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Product Lifecycle Management Value Stream Deep-Dive Webinar (30 November 2023) – Questions & Answers

Date: 30/11/2023

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Link: Product Lifecycle Management (PLM) Value Stream Deep-Dive Webinar | European Medicines Agency (europa.eu)

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the Product Lifecycle Management Value Stream Deep-Dive Webinar and their written answers.

In principle this document will not be updated.

The responses represent the expert view of the Product Owners 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	Application Programming Interface
AMP	Authorised Medicinal Product
CAPs	Centrally Authorised Products
CESP	Common European Submission Portal
CP	Centralised Procedure
CRM	Customer Resource Management
DCP	Decentralised Procedure
DMP	Development Medicinal Product
eAF	electronic Application Form
eCTD	electronic Common Technical Document
EMRN	European Medicines Regulatory Network
EMA	European Medicines Agency
ePI	Electronic Product Information
IDMP	Identification of Medicinal Products
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedures
MVP	Minimum Viable Product
NAPs	Nationally Authorised Products
NCA	National Competent Authority
NeeS	Non-eCTD electronic Submissions
OMS	Organisation Management Service
PIL	Patient Information Leaflet
PLM	Product Lifecycle Management
PSUSA	Periodic Safety Update Report Single Assessment
QC	Quality Control
QPPV	Qualified Person for PharmacoVigilance
RPM	Regulatory Procedure Management
SIAMED	Sistema de Información Automatizada sobre Medicamentos
SME	Subject Matter Expert
SOR	Substances, Organisations, Referentials
SPOR	Substances, products, organisations and referentials
UI	User Interface
UPD	Union Product Database

VNRA	Variations Not Requiring Assessment
XEVMPD	Extended EudraVigilance Medicinal Product Dictionary

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Electronic Application Form (eAF) / PLM Portal

Question	Reply
Does the eAF team have a status on the use of Alternative company names from OMS in the eAF?	The requirement is listed in the backlog with Priority 2 (out of 4). The current Priority 1 goal is system stabilisation, cloning, adding a package and getting ready for NAPs. Alternative OMS names are next on the list.
How will initial data be entered into PMS to be leveraged within the eAF for initial applications and ePI, considering XEVMPD is of course only submitted after approval?	The idea is that the New Marketing Authorisation Application eAF will be used to gather data for new products and this data will be used to populate PMS. Additionally, EMA will hold some information for new MAAs that is provided by the applicants during the pre-submission period. This information can be used in the initial MAA eAF.
PLM Portal will consume structured data from PMS in a stepwise approach: can you provide a timeline for that stepwise approach?	For the moment, only CAPs data is in PMS and used in the PLM Portal by the eAF. In the future, non-CAPs data will also be released in PMS and in the PLM Portal so eAF can use those products as well. Moreover, the PLM Portal will also host the Product UI, which will be used to get access to the full product data that is stored in PMS. We do not have concrete timelines for these releases, we just have a sequence of the work as stated in the webinar.
If the Human variation eAF has been completed, does this mean application data can be uploaded automatically in IRIS from January 2024?	IRIS will be used for the management of procedures only. Other functions, like eAF creation, eCTD/NeeS submission, will continue to be performed on separate portals.
In the future, for MAA, will we need to first submit the data for PMS to be populated before creating the eAF?	There may be some differences for CAPs and NAPs. However, it is foreseen that, for new MAAs for CAPs, a certain level of information will be already provided to EMA through pre-submission activities and the MAA form can be created based on this initial information. The data provided in the MAA eAF will be then fed into IRIS RPM and PMS.
Is it expected to roll out Product UI and web-based eAF to production together at the same time?	The web-based eAF has already been released to production. There will be a future joint release where the integration will be done.
The data scope of PMS & the initial eAF are not aligned, how do you see the pulling together of these two in order to support using the eAF to populate PMS? Will other streams (e.g. ePI) also be leveraged to populate PMS downstream?	The PMS and eAF teams have invested a substantial amount of time to align the eAF MAA form and PMS Implementation Guide. Many updates on the EU IG that are happening are a result of that. Additionally, section 2 of the MAA form will receive a revamp to be IDMP compliant.
The Web eAF currently in production contains some structured changes that do not use Product UI - will these structured changes remain for the transition to mandatory use, be removed, or be replaced by Product UI? What will happen when?	The current structured changes in the eAF were done as a prototype to give regulators and applicants an idea of how PMS updates could work. This has provided the feedback we needed to come up with the "Product UI" as a solution. Once it is on place, the current structured changes will get removed and replaced by the Product UI integration.
What is the benefit of consuming data into Product UI from eAF instead of directly from PMS through IRIS dataverse?	Product UI is not consuming data from eAF. Data in Product UI comes from IRIS dataverse. eAF will use some components from the Product UI for structure changes. And we might use the eAF to get the approved data to update PMS.

Question	Reply
Why is the ePI user guideline in the PLM Portal considering that PLM Portal is only for eAF creation?	ePI can be created and managed in the PLM Portal. It is currently live in the PLM Portal, but only for pilot participants. This is why the ePI guidance is also available in the PLM Portal. The PLM Portal is not only for eAF creation, but also hosts the Product UI. The eAF was the first product that became available in the PLM Portal.
Will eAFs for variations be connected in such a way that XEVMPD submissions for variations will not be needed anymore?	Ideally, once the full circle is implemented, XEVMPD will no longer be needed. PMS will be the database to contain the product data including Art. 57. We are working on ways to facilitate these submissions as much as possible.
Why are veterinary products not going live first with variations web-based eAF and instead of directly with initial MA?	The VMP regulation introduced quite significant changes to the procedures and one of these was the abolishment of 'extension' applications and introduction of the 'I scope variations'. These I scope variations require almost all of the fields from the MAA form and, as the eAFs are developed using various different 'shared data fields', it makes sense to first develop the MAA form and then 'add' the variation fields rather than create the Vet variation form from 'scratch' and potentially then need to replace this design once the MAA form fields become available. This will also allow us to design the new veterinary variation form in the most user friendly and efficient way.

eCTD v4.0

Question	Reply
Do you plan to introduce central repository together with eCTD v4.0?	We are currently discussing this possibility together with our partners in the EMRN. The introduction of eCTD v4.0 creates an opportunity to potentially progress towards the vision of a central repository, but this is at an early stage.
How likely is it that eCTD 4.0 will be used for Medical Devices, VET and other Regulatory Products?	eCTD v4.0 specification indeed has this flexibility that allows it to be used for many new submission types. We will carefully look at the business areas that would most benefit from lifecycle management aspects that eCTD implementation can offer.
Is there an expectation that eCTD metadata (e.g. manufacturer) will be corrected and aligned with IDMP/ SPOR?	Yes indeed, eCTD v4.0 specification allows the use of SPOR data for manufacturers for example.
Regarding eCTD v4.0, will there be a single submission portal instead of EMA gateway + CESP?	As both EMA eSubmission Gateway and the Network CESP are also used for other submission processes, it is not planned to replace these systems. However, we are looking at solutions that would direct all submissions to a single repository. Technical feasibility will need to be investigated and implementation plans to be drafted together with the Network.
There are two documents available on eSubmission website for eCTD Guidance: the EU Harmonised technical eCTD guidance version 4.0 and the EU Harmonised technical eCTD guidance	These documents are the practical implementation guidance documents for the use of eCTD v3.2.2 in the ERMN. The v5.0 is an updated version of the guidance document, released in December 2021. The version 4.0 is an outdated version of the same guidance, released

Question	Reply
version 5.0, what is the difference between the two?	in 2016 and succeeded by the v5.0 in 2021. The v5.0 is in force and only that guidance should be followed.
Will ePI implementation affect how Product Information is submitted in eCTD Module 1.3.1?	ePI implementation, as we are currently piloting it, will not affect how Product Information is submitted in eCTD. The aim is affecting core business as little as possible in our implementation and focusing on having Product Information freely available in a format that can be used for dissemination to patients and healthcare professionals. It will still be required to submit Word/PDF Product Information in eCTD.
Would you advice the Industry to clean the metadata of eCTD applications created with v. 3.2.2 prior to switching to eCTD v. 4.0? Or should we wait until the switch since eCTD v. 4.0 provides more flexibility in metadata assignment?	In certain cases, this can indeed make sense. However, we are not planning to recommend/require systematic reformatting of dossiers prior to moving to eCTD v4.0, where the flexibility of metadata changes is inherent. Once we gain experience through Pilot, we will be able to provide more detailed guidance on different scenarios.

Electronic Product Information (ePI)

Question	Reply
Are there plans to create/utilise an open-source common data standard to enable machine-to-machine loading of Product Information to the ePI?	The EU ePI Common Standard, based on FHIR, has been adopted by the Network and will be used for ePI. Regarding machine-to-machine loading, this is a future ambition. Currently, a basic FHIR upload is possible in the PLM Portal.
Can we upload ePIs instead of authoring them in PLM Portal?	Currently, users can only upload ePI documents that have been previously exported from the portal. In the future, we will be enhancing this feature to allow users to upload FHIR ePIs created by other systems
Can you share first input from regulators and industry on the use of ePI and the ePI solution in the current Pilot setting?	ePIs have been successfully created and published (see PLM Portal). Feedback and outcomes are being collected and will be analysed, compiled in a report and will inform next steps.
Is there a read-aloud function in ePI for the visually impaired?	No, it is currently not a built-in feature. However, we have an ePI display webpage for published ePIs (https://plm-portal.ema.europa.eu/ePIall/) and users can enable a screen reader via their preferred browser. Most modern browsers offer a screen reader functionality.
How will ePI documents be linked to batch specific products in order to support correct Product Information vs products released with paper PIL post variation?	This is currently under investigation.
How will initial data be entered into PMS to be leveraged within the eAF for initial applications and ePI, considering XEVMPD is of course only submitted after approval?	The idea is that the New Marketing Authorisation Application eAF will be used to gather data for new products and this data will be used to populate PMS. Additionally, EMA will hold some information for new MAAs that is provided by the applicants during the pre-submission period. This information can be used in the initial MAA eAF.
If ePI is going to be used to receive, assess and make Product Information	ePI is not used for assessment in the initial piloted implementation. The applicant provides the ePI ID in

Question	Reply
publicly available, how will the submitted dossier be linked to the Product Information (and its assessment) in ePI to maintain compliance and traceability?	the dossier (in the cover letter and in future in the electronic application form).
Is it the intention for ePI to replace the Word and PDF files in the submission package? If so, what is the timeline?	Our focus is on providing ePI for dissemination to patients and healthcare professionals. Word and PDF will still be needed for submission/ assessment. However, creation of digital Product Information will pave the way for further digitalisation along the lifecycle in the future.
Is the ePI tool a separate web-based system?	It is a web-based system in the PLM Portal.
Is there still opportunity for additional companies to join the ePI pilot? Will machine-to-machine ePI piloting be offered to companies at some point in time?	Unfortunately, we will not be able to open up the pilot for more companies. However, please stay tuned for ePI engagement activities in 2024.
Why is the ePI user guideline in the PLM Portal considering that PLM Portal is only for eAF creation?	ePI can be created and managed in the PLM Portal. It is currently live in the PLM Portal, but only for pilot participants. This is why the ePI guidance is also available in the PLM Portal. The PLM Portal is not only for eAF creation, but also hosts the Product UI. The eAF was the first product that became available in the PLM Portal.
Will ePI be integrated at all with the eAF portal related to proposed changes, or will the integration only be made with PMS (i.e. approved values only)?	eAF is one of the products in the PLM Portal. The PLM also hosts ePI and Product UI. ePI and eAF are at different stages of maturity, but there are indeed opportunities for integration in the future, such as the present/ proposed changes to the Product Information section of the eAF.
Will ePI implementation affect how Product Information is submitted in eCTD Module 1.3.1?	ePI implementation, as we are currently piloting it, will not affect how Product Information is submitted in eCTD. The aim is affecting core business as little as possible in our implementation and focusing on having Product Information freely available in a format that can be used for dissemination to patients and healthcare professionals. It will still be required to submit Word/PDF Product Information in eCTD.
Which product data will be published in the Human medicines Portal (including the ePI)?	The ambition for the Human Medicines Web Portal is to have information on all CAPs and NAPs in the EU available, including their ePIs. This is intended to be in all EU languages. The vision and strategy towards the web portal will be progressed further in 2024, including discussions on the scope and alignment with the national level.
Will the ePI "pull" product data (e.g. pharmaceutical product, packaged product) from the PMS or will this not be possible?	Initially, we envisage linking ePI to the relevant product. This will evolve pulling further specific data from PMS to serve business use cases.
Will the ePI be revised through the PLM by the Authority or will comments be shared offline in the word texts for example? How the linguistic review will be managed?	The exchange of comments during the assessment is carried out via Word as today, and core business processes are minimally touched with the initial piloted implementation of ePI. Please see the published procedural guidance on the PLM Portal for more details.
Since you cannot submit multiple versions of the same Product Information for	Please note that ePI will not be used for assessment. ePI can currently be exported to Word and the

Question	Reply
assessment (ePI and dossier), we are running into compliance risk. How can you guarantee alignment unless the ePI data is cascading from the end of the assessment process?	exported Word used for submission or for QC. Currently, companies in the Pilot are using the export to Word functionality for QC of the ePI. Further validation functionality will be considered for post-MVP development.
It was mentioned that the ePI online application went live earlier in November 2023. Where can I find it?	We are live for pilot participants only. All the ePI guidance and published ePIs from the pilot to date can be viewed at the PLM Portal.

Product Management Service (PMS) & Product Data Management User Interface (UI)

Question	Reply
Will the VNRA API also support VNRA super grouping?	For NCAs, yes. The MAH API will initially be read only. Later the API for MAH will allow write but limited to availability status and volume of sale data.
For PMS, can we understand that ongoing work is the current quarter (Q4 2023) and future work is next quarter (Q1 2024)?	Not necessarily. Some of the future work has already been discussed but this does not mean that we are delivering it right next quarter. Some of those points mean that we will start discussing and designing in the future, but some of those will still take time.
How can Industry submit questions relating to PMS, associated processes and data enrichment? Is this managed via the PMS SME team?	Yes, you can contact the PMS Industry SMEs (full names & contacts available here) or you can ask a question via Service Desk.
PLM Portal will consume structured data from PMS in a stepwise approach: can you provide a timeline for that stepwise approach?	For the moment, only CAPs data is in PMS and used in the PLM Portal by the eAF. In the future, non-CAPs data will also be released in PMS and in the PLM Portal so eAF can use those products as well. Moreover, the PLM Portal will also host the Product UI, which will be used to get access to the full product data that is stored in PMS. We do not have concrete timelines for these releases, we just have a sequence of the work as stated in the webinar.
If XEVMPD is to be decommissioned, how will industry comply with the law stated on Art.57?	Industry will comply through PMS. Indeed, PMS contain all the fields from XEVMPD. Therefore, when XEVMPD submissions are decommissioned, product data will be updated via PMS (through the User Interface or the API).
In the future, for MAA, will we need to first submit the data for PMS to be populated before creating the eAF?	There may be some differences for CAPs and NAPs. However, it is foreseen that, for new MAAs for CAPs, a certain level of information will be already provided to EMA through pre-submission activities and the MAA form can be created based on this initial information. The data provided in the MAA eAF will be then fed into IRIS RPM and to PMS.
Industry is using in-house tools (like VRIM) to update XEVMPD database. For the future, will these in-house tools need to be recalibrated to interact with the Product UI instead for updates such as changes in QPPV?	An adaptation of these tools will not be needed to interact with the Product UI, but with the PMS API. Those systems are now connected to XEVMPD API and in the future they will have to submit this data to PMS. For the moment, XEVMPD submissions are the only way to update product data and we will provide additional information when PMS will be used to

Question	Reply
	maintain the data.
Will IRIS Dataverse be a database/ application itself? Can you explain further what is it?	This is a technical component that is behind the scenes to ensure that PMS data is shared with a number of systems. It is part of the architecture but is not a component that will be visible to users. Access to product data will be via the PMS API and the Product Data Management UI in future.
Is data from the XEVMPD adjusted by EMA in anyway before being released into PMS?	All the initial migration of data from XEVMPD to PMS can be found in Chapter 7 of the EU IG. We have just created mappings between XEVMPD terms and SOR terms (substances, ORGs and referentials).
Is it expected to roll out Product UI and web-based eAF to Production together at the same time?	Web eAF has already been released to production. There will be a future joint release where the integration will be done.
Is there any information available on the proposed process and timelines for decommissioning XEVMPD?	Not for the moment, as we still need some enablers to be able to decommission XEVMPD submissions.
When is PMS & XEVMPD Synchronisation expected to go live?	There are two ways of synchronising XEVMPD & PMS: 1. XEVMPD to PMS: will go live as soon as we migrate the data from XEVMPD to PMS. 2. PMS to XEVMPD: still needs to be developed and it is essential to decommission XEVMPD submissions. This synchronisation has no timeline for delivery at the moment.
Regarding PMS, AMP from XEVMPD will be migrated and then submitted through PMS. What about DMP (developmental)?	Development medicinal products are out of scope of PMS for the moment.
The data scope of PMS & the initial eAF are not aligned, how do you see the pulling together of these two in order to support using the eAF to populate PMS? Will other streams (e.g. ePI) also be leveraged to populate PMS downstream?	The PMS and eAF teams have invested a substantial amount of time to align the eAF MAA form and PMS Implementation guide. Many updates on the EU IG that are happening are a result of that. Additionally, section 2 of the MAA form will receive a revamp to be IDMP compliant.
The Web eAF currently in production contains some Structured Changes that do not use Product UI - will these Structured Changes remain for the transition to mandatory use, be removed, or be replaced by Product UI? What will happen when?	The current structured changes in the eAF were done as a prototype to give regulators and applicants an idea of how PMS updates could work. This has provided the feedback we needed to come up with the "Product UI" as a solution. Once it is on place, the current structured changes will get removed and replaced by the Product UI integration.
What is the benefit of consuming data into product UI from eAF instead of directly from PMS through IRIS dataverse?	Product UI is not consuming data from eAF. Data in Product UI comes from IRIS dataverse. eAF will use some components from the Product UI for structure changes. And we might use the eAF to get the approved data to update PMS.
What is the near future for XEVMPD migration?	We will be discussing in the next Programme Increment event which are the features that are missing so we can guarantee a proper migration and maintenance of XEVMPD data in the next months.
What is the intention concerning the Product Data Management UI? Will it be only for medicinal products for human use?	Yes, Product UI will be only for Human medicinal products. It will be used to see product data but also to be able to maintain this data.
When will it be possible to see, in addition	For the moment, data from other national databases

Question	Reply
of SIAMED data, data from Pharos, Amanda and other national databases?	will not be uploaded in PMS. Only SIAMED and XEVMPD data will be seen so far in PMS.
Who owns the data in PMS and will be able to change them (EMA, NCAs, Industry)? Could we have a situation where a MAH and a NCA have to perform a variation based on data which have been modified by EMA?	This is part of the validation strategy that will be discussed. We know some requirements from NCAs and from Industry and we do not want to repeat the same processes as in XEVMPD but this process has not been discussed yet. It is also true that, for the moment, only SIAMED/XEVMPD data is taken into account, so their validation strategies still apply.
Will be any training before product UI (write/ edit) go-live?	Yes, whenever the edit pages are opened in the user interface, training will be provided. We will also generate guidelines, step-by-step guidance, etc. We will communicate, in principle, 6 months in advance.
Will eAFs for variations be connected in such a way that XEVMPD submissions for variations will not be needed anymore?	Ideally, once the full circle is implemented, XEVMPD will no longer be needed. PMS will be the database to contain the product data including Art. 57. We are working on ways to facilitate these submissions as much as possible.

Regulatory Procedure Management (RPM) for PLM

Question	Reply
As EMA implements the new CRM (RPM), you mentioned many NCAs are also implementing their own CRM systems. How widespread is this amongst the NCAs? Do they also plan to integrate those systems with PMS?	The EMRN is a vast network of many different implementations. 11 NCAs are part of UNICOM and actively engaged in updating their databases to be IDMP compliant. This will enable easier exchange with PMS. In addition, a survey showed that at least 7 NCAs are in various stages of implementing the integration of the new eAF FHIR standard into their systems, while some other NCAs will either wait a bit before investing into a revamp of their IT system or use the PDF of the eAF to see product changes.
Can you provide more information on IRIS Dataverse? is it a technical data services layer /API? Assuming this is not exposed to the Industry directly and an internal architecture for EMA?	This is indeed a technical component that is behind the scenes to ensure that PMS data is shared with a number of systems. It is part of the architecture but is not a component that will be visible to users. Access to product data will be via the PMS API and the Product Data Management UI in future.
Documents belonging to cases managed in IRIS, are stored in IRIS' SharePoint. Product variations migrated to IRIS, will have product documents also in IRIS' SharePoint. What is the plan with the DREAM replacement?	DREAM is EMA's internal Document Management System. There is an EPIC (i.e. committed work) to investigate what its successor should be. This is part of the Managing the Agency Value Stream. As this Value Stream is more internally focused, it was not shown in our slides very prominently.
Will RPM apply to CP only?	The transition of RPM to IRIS will almost exclusively impact CAPs, as IRIS is designed for managing regulatory procedures with EMA. However, a small subset of NAPs, MRPs and DCPs that are included in procedures overseen by EMA (e.g. Worksharing, PSUSA), will also be affected by IRIS.

Union Product Database (UPD)

Question	Reply
What are the plans to improve the data quality in UPD? Frequently wrong data is spotted. There are also important delays related to the upload of approved Product Information.	The UPD Data Quality Framework was launched in April 2023. Since then, Member States have improved the UPD data quality by 10%. For any missing or wrong product data, MAHs should contact the relevant Competent Authority.

Human Medicines Web Portal

Question	Reply
Which product data will be published in the Human Medicines Web Portal (including the ePI)?	The ambition for the Human Medicines Web Portal is to have information on all CAPs and NAPs in the EU available, including their ePIs. This is intended to be in all EU languages. The vision and strategy towards the web portal will be progressed further in 2024, including discussions on the scope and alignment with the national level.