Technical Webinar: Information and Q&A session on updated CAPs in web-based eAF (07 May 2024) – Questions & Answers

Date: 07/05/2024

Location: Online, 10:00 – 11:00 Amsterdam time (CET)

Link to the recording: recording

Link to the slides presented: presentation

Disclaimer

This document contains a direct record of questions asked through Slido.com during the Technical Webinar on updated CAPs in web-based eAF which were not answered live during the session. The answers to the other questions are available in the recording of the webinar.

In principle this document will not be updated.

The responses represent the expert view of the Product team at the time of the webinar and are not official statements by the European Medicines Agency nor its partners.

Acronym key and glossary terms

CAPs	Centrally Authorised Products
DCP	Decentralised Procedure
eAF	Electronic Application Forms
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
IG	Implementation Guide
IS	Iceland country code
LI	Liechtenstein country code
MPID	Medicinal Product Identified
MRP	Mutual Recognition Procedure
NAPs	Nationally Authorised Products
NO	Norway country code
PCID	Packaged Medicinal Product Identifier
PLM	Product Lifecycle Management
PMS	Product Management Service
SmPC	Summary of Products Characteristics
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary

Q&A

1- EMA has two options for eAF tickets: one for "Incident", the other for "Request". I have been advised, for the "Incident" option (previously used & successful corrections by EMA) to use the "Ask a question" option which directs to PLM eAF PMS Prod Data. Could you please confirm?

Indeed, there are two options under the PLM Portal eAF; one for incidents, which should be used in case there is a new or serious technical issue in the system that prevents you from creating/finalising your application. It can also be selected if you need to create a variation and the scope/procedure type you require is not available. Incidents have faster turnaround time in comparison to requests. This option should not be used for general feedback or questions on 'How to' use the system. This option also should not be used for requesting procedural support, for example, you are thinking of sending a variation but are not sure which category to select, please do not use this option. The option for Request for information can be used for example for change requests or advice on how to use the system and other non-urgent queries about the use of the web-based eAF, however, not procedural questions. For procedural questions, please select 'Business services -> Human Regulatory'.

2- When do we expect these lists of bugs to be resolved. I will likely be putting my team on hold until these are resolved.

We will keep on working on all bugs in a priority order (the ones that I presented during the webinar of May 7 are just a small subset of important bugs that I wanted to highlight). The bugs are always addressed in the order of criticality but also we consider how many users will be impacted by these issue and also, importantly, some intermitted issues can be very difficult to address due to their intermitted nature i.e. we cannot reproduce the issue 100% of time which makes the investigation of the source very difficult. Unfortunately, we do not have clear timelines on when all bugs will be addressed as we also need to often respond to urgent newly found bugs that might have higher priority.

3- Are PMS-IDs of CAPs available in PLM portal the final stable ones?

PMS ID is available. MPID, PCID are not available due to lack of data elements as outlined in EU IG chapter 7. Please note that as outlined in EU IG Chapter 2 PMS ID is deemed not change during the life cycle of the medicinal product while MPID and PCID can be updated based on specific business rules reported in EU IG Chapter 2.

4- What will happen to the EEA records of CAPs in PMS? For eAF I only need to select the EU PMS ID. Will those be "merged" into the EU PMS ID?

If you are referring to the NO, LI, IS records, they will be covered as a part of the EU product that is selected and they will not become available in the eAF.

5- Who should we contact to correct an authorised dose form after match and merge? The dose form in XEVMPD was correct but the one in SIAMED II was wrong. Now the wrong dose form is used in the eAF.

Please raised an Incident in EMA Service Now and detail as much as possible the issue. Please refer to slides 22 - 24 of the presentation delivered during the webinar of May 7.

6- Starting 14th May, can we use the eAF web-form for MRP/DCP and national products? (The ones that are already available.)

Unfortunately, there will be no non-CAPs available yet. The only products that are currently available in the system are CAPs. We are working very hard to improve the performance of the system so that we can release the NAPs as soon as they become available in PMS. This is currently expected to be in Q3 2024 earliest.

7- How many days will it take to get a resolution of bugs with the eAF? In the past, it took a while to get an answer. If the bug cannot be fixed in a reasonable time, will there be any communication (Q&A, Best Practices) to inform all users.

The resolution time will depend on many different factors, starting from the priority of the bug, i.e. does it prevent users from using the form/performing an important function, how many users are impacted and how easy or difficult it is to identify the source of the issue and how difficult it is to fix the issue. We also take into consideration upcoming 'redesigns' of certain sections where it might not make sense to fix issues that are directly related to specific design of the section. We aim to inform the users through various channels on bugs that are present and which bugs and issues we are hoping to address soon although this is always subject to change depending on changing priorities.

8- From which RMS list is the term for pack size in eAF PLM portal consumed? I have noticed some possible incoherence.

The pack sizes come with the product information from SIAMED or XEVMPD. If you have a concern on a pack size of a specific product and it is different from the published product information/SmPC, please raise a query to PMS.

9- You provided the information about the process on how the use of the web-based form will become mandatory. Do you have updated timelines?

Unfortunately, we do not yet have confirmed timelines for the mandatory use. We know the steps that we need to take to reach this point, however, due to various dependencies, it is very hard to reliably estimate a fixed date/timeline. We are currently concentrating on performance improvements, redesign of some key sections of the form and bug fixes in addition to implementing the final features that are still missing/preventing users from using the web-based form. Once the performance allows and the NAPs data is readily available from PMS, we will release the NAPs in the system for optional use. As the next step, we will have an external UAT to confirm that the system meets minimum viable product, i.e. it can be used for all types of European variation procedures. Once the UAT is passed, we will trigger the 6 months transitional period after which the use of the web-based eAF will become mandatory.

10- Why EMA has decided to move to mandatory use only when national products are in PMS, instead of applying a step-by-step approach (CAPs and then NAPs)?

We decided to start the mandatory use for all procedures at the same time to avoid any confusion related to procedures that contain both CAPs and NAPs and also as we would like to run only one external UAT to confirm that all requirements are met before the mandatory use starts. We are however, moving to a period where we strongly recommend the use of the web-based form for all CAP variations. This could be considered as the first step towards mandatory use, however, it will still allow use of the interactive pdf eAF if an issue is found.

11- In the example on slide 11, was the authorised dosage form SIAMED "solution for injection" or am I mistaken? That's an administrable form?

The RMS term solution for injection reported in the example in slide 11 is a current pharmaceutical dose form.

12- When can we expect to have the delete option available in the system?

We are working on backlog in the order of priority and effort, as the 'soft delete' option of deactivating application forms is already available, we have had to delay the implementation of 'delete' option to allow us time to work on bugs and stories that have higher priority. The delete functionality is currently scheduled for development in Q3 2024.