Technical Webinar: Information session on add package in web-based eAF (18 July 2024) – Questions & Answers

Date: 18/07/2024

Location: Online, 11:00 – 12:00 Amsterdam time (CET)

Disclaimer

This document contains a direct record of questions asked through Slido.com during the Technical Webinar on add package in web-based eAF.

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

API	Active Pharmaceutical Ingredient
CAPs	Centrally Authorised Products
DCP	Decentralised Procedure
eAF	Electronic Application Forms
EMA	European Medicines Agency
MAHs	Marketing-Authorisation Holders
MRP	Mutual Recognition Procedure
NAPs	Nationally Authorised Products
PMS	Product Management Service
PUI	Product User Interface
xEVMPD	eXtended EudraVigilance Medicinal Product Dictionary
UAT	User Acceptance Testing
UI	User Interface

Q&A

1- What are the updates with respect to MRP and DCP web-based forms used for EU variations?

The eAF team has been working on performance updates to ensure that the web based eAF is working in an optimum way and we are now planning to release the NAPs in the form soon after PMS goes live with these products. This is expected in Q4 2024.

2- After approval of the variation, the new package will be available in PMS, is this correct? Or will it come from xEVMPD, which is still mandatory?

For CAPs the new packages will be included in the system, however, the current xEVMPD submissions continue for the time being. For NAPs the new packages will be retrieved from xEVMPD.

3- Will applicants be asked to do data cleaning in PMS after NAPs load?

There will be separate announcements made by the PMS/Product UI team on any required actions to be taken by the MAHs.

4- What would be the purpose of the UAT in early 2025? How could one be part of the UAT?

The purpose of the UAT will be to confirm that the web based eAFs contain all functionalities currently available in the interactive pdf eAF. Following a successful UAT, we will launch the transitional period and subsequently the pdf eAF will be decommissioned. Details on how to participate in the UAT will be launched closer to the time.

5- The information we had before is that NAPs will go live after a UAT. I understand that this plan has changed now that the NAPs are going live in eAF along with PUI. Will there be an updated timeline?

This is correct, the plan has changed, the NAPs go-live will take place prior to the UAT. The UAT will be a final UAT, not for products/product data, but for the functionalities of the eAF for all EU procedures to confirm that the pdf eAF can be decommissioned. We had hoped to go-live with the NAPs in the eAF and PUI at teh same time. Due to the necessary performance improvements in the eAF, it currently seems that the PUI will have the NAPs some weeks before they become available in the eAF.

6- To use the "add package" function correctly after implementing NAPs do we need to revise all xEVMPD submission for each registered pack-size? Currently is this only necessary for products listed at the union list of critical medicines?

There will be separate announcements made by the PMS/Product UI team on any required actions to be taken by the MAHs.

7- Just for clarification, what is the difference between product UI and PMS API?

Product UI is hosted on the PLM Portal and is the web interface that allows users to view the data from PMS in the portal. More information can be found here https://plm-portal.ema.europa.eu/Guidance/article/KA-01039/en-us

The PMS API is the Application Programming Interface used to read the data from PMS from a different system (machine to machine connection).

8- What date is the NAP product data planned to be optionally useable in the web-based eAF? e.g. for MRP/ DCP/ Worksharing.

We are hoping to release the NAPs in the eAF soon after the PMS go-live which is expected in September 2024. This would mean that these products could become available in the eAF in the first half of Q4 2024.

9- When do you anticipate the web eAF use for MRP?

We are hoping to release the NAPs in the eAF soon after the PMS go-live which is expected in September 2024. This would mean that these products could become available in the eAF in the first half of Q4 2024.

10- Will there be any step related to the creation of the following additional packages in xEVMPD: 1 - after the approval of the variation, 2 - until xEVMPD data entry for industry is handed over to PMS write?

There will be separate announcements made by the PMS/Product UI team on any required actions to be taken by the MAHs.

11- What are the next steps of the process yielding to the additional packages to be seen in PMS ?

There will be separate announcements made by the PMS/Product UI team on any required actions to be taken by the MAHs. The functionality introduced in the eAF is simply to allow the users to use the web based eAF variation form for variations adding a package.

12- What will be the level of aggregation for data selection within the eAF for NAPS? Will it be at the Medicinal Product level or the package set level?

This depends on the level of product data available for each product in question in XEVMPD. Further details on any requirements for enrichments will be announced by the PMS team.