 etc.) should follow the eCTD or Nees guidelines.

The logo for the European Medicines Agency (EMA) is located in the bottom left corner of the slide. It features a stylized number '2' in yellow and orange, with the text 'EMA' below it.

# Essentials / 1



- Submissions have to be splitted into separate submissions based on format and lifecycle of related products:
  - Do not mix different sequences
  - Do not mix different submission formats

# Essentials / 2

## excerpt from EMA manual for MAH



### 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.

### 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 a **separate** eCTD product lifecycle. A separate submission is required for **each product** to ensure continuity of the eCTD lifecycle. **A separate delivery file needs to be created and attached for each submission.**

# Essentials / 3

## excerpt from EMA manual for MAH



### *Using the “grouping-feature” for submissions*

#### **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 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 supplementary information sequences.

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



# Essentials / 4

## excerpt from EMA manual for MAH



### *Summarizing example*

#### *2.3. 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	Authorisation procedure
Product A	eCTD	CAP
Product B	eCTD	CAP
Product C	NeeS	NAP
Product D	NeeS	NAP
Product E	eCTD	NAP (MRP)
Product F	eCTD	NAP (MRP)
Product G	eCTD	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.
- 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.


# Live Demo



# eCTD EU Single assessment

e.g. PSUSA/00002608/201604





**EUROPEAN MEDICINES AGENCY**  
SCIENCE MEDICINES HEALTH

Regulatory activity: \*   Subject to or related to a single assessment

\*Denotes mandatory fields

**EU-Single assessment**

Procedure number: \*   Submission deadline:  Data lock point:

Active substance: furosemide / ramipril  
Rapporteur name: Jan Neuhauser  
Rapporteur country: Austria

Work on a group of associated submissions?  No

Submission format: \*  Select products: \*  3

#Seq No 0015

Contact e-mail:

Procedure number: PSUSA/00002608/201604

Sequence number: \*

MAH name	Product full name	Drug ingredient	Country	Authorisation no.	EMA product/MRP...
<input checked="" type="checkbox"/>	SANOPI-AVENTIS OMBH OSTERREICH	LASITACE 5 MG/40 MG-KAPSELN	RAMIPRIL, FUROSEM...	AT	1-21361
<input checked="" type="checkbox"/>	SANOPI-AVENTIS OMBH OSTERREICH	LASITACE 5 MG/20 MG-KAPSELN	FUROSEMIDE, RAMP...	AT	1-21360


Total Items: 2 (Selected Items: 2)

Please do ensure that you have selected ALL your products for which you are submitting PSUR for. As this will be the main source for data used by EMA as opposed to the cover letter or PSUR document.

© European Medicines Agency | PSUI

# Non EU-single assessment Nasengel





**EUROPEAN MEDICINES AGENCY**  
SCIENCE MEDICINES HEALTH

Regulatory activity: \* PSUR

Subject to or related to a single assessment

\*Denotes mandatory fields

---

**Non-EU single assessment**

Member state \* Austria

Data lock point \* 24/05/2016

Submission format: \* NasS

MAH products to which the submission relates: \* Product short name

**NASENGEL** Sequence number: 0015

Sequence number \* 0015

MAH name	Product full name	Country	Authorisation No.	EMA Product/MRP/DCP ...
ALIUD PHARMA GMBH	Nasengel AL	DE	11037.00.01	
<input checked="" type="checkbox"/> RATIOPHARM GMBH	NasenGel-ratiopharm® Xylometazoli...	LU	0687/10040739	

Total Items: 2 (Selected Items: 1)

# EU-single assessment Deduplication



This screenshot shows the "EU-Single assessment" form with several fields highlighted in red circles. The highlighted fields include: "Use existing or create new" (with value "00000000"), "Submission format" (with value "#Seq No: 0011"), and "Contact e-mail". The form also displays "Regulatory activity" as "PSUR", "Procedure number" as "PSUSA/00001752/201604", "Submission deadline" as "25/06/2016", and "Data lock point" as "Apr 2016".

This screenshot shows the "EU-Single assessment" form with several fields highlighted in red circles. The highlighted fields include: "Use existing or create new" (with value "00000000"), "Submission format" (with value "#CTD"), and "Contact e-mail". The form also displays "Regulatory activity" as "PSUR", "Procedure number" as "PSUSA/00001752/201604", "Submission deadline" as "25/06/2016", and "Data lock point" as "Apr 2016".

Use grouping to inform regulatory bodies that submissions belong together

# NCA view for grouped submissions



## Results

PSUSA/00000170/201508 amitriptyline, perphenazine		Document Type...	Submitter	Countr...	Date Received	Products (MAH)
<input checked="" type="checkbox"/>	PSUR	-	-	10/09/2015	Peripriptyl (Orion oyj, 4473), Triptafen (Mercury pharmaceuticals ltd., PL 1.	
<input checked="" type="checkbox"/>	Updated Assess...	wallacem	EU	11/09/2015		
<input checked="" type="checkbox"/>	Comment	wallacem	EU	11/09/2015		
<input checked="" type="checkbox"/>	PSUR	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 19609/22-	
<input checked="" type="checkbox"/>	PSUR	-	-	11/09/2015	Peripriptyl (Orion oyj, 4472)	
<input checked="" type="checkbox"/>	PSUR	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 39523/21-9-2009),	
<input checked="" type="checkbox"/>	Supplemental In...	-	-	10/09/2015	Mutabon mite (Neopharmed gentili s.r.l., 021460074), Peripriptyl (Orion oy	
<input checked="" type="checkbox"/>	Supplemental Infor...	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 39523/21-9-2009),	
<input checked="" type="checkbox"/>	Supplemental Infor...	-	-	10/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 19609/22-11-2011)	
<input checked="" type="checkbox"/>	PSUR	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 39521/21-	
<input checked="" type="checkbox"/>	PSUR	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 19609/22-11-2011)	
<input checked="" type="checkbox"/>	PSUR	-	-	11/09/2015	Mutabon mite (Neopharmed gentili s.r.l., 021460074), Peripriptyl (Orion oyj, 4472)	
<input checked="" type="checkbox"/>	Supplemental Infor...	-	-	11/09/2015	Minitran (Adelco chromatourgia athinon e colocotronis bros sa, 19609/22-11-2011)	

Total Items: 13

# User Interface allows selection of multiple products - special case



- It is **not allowed** to add **2 different “products”** in eCTD format in a **single** delivery file! If the product has its own eCTD lifecycle the PSUR submission is part of the that eCTD lifecycle and it is not allowed to combine these 2 “products” and create a standalone eCTD sequence just for the PSUR.
- User-Interface allows to select different products due to selection reasons
- See screenshot how to add “different” products where the products do have a single eCTD lifecycle and a single submission would be allowed;

Submission format: eCTD MAH products to which the submission relates: Product short name

ASPIRIN BP BRISTOL LABORATORIES LTD

Sequence number

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin 300mg Tablets BP	UK	PL 17907/0377	

Total Items: 1

ASPIRIN BP BRISTOL LABORATORIES

MAH name	Product full name	Country...	Authorisation No....	EMA Product/MRP/DCP...	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin 300mg Tablets BP	UK	PL 17907/0152	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin 300mg Tablets BP	UK	PL 17907/0153	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin Tablets BP 300 mg	UK	PL 17907/0447	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin Tablets BP 300 mg	UK	PL 17907/0446	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Aspirin Tablets BP 300 mg	UK	PL 17907/0445	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Dispersible Aspirin 75mg Tablets BP	UK	PL 17907/0155	
<input checked="" type="checkbox"/>	BRISTOL LABORATORIES LTD (BERKHAMSTED)	Dispersible Aspirin 75mg Tablets BP	UK	PL 17907/0156	

Total Items: 7

# Submission deadline has passed



Please contact EMA helpdesk to receive a "late submission id"

A screenshot of a web application interface. A modal dialog box is open in the center, displaying a message: "Submission deadline (16/03/2015) has passed for the procedure number: PSUSA/00000007/201412." Below the message is a text input field labeled "Late submission id:". At the bottom right of the dialog are "Submit" and "Close" buttons. The background form is dimmed and shows a section titled "EU-Single assessment". It includes fields for "Procedure number:" (with a sub-field "Enter procedure No."), "Submission deadline:", and "Data lock point:". Below these are labels for "Active substance:", "Rapporteur name:", and "Rapporteur country:". A toggle switch for "Work on a group of associated submissions?" is set to "No". At the bottom of the form are "Generate delivery file" and "Reset form" buttons.



# EMA Helpdesk



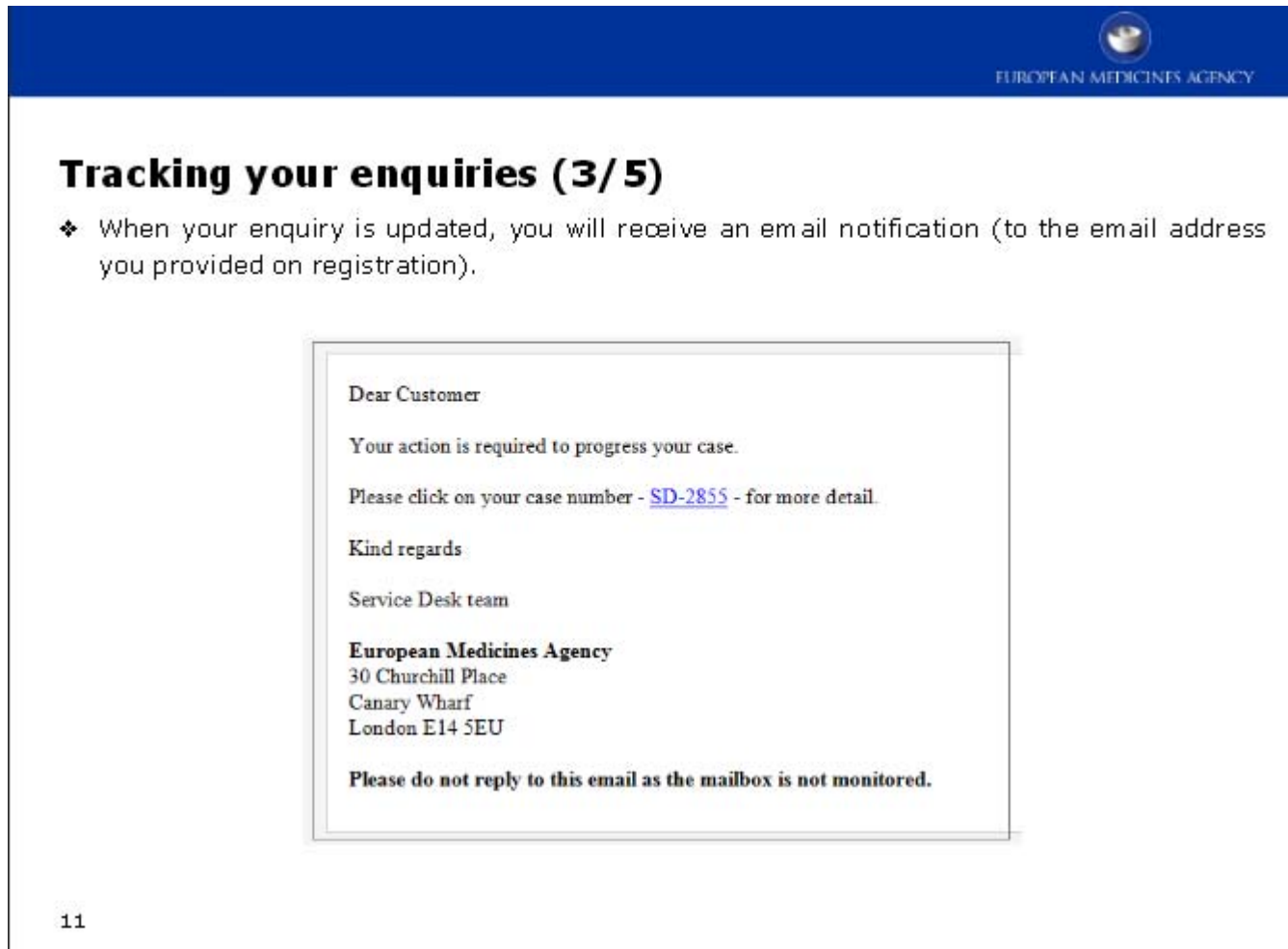
# EMA Helpdesk




- All technical or usability queries should be sent to EMA via the EMA helpdesk tool <https://servicedesk.ema.europa.eu>
  - no Emails

A screenshot of the EMA Service Desk self-service portal. The header is blue with the EMA logo and the text "EUROPEAN MEDICINES AGENCY". Below the header, the page title is "Service Desk" and the subtitle is "Service Desk". A welcome message reads: "Welcome to the EMA Service Desk self-service portal which enables you to request the services you require from the Agency." There is a search bar with the placeholder text "Find a solution". On the left side, there is a vertical menu with the following options: "Ask a Question", "Request a Service", "Report an Issue" (highlighted with a red border), and "Propose a Change". On the right side, there are three categories of issues:

- Report an issue with business applications / software**: Issues (known as incidents) with business applications (e.g. DREAM, SAP, MMS) or software (e.g. MS Office, Windows).
- Report an issue with audio visual, audio/video conference, virtual meeting or multimedia services or equipment**: Issues (known as incidents) with audio visual meeting room equipment (e.g. projectors, voting system or audio quality).
- Report any other issue**: Issues (known as incidents) that are not covered by any of the specific categories above.

A screenshot of an email notification from the European Medicines Agency. The email has a blue header with the EMA logo and the text "EUROPEAN MEDICINES AGENCY". The main content is titled "Tracking your enquiries (3/5)" and contains a message from the Service Desk team. The message asks the customer to click on their case number "SD-2855" for more detail. The email is signed by the Service Desk team and includes the address of the European Medicines Agency. A note at the bottom of the email states "Please do not reply to this email as the mailbox is not monitored." The number "11" is visible in the bottom left corner of the screenshot area.

 EUROPEAN MEDICINES AGENCY

## Tracking your enquiries (3/5)

- ❖ When your enquiry is updated, you will receive an email notification (to the email address you provided on registration).

Dear Customer

Your action is required to progress your case.

Please click on your case number - [SD-2855](#) - for more detail.

Kind regards

Service Desk team

**European Medicines Agency**  
30 Churchill Place  
Canary Wharf  
London E14 5EU

**Please do not reply to this email as the mailbox is not monitored.**

11

# EMA Helpdesk



The screenshot displays the EMA Helpdesk interface. At the top, there is a blue header with the European Medicines Agency logo and the text "EUROPEAN MEDICINES AGENCY". Below the header, the main content area is titled "Tracking your enquiries (4/5)". A sub-header reads: "❖ To view the details and progress of your raised enquiries, click on the title of your request".

The interface shows a "My requests" section with a search bar and a "Search" button. Below the search bar, a list of requests is displayed. One request is highlighted with a red box: "SD-2885 Submission of AMPs as per Article 57 requirements in Service Desk [open]". Below the title, it says "Today 5:45 PM Request created".

An arrow points from this request to a detailed view of the request. The detailed view shows the title "Submission of AMPs as per Article 57 requirements" with a "GPEB" tag. Below the title is a "Comment on this request" field. The "Details" section shows "Today 5:45 PM" and a description: "Can you please advise what are the timelines of submission of AMP as per Article 57 requirements? Thank you." On the right side, there are sections for "SLAs" (Reference: SD-2885), "People involved" (Creator), and "You can" (Add a comment, Add attachment).

12

