EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF - Information and Q&A session on updated CAPs in web-based eAF

07 May 2024

Agenda

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1 **Welcome & Introduction**
10:00 – 10:10

Kristiina Puusaari
eAF Product Owner

2 **Updates on updated CAPs in web-based eAF**
10:10 – 10:35

Kristiina Puusaari
eAF Product Owner

Marcos Fernandez Gomez
PMS Co-Product Owner

3 **Q&A**
10:35 – 10:55

Moderator:
Isabella Pedon
eAF Change Management Team

4 **Closing**
10:55 – 11:00

Kristiina Puusaari
eAF Product Owner

For Questions: www.slido.com code: #UPCAPEAF

Housekeeping

To ask questions, you can use **Slido**.

We might not be able to respond to all questions, but we will collect them in a document and try to reply in a timely manner.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you choose to use Slido, ***you consent to the processing of your personal data*** *as explained in the EMA Data Privacy Statement for Slido.*

We will **record** the session and make it available on EMA YouTube Channel and on the event web page

For Questions: www.slido.com code: #UPCAPEAF

Send your questions via Slido

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Join at
slido.com
#UPCAPEAF

1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

3. Questions will be shown on the screen and managed live in the Q&A session

Updates on updated CAPs in web-based eAF

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New Centrally Authorised Product (CAP) load is now available in the web-based eAF

Some data issues and some new (minor) issues in the form functions have been found since the new load

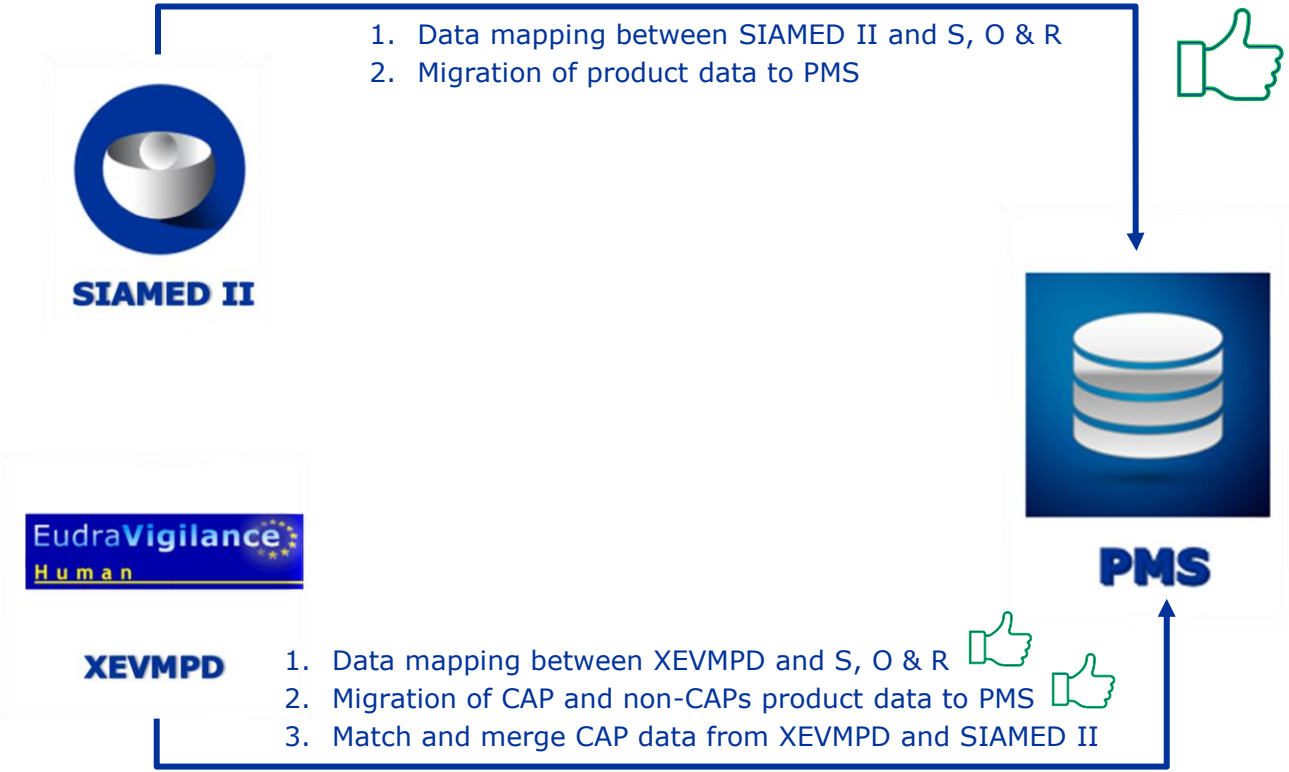
We now feel confident to **recommend the use of the web-based eAF for all CAPs' variations starting from 14 May 2024**

However, please note there are still some known issues and limitations!

Add package feature still pending – for variations adding package please use the interactive pdf eAF

Please report ALL issues that you find via ServiceNow – select the correct category carefully

Match and merge CAP products



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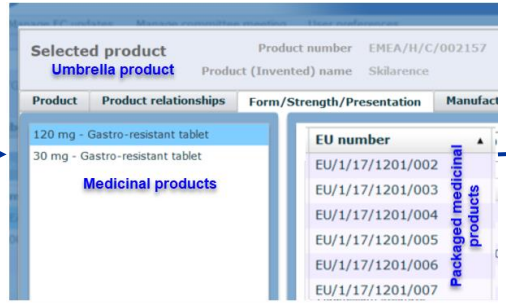
Match and merge CAP products

SIAMED II

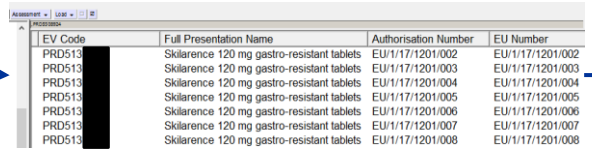


PMS ID	Medicinal product name	Packaged medicinal product
600000003227	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000001121	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Match and merge of this pair of products

EudraVigilance Human

XEVMPD



EV Code	Full Presentation Name	Authorisation Number	EU Number
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/002	EU/1/17/1201/002
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/003	EU/1/17/1201/003
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/004	EU/1/17/1201/004
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005	EU/1/17/1201/005
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/006	EU/1/17/1201/006
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/007	EU/1/17/1201/007
PRD513[redacted]	Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/008	EU/1/17/1201/008

Medicinal product name	Packaged medicinal product
Skilarence 30 mg gastro-resistant tablets	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

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Match and merge CAP products

PMS ID	Medicinal product name	Packaged medicinal product
600000003227	Skilarence - 30 mg – Gastro-resistant tablet	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
600000001121	Skilarence - 120 mg – Gastro-resistant tablet	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

Match and merge of this pair of products

↓ PMS ID	Full Name	Authorised Dose Form	MA Holder
600000001121	Skilarence 120 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.
600000003227	Skilarence 30 mg gastro-resistant tablets	Gastro-resistant tablet	Almirall S.A.

Medicinal product name	Packaged medicinal product
Skilarence 30 mg gastro-resistant tablets	EU/1/17/1201/001 EU/1/17/1201/013 EU/1/17/1201/014
Skilarence 120 mg gastro-resistant tablets	EU/1/17/1201/005 EU/1/17/1201/006 EU/1/17/1201/007

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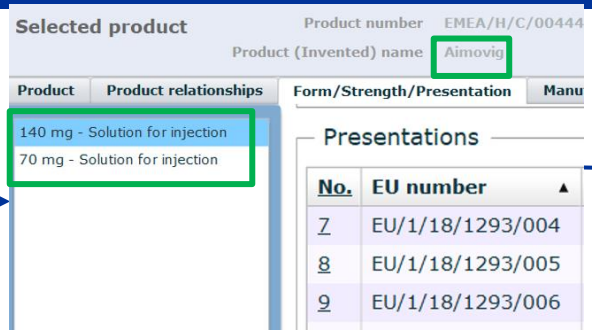
Split of products from SIAMED II



SIAMED II

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005 EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001 EU/1/18/1239/002 EU/1/18/1239/003

Match and merge can't happen as there are two products coming from XEVMPD and one from SIAMED II

EudraVigilance Human

XEVMPD

EV Code	Full Presentation Name	Authorisation Number
PRD7257406	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1293/004
PRD7257410	Aimovig 140 mg solution for injection in pre-filled pen	EU/1/18/1293/005
PRD7257414	Aimovig 140 mg solution for injection in pre-filled syringe	EU/1/18/1293/006

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection **in pre-filled pen**	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection **in pre-filled syringe**	EU/1/18/1239/006

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Split of products from SIAMED II

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005 EU/1/18/1239/006
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PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection **in pre-filled pen**	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection **in pre-filled syringe**	EU/1/18/1239/006

For Questions: www.slido.com code: #UPCAPEAF

Split of products from SIAMED II

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005
600000009012	Aimovig - 140 mg - solution for injection	EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001
600000003456	Aimovig - 70 mg - solution for injection	EU/1/18/1239/002 EU/1/18/1239/003

There is a perfect match now and therefore merge can happen

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection **in pre-filled pen**	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection **in pre-filled syringe**	EU/1/18/1239/006

- Product from SIAMED II (already in PMS) is split to contain the same presentations as in XEVMPD.
- Two medicinal products are created out of the former one already existing.

Full Name ↑	Authorised Dose Form
Aimovig 140 mg - Solution for injection	Solution for injection
Aimovig 70 mg - Solution for injection	Solution for injection

Total 2 entries

Split of products from SIAMED II

PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig - 140 mg - solution for injection	EU/1/18/1239/004 EU/1/18/1239/005
600000009012	Aimovig - 140 mg - solution for injection	EU/1/18/1239/006
600000005678	Aimovig - 70 mg - solution for injection	EU/1/18/1239/001
600000003456	Aimovig - 70 mg - solution for injection	EU/1/18/1239/002 EU/1/18/1239/003

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PMS ID	Medicinal product name	Packaged medicinal product
600000001234	Aimovig 140 mg solution for injection **in pre-filled pen**	EU/1/18/1239/004 EU/1/18/1239/005
600000005678	Aimovig 140 mg solution for injection **in pre-filled syringe**	EU/1/18/1239/006

- Product from SIAMED II (already in PMS) is split to contain the same presentations as in XEVMPD.
- Two medicinal products are created out of the former one already existing.

↓ PMS ID	Full Name	Authorised Dose Form
600000252661	Aimovig 140 mg solution for injection in pre-filled syringe	Solution for injection
600000252662	Aimovig 140 mg solution for injection in pre-filled pen	Solution for injection
600000252718	Aimovig 70 mg solution for injection in pre-filled syringe	Solution for injection
600000252719	Aimovig 70 mg solution for injection in pre-filled pen	Solution for injection

- Full presentation name is taken from XEVMPD
- Authorised dose form is kept from SIAMED II

Match and merge CAP products

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Business rules of the match and merge

Two medicinal products will be matched when the following conditions are all met:

- All presentations in XEVMPD must match the presentations from SIAMED II
- MAH (LOC ID) in SIAMED II and XEVMPD are the same
- Only EU records from XEVMPD will be matched (CAPs with authorisation country LI, NO and IS are considered different records)

If the match happens, the next step is the merge, when the two medicinal products are merged into one and the data between them is consolidated:

- Full presentation name from XEVMPD will survive
- Authorised dose form from SIAMED will survive
- …

Business rules on which source survives after the match and merge can be found in Chapter 7 of the EU IG

Known issues in the web eAF – Authorisation status

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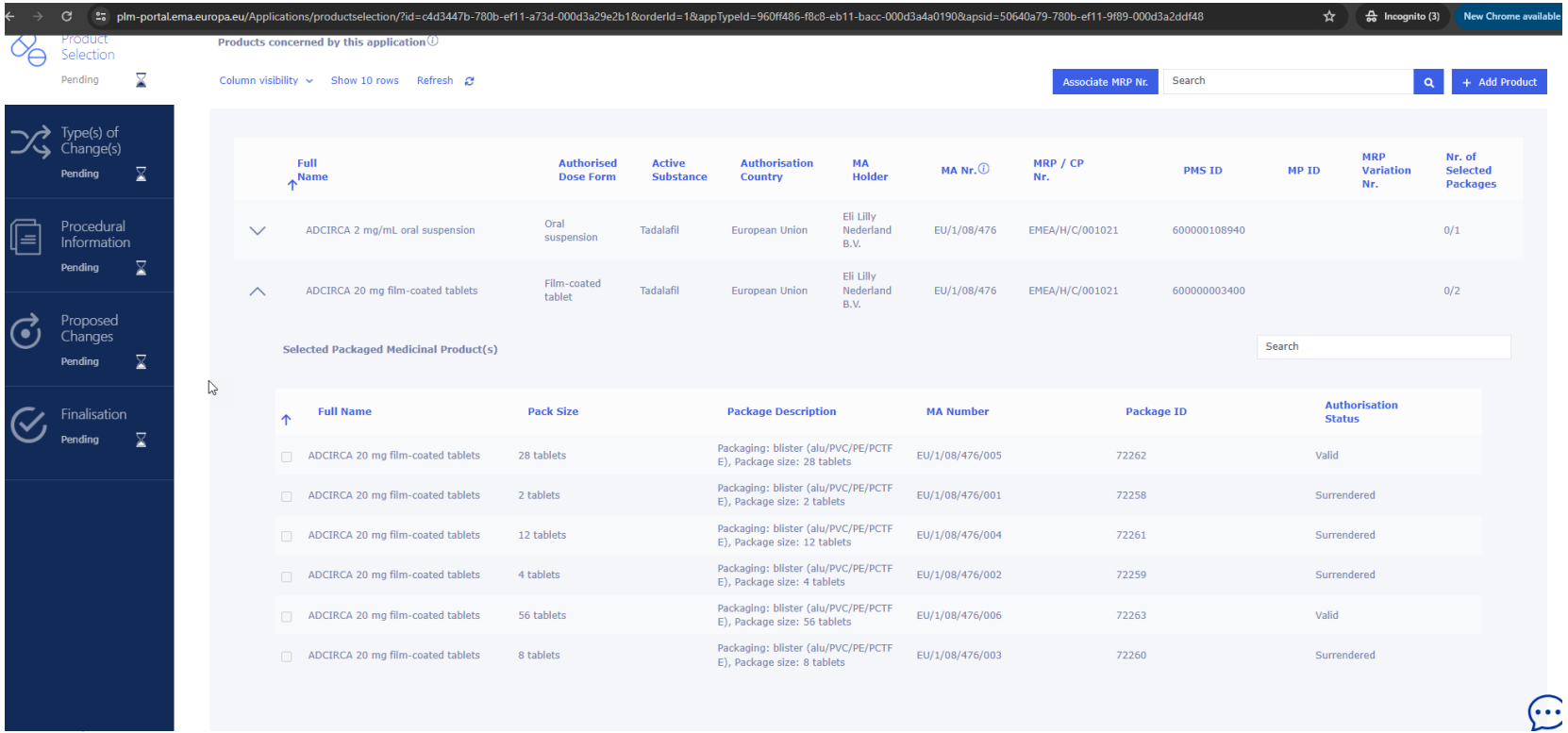
Surrendered products are shown in the product selection view – after page/browser refresh they disappear



Known issues in the web eAF – product selection issue

There is a new bug in the system which allows the selection of the same medicinal product and the same packages multiple times

1. The same packages are listed multiple times in the same form, and this can lead to validation/billing issues – always carefully check the **exported pdf form** to ensure that the form correctly reflects the changes you wish to introduce in the variation

2. There maybe **discrepancies between the web user interface and the pdf** – however, it is important to ensure that the pdf is correct – pls report any discrepancies through the ServiceNow

3. If issues cannot be solved/the pdf is not correct/the data in the xml is not reflecting correctly the pdf content – please **use the interactive pdf eAF instead** and report the issues to EMA asap using ServiceNow

Known issues in the web eAF – copy application

Issues with ‘Copy Application’ feature

1. Form content is not always copied
2. Error message informing of failed copy – however perfect copy has been created
3. Creating a copy times out or takes very long time

Do not use this feature to copy applications created prior to the new product load

Split products/products that have been ‘removed’ are also copied, but cannot be removed/changed and this can lead to discrepancies/errors in the forms (e.g. PDF and the xml are not aligned)

Known issues in the web eAF – split product

We strongly recommend creating new forms

i.e. do **not** continue working on a form you created prior to the new product load

1. If the product has been split **it is not possible to delete** the previously selected product from the form and as a result the pdf export may fail:

   - The product details are incorrectly displayed on the pdf export which may lead to validation issues/rejection or incorrect billing
   - The split products are not exported i.e. the medicinal product and packaged medicinal products are missing from the pdf export (although visible in the web UI)
   - The product names of almost all products have changed following the 'match-merge' protocol which can also cause issues if you continue editing previously created form (even in the case where the product has not been split)

Known issues in the web eAF – export/finalisation (1/2)

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Occasionally you may receive an error message when trying to export or finalise the form

1. Try pressing the 'export' button again, occasionally this requires 2 or 3 tries and eventually the form is correctly exported

2. If the product has been split **it is not possible to delete** the previously selected product from the form and as a result the pdf export may fail:

   - The product details are incorrectly displayed on the pdf export which may lead to validation issues/rejection or incorrect billing
   - The split products are not exported i.e. the medicinal product and packaged medicinal products are missing from the pdf export (although visible in the web UI)

Product(s) you selected are no longer available. Please double-check your product selection is correct. For assistance, contact the EMA Service Desk.

Known issues in the web eAF – export/finalisation (2/2)

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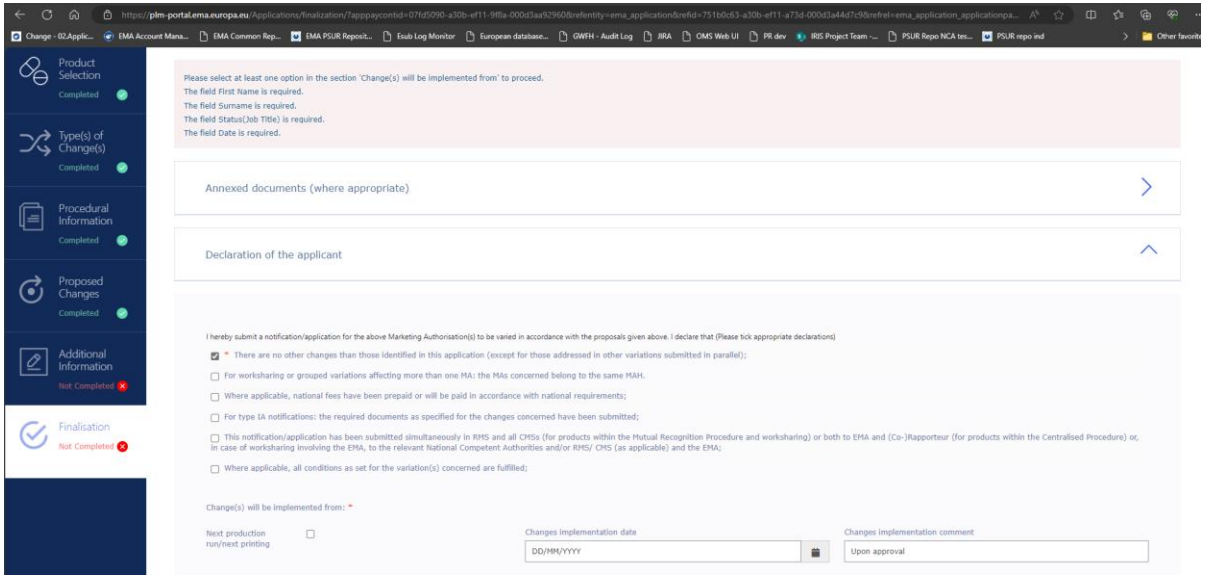
Occasionally, you may receive an error message when trying to export or finalise the form

1. Red error messages in the web form for fields that have been filled in – simply ignore the error message and click the finalise button



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Known issues in the web eAF – Recommended Change(s)

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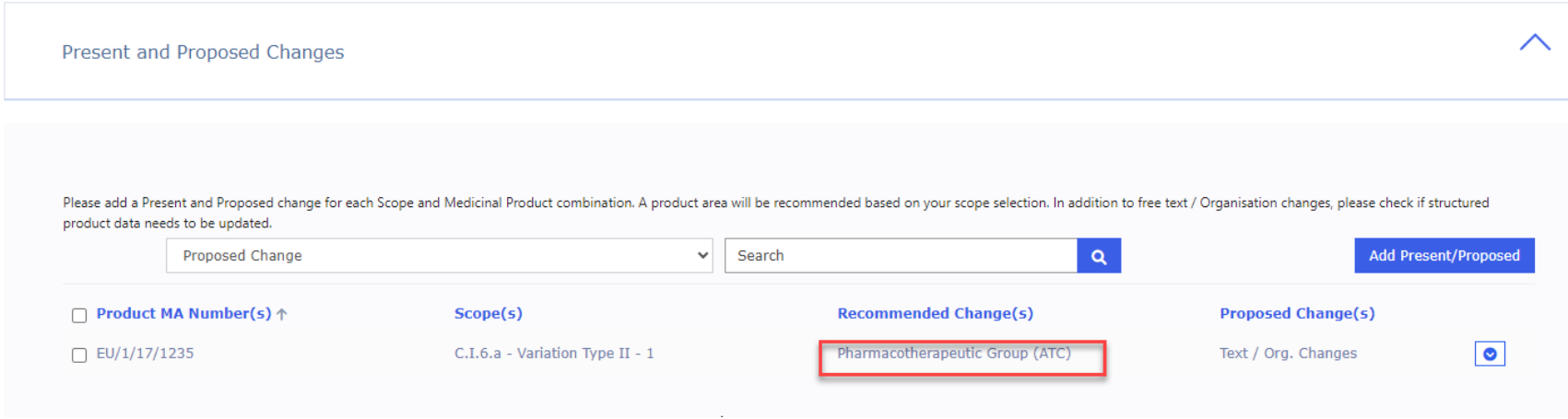
In the "Proposed changes" section:

1. On the home page, under present and proposed – the categorisation under column 'Recommended change(s) is misleading and can be ignored (it is not visible in the pdf export)



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Known issues in the web eAF – Inactive locations

There may be some inactive locations available in sections where only active locations can be selected

1. For example, the MAH contact person and ‘proposed’ organisation in present and proposed must always be an ‘active location’

2. It appears that some organisations that have been marked ‘inactive’ in OMS are appearing as ‘active’ in the eAF. Also, organisations that have been marked inactive are not available in the ‘present’ field of the eAF where inactive organisations can be selected

3. Please pay very careful attention when selecting locations to ensure that only active locations are selected to avoid any business validation issues

Known issues in the web eAF – Other applications

The ‘Other applications’ function doesn’t work as expected

1. Only Type II variations and line extensions from SIAMED are currently displayed

2. If ‘other application’ is selected from the list and the selected ‘medicinal product’ is changed this section is not ‘cleared’ automatically, the incorrect ‘other application’ number will remain in the field.

Issue found – what to do? (1/3)

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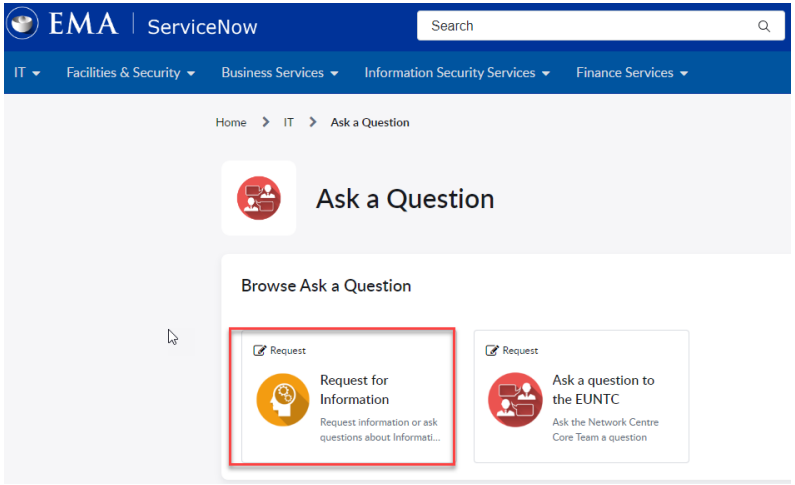
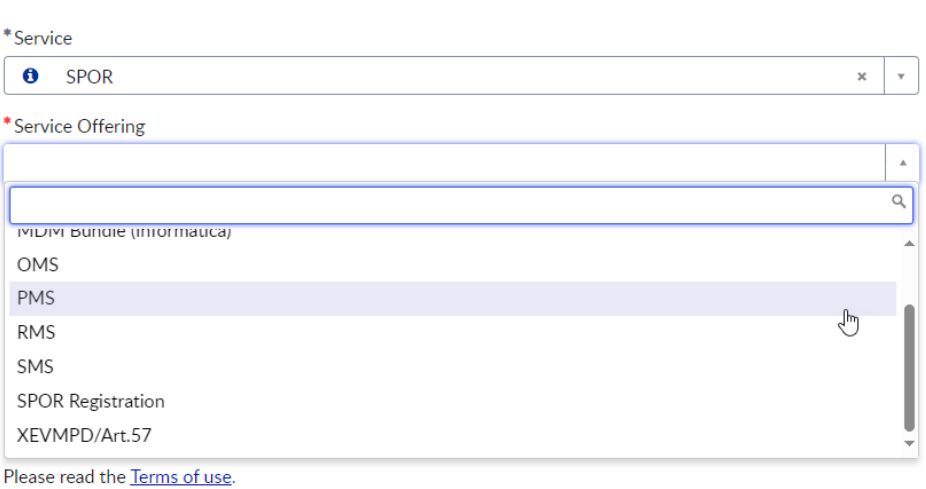
Try to determine whether the problem is:

1

Data issue (active substance is incorrect, package missing):

1. Check **XEVMPD**
2. If the issue cannot be fixed in XEVMP – raise ticket and select 'Report an issue with **PMS**' and sub category (do not select PLM Portal or eAF)





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Issue found – what to do? (2/3)

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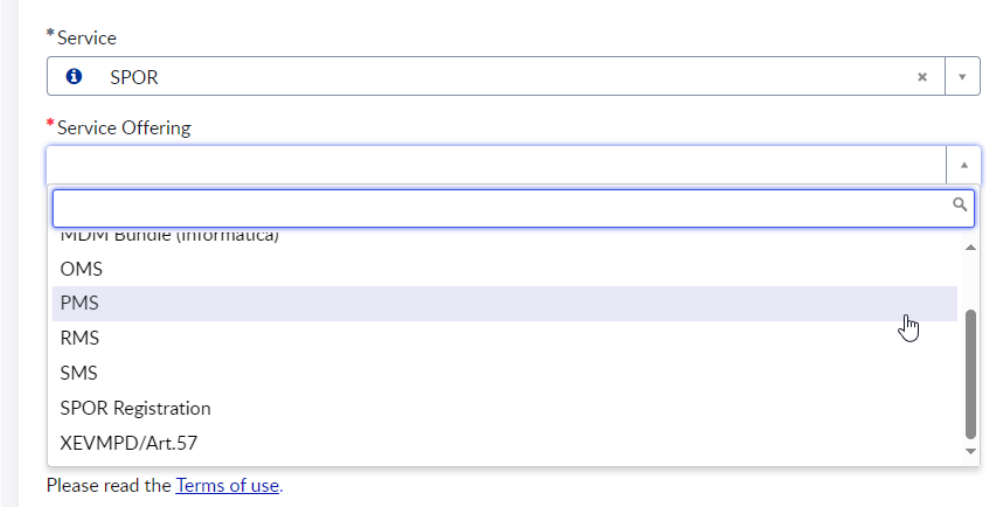
Try to determine whether the problem is:

2 **SPOR** issue (e.g. active substance missing, incorrect address in OMS):

1. Select the relevant SPOR service, e.g. RMS for missing terms, SMS for missing substances/excipients, OMS for address issues you cannot fix yourself (do not select PLM Portal or eAF)



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Issue found – what to do? (3/3)

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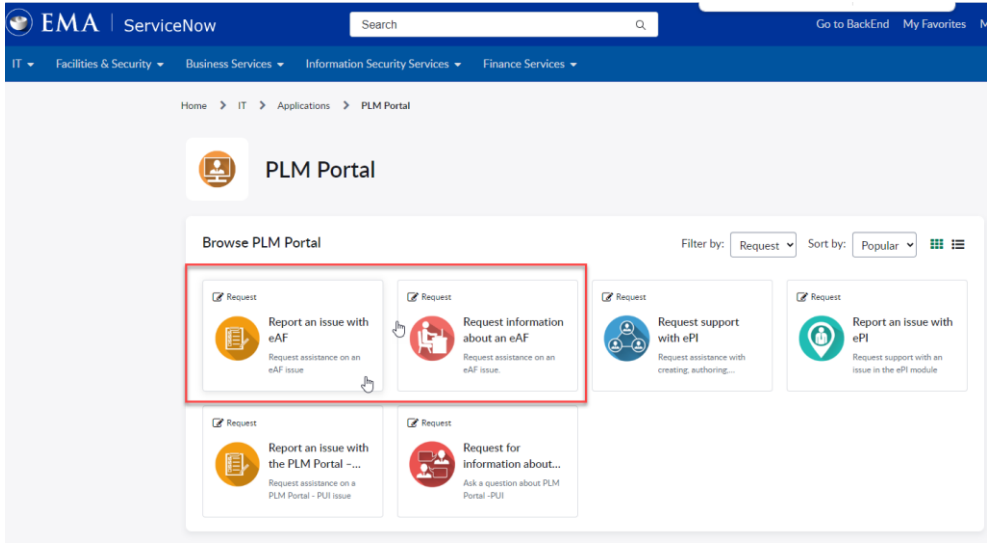
Try to determine whether the problem is:

3 **Technical** issue with **eAF** (e.g. export not working or cannot find the correct scope or incorrect business rule)

- For PLM Portal web based eAF select PLM Portal and try to select the correct category



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What has changed & Next Steps

What has changed

- Package description column provides information helping identification of the package content
- Package ID column renamed on the 'Packaged Medicinal Product' level
- Product names of all products have changed
- Number of medicinal products (approx. 130) have gone through a 'split' protocol where for example 1 medicinal product 'solution for injection' has been split to 2 or more medicinal products

Next steps

- Strongly **recommended** to start using the PLM Portal web based eAF **for all CAPs' variations** (where possible in the view of the known limitations) from **14 May 2024**
- **'Add package'** feature will be available soon
- We are **fixing the known issues** mentioned earlier and we are also focusing on **performance improvements** to enhance the user experience
- **New PLM Portal Home page** will be launched on **31 May 2024**

Q&A

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Please, connect to the above Slido
to ask your questions and leave your comments

Conclusion – Thank you!

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Please, connect to the above Slido
to leave your feedback on this session