Fit for PSUR Repository
IT guidance and Live Demo

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Status / Overview

- The use of the PSUR Repository will become mandatory from 13th 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

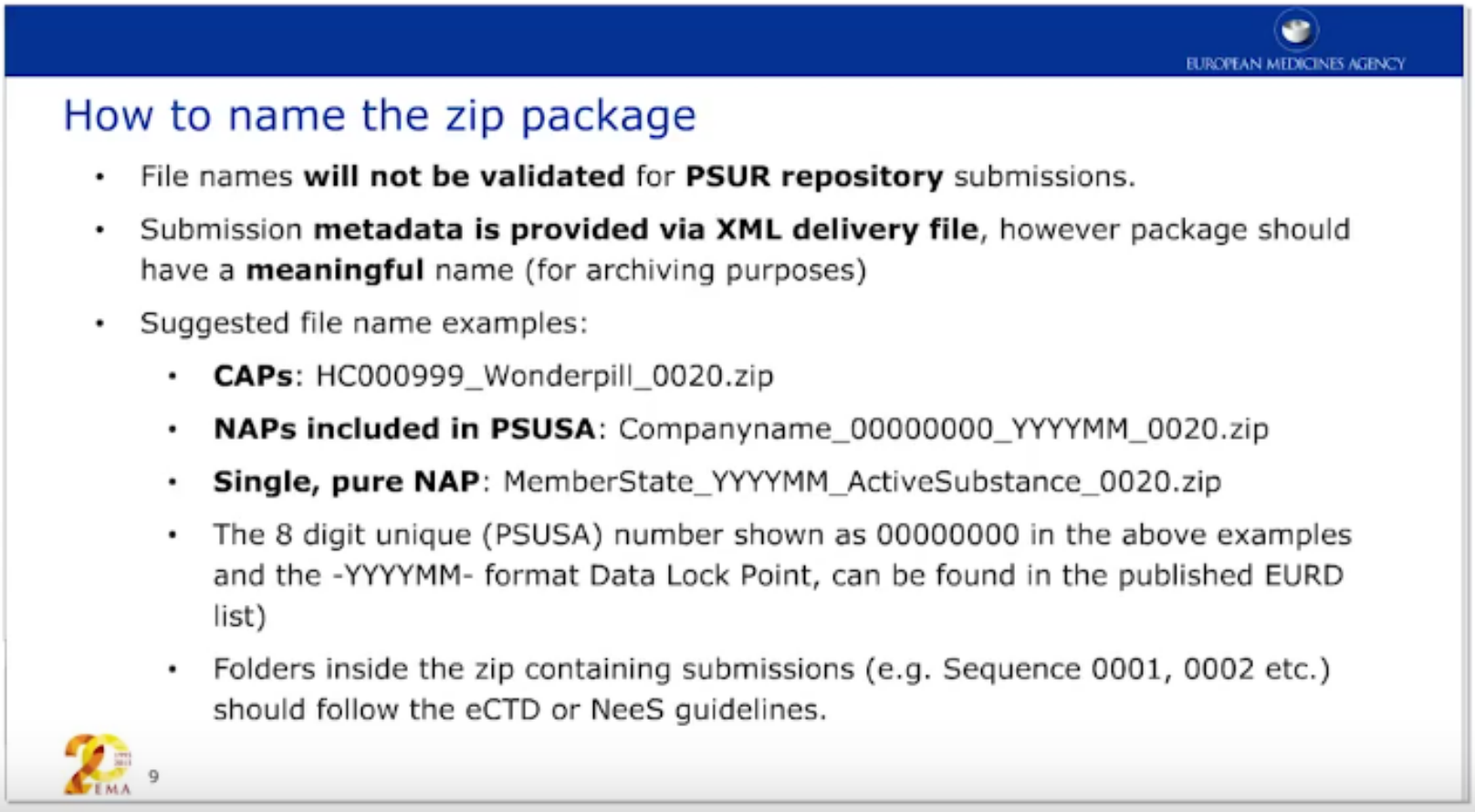
Links

- General information [EMA]
  - http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000041.jsp
- Technical Information PSUR
  - 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

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!



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)

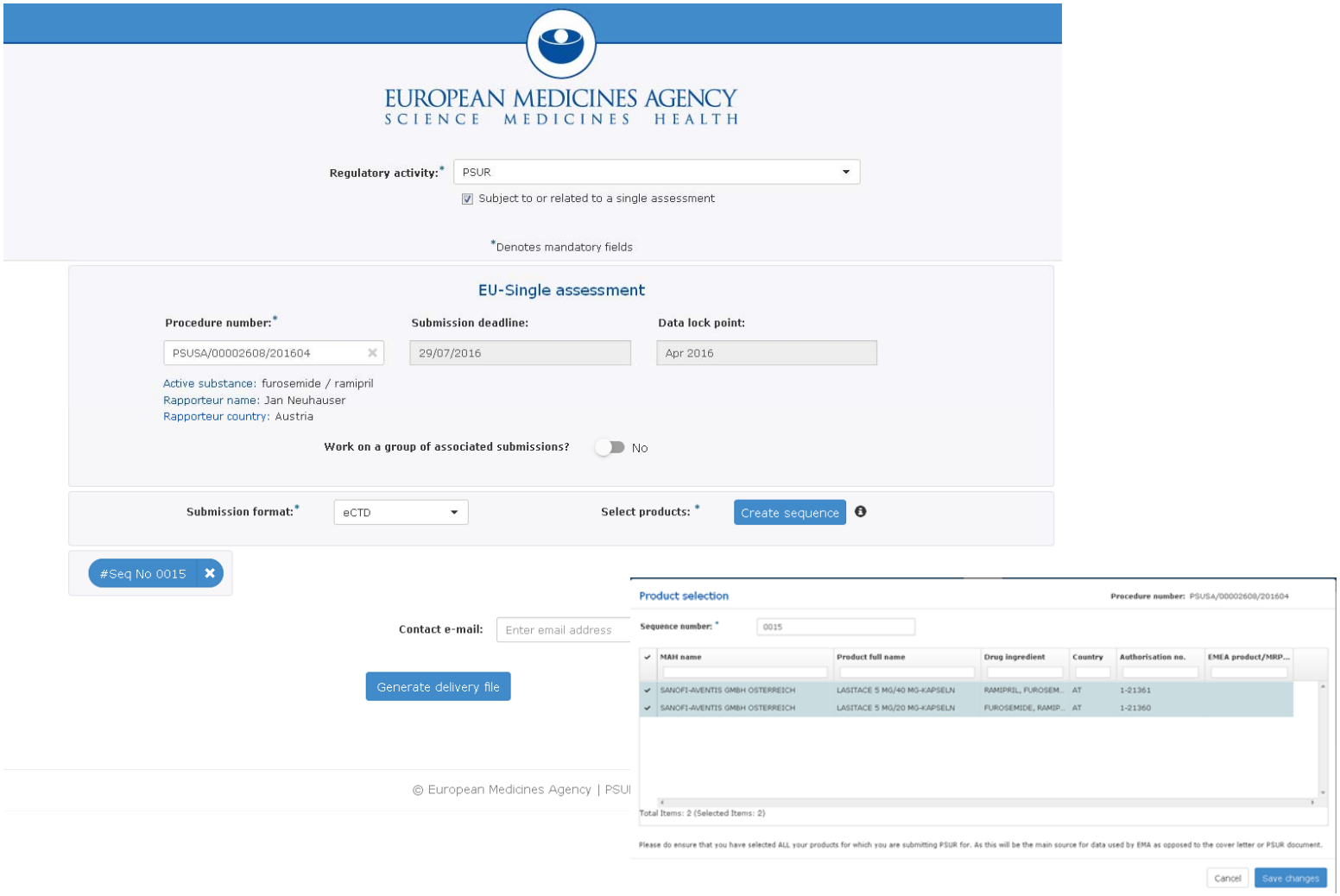
In this example 5 delivery files need to be created and five separate submissions must be made:

- 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

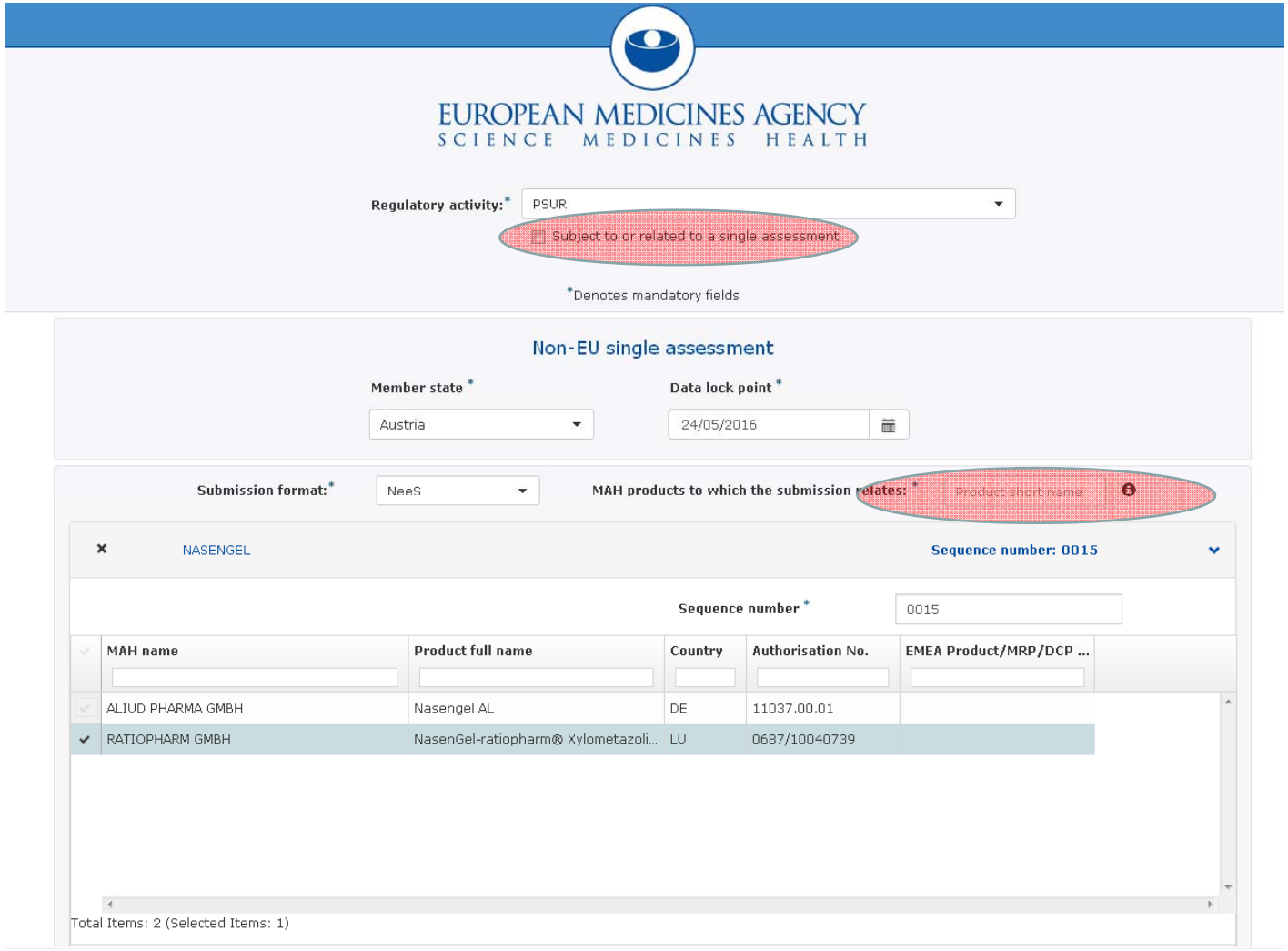
eCTD EU Single assessment

e.g. PSUSA/00002608/201604

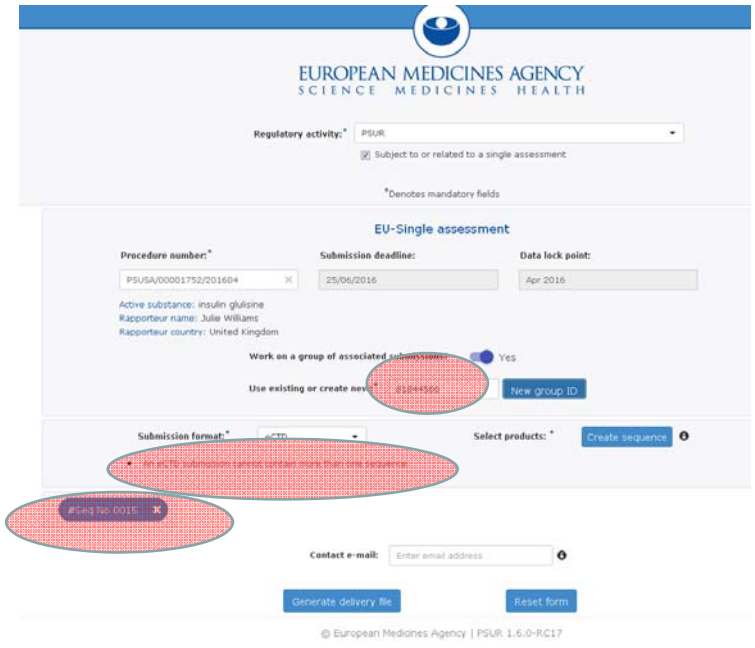


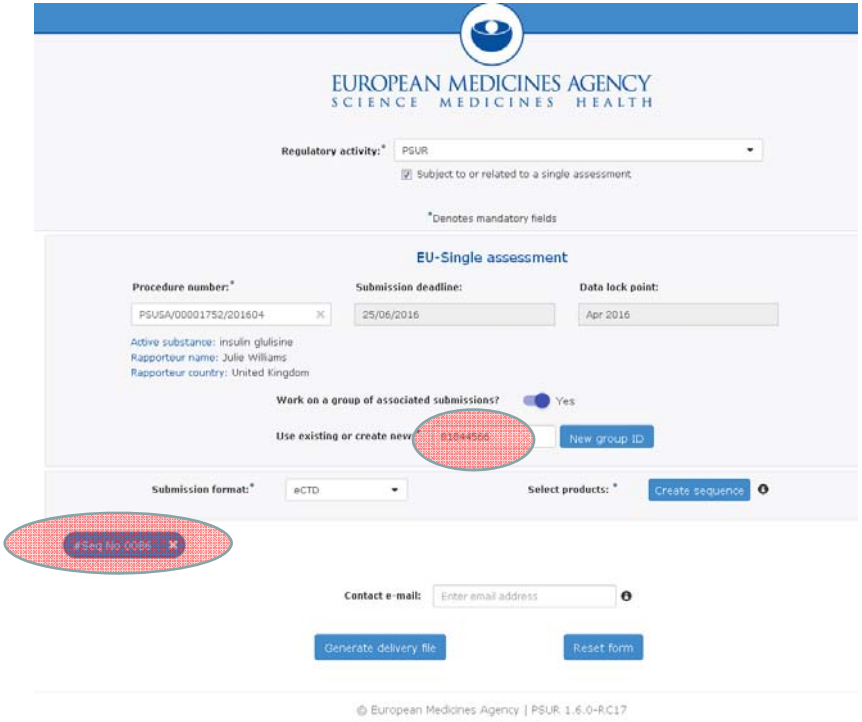
Non EU-single assessment

Nasengel



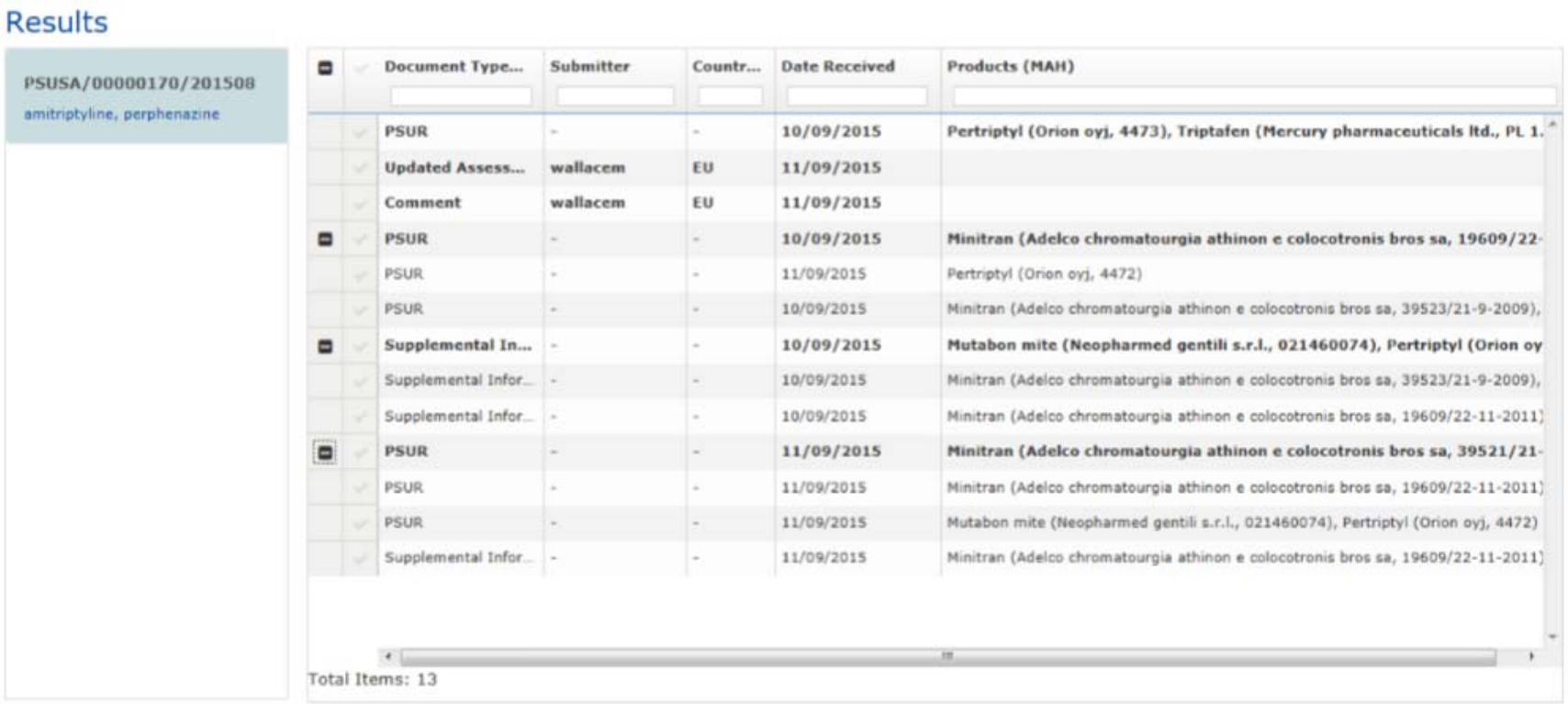
EU-single assessment
Deduplication





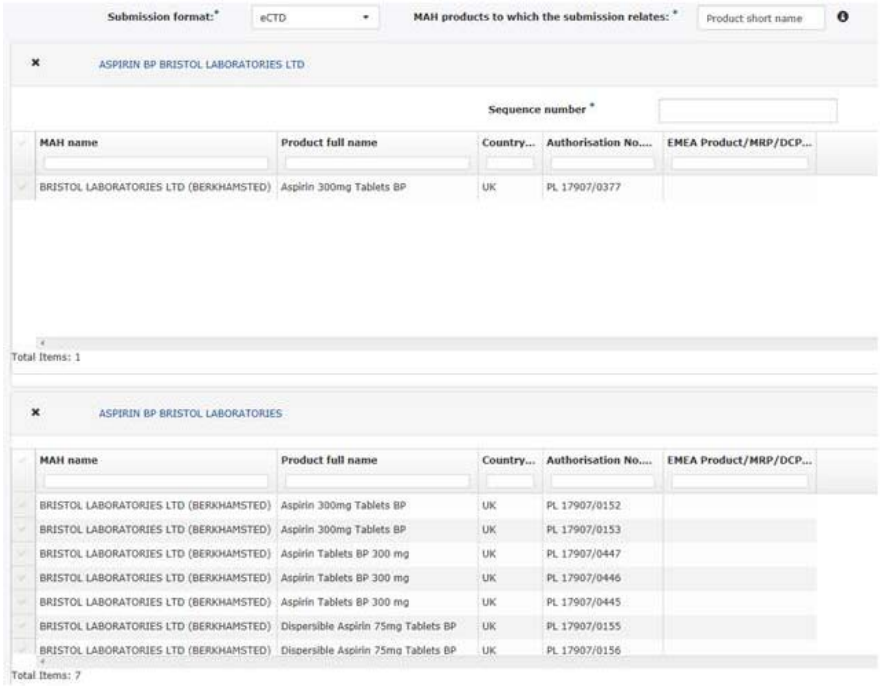
Use grouping to inform regulatory bodies that submissions belong together

NCA view
for grouped submissions



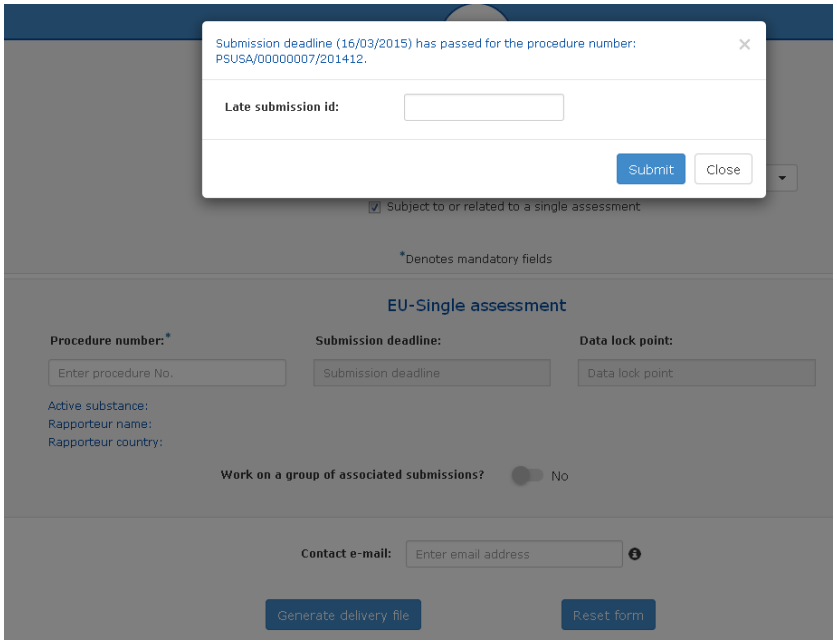
User Interface allows selection of multiple products - special case

- 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 deadline has passed

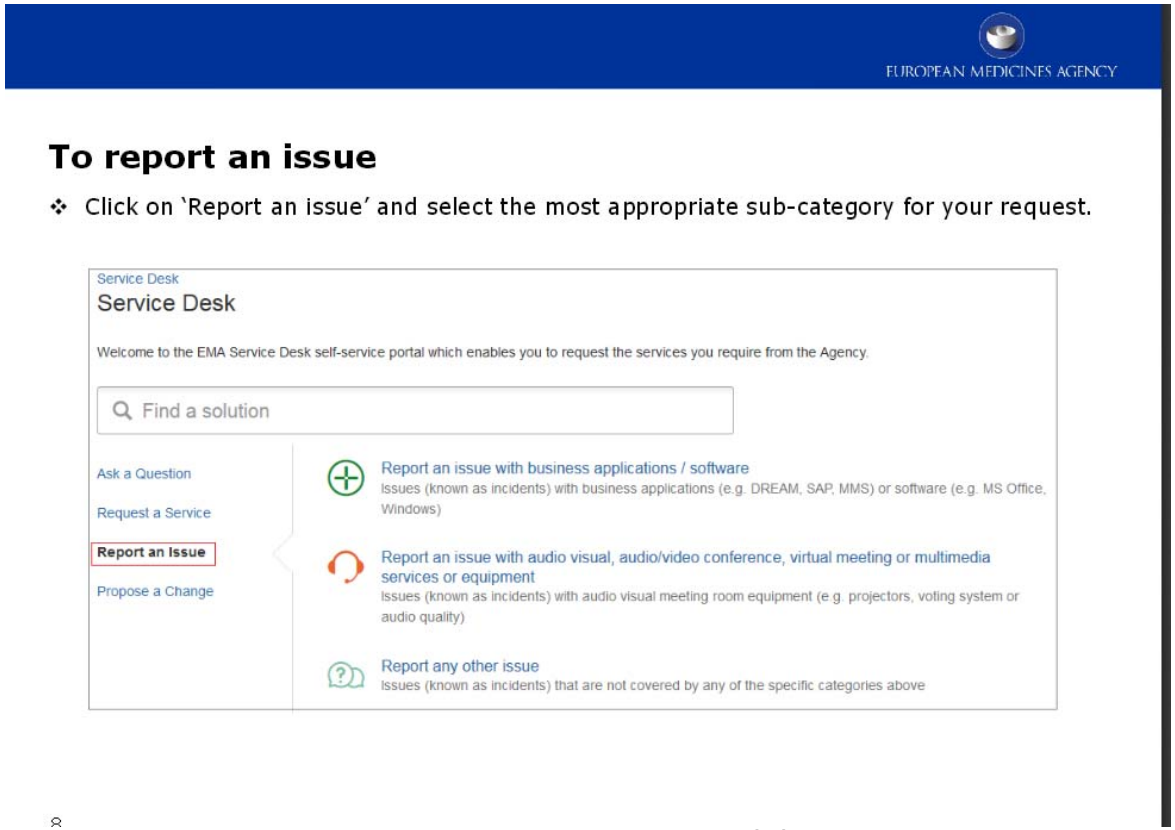
Please contact EMA helpdesk to receive a “late submission id”



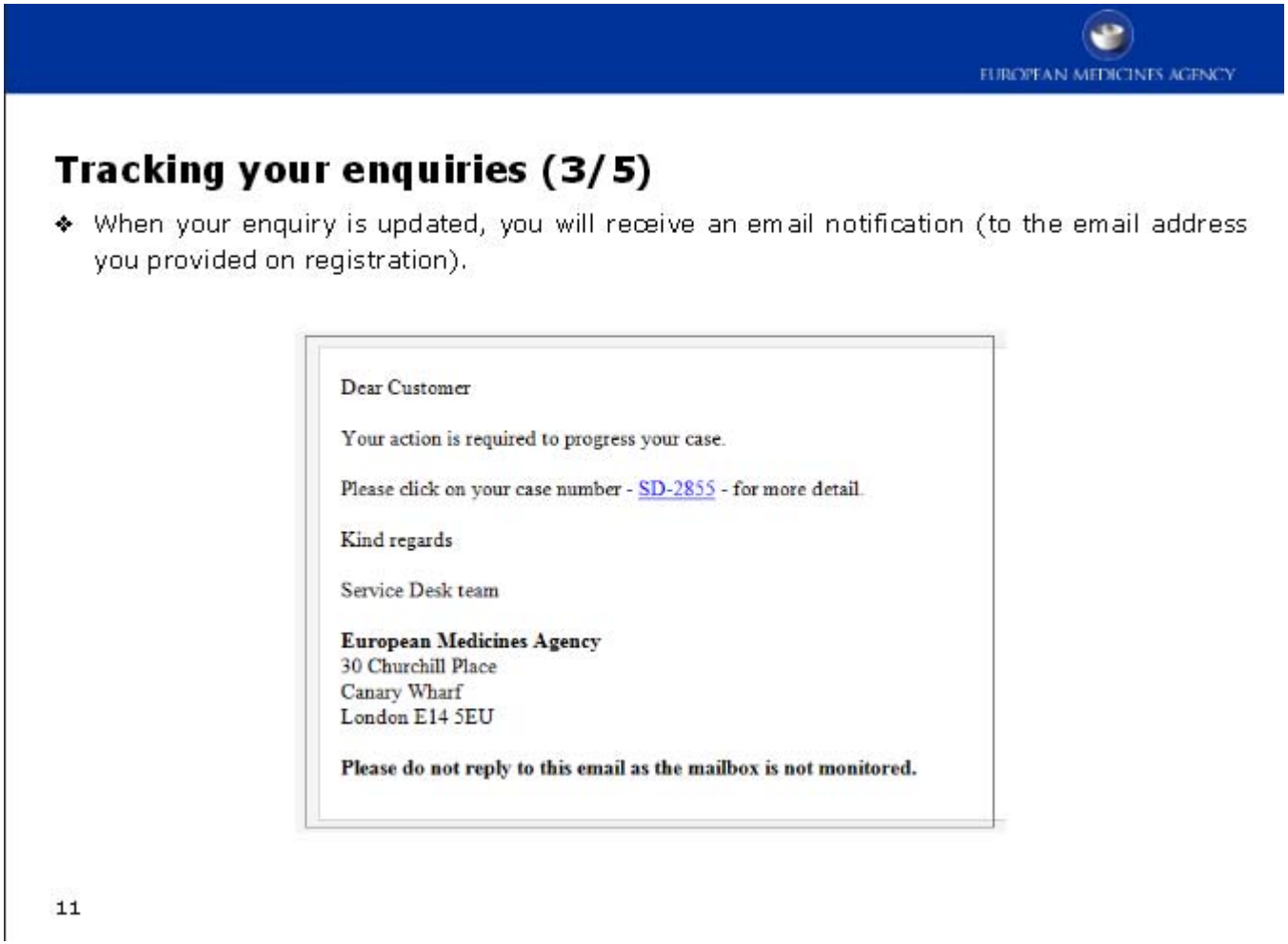
EMA Helpdesk

EMA Helpdesk

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



EMA Helpdesk



EMA Helpdesk