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Q&A Q3 2024 System Demo

Date: 18 September 2024

Location: Online, 09:00 - 13:15 Amsterdam time (CEST)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2024

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the System Demo and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below where either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "Plenary" room were generally taken as not addressing specific IT products and are not included below.

Generally, the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com.

The responses represent the expert view of the development teams at the time of the System Demo and are not official statements by the European Medicines Agency nor its partners.

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Monitoring Value Stream

European Shortages Monitoring Platform (ESMP)

Question	Reply
Could you give us some information as to what manufacturing information exactly is expected by December?	*Question answered verbally during the demo.*
Some national agency have national shortage platforms. Will they be harmonized with the ESMP, or will EU and national platforms have to be maintained in parallel.	*Question answered verbally during the demo.*
In your slide you showed that NCAs will only report on demand, but the demand is not given per pack size but only per product. Will there then be a mapping to pack size from NCAs? Or only for those that authorize per pack size.	*Question answered verbally during the demo.*
On the webinar in June earlier this year, you shared that it will be possible to upload data to ESMP via M2M. Today you're only demoing manual upload. When will it be possible to use M2M?	*Question answered verbally during the demo.*
Can any MAH sign up to participate in the ESMP UAT?	*Question answered verbally during the demo.*
Is it acceptable to include in the ESMP template additional lines with pack sizes in case these are missing in PMS?	*Question answered verbally during the demo.*
There was been no new timelines shared since PMS info day. Is the plan still to mandate MAHs to submit structured pack sizes for critical medicines for the use of ESMP by February 2025?	*Question answered verbally during the demo.*
When can we expect submitting the data in the ESMP system itself rather than using excel sheets?	*Question answered verbally during the demo.*

Question	Reply
If the demand is reported at medicinal product level, do MAHs still have to enrich XEVMPD (PMS) with information at pack size level for nationally authorised products?	*Question answered verbally during the demo.*
If in the ESMP template lines for pack sizes are not present, how will NCAs report on "demand" then? When will the mapping of NCAs be done for the entries of pack sizes?	*Question answered verbally during the demo.*
Could you please share the official EMA definition of Shortage.	*Question answered verbally during the demo.* Please also find the definition of "shortage" in the Regulation (EU) 2022/123 which you can also find under this link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022R0123-20220131 *"(h) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State or of a CE-marked medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause;"*
When should we expect a new version of the Critical Medicines list to be published?	*Question answered verbally during the demo.*
9:18 Number of units: what do you mean with this, as you do not want to receive numbers of packs? Can you give some examples?	*Answer added to Rev. 1 of this document.* In crisis situations, the data will have to be submitted on package level (stock & supply). In MSSG-led preparedness activities, the data for national demand is to be submitted on medicinal product level, therefore the number of units is required instead of pack data. The number of units refers to the unit of presentation. The unit of presentation is a qualitative term describing the discrete unit in which a manufactured item is presented. This data element is pre-populated in the data submission template if the file is downloaded from the ESMP. Examples: 100 Vials/tablets/bottles/capsules.
If I understand, the monitoring country tool will be available for preparedness and crisis cases only, not for the routine reporting?	*Question answered verbally during the demo.*
Given that the national health codes will lead some countries to request double reporting from MAHs in "Routine short reporting", has any API been planned to enable NCAs to retrieve the data declared in the ESMP by MAHs ?	*Answer added to Rev. 1 of this document.* EMA is working on the interoperability of the ESMP with Member States' and MAHs' systems and is constantly engaging with NCAs and MAHs to facilitate the interoperability by providing technical solutions. At least one machine-to-machine dataset will be available with the launch of the ESMP MVP in February 2025. Then, depending on the usage of this API and depending on the interest to use

Question	Reply
	more APIs, EMA will develop additional APIs. However, in parallel with the reporting requirements to EMA through the ESMP, national reporting requirements remain applicable. Steps on EU level for harmonisation are being undertaken. The prerequisite for a comprehensive harmonisation is for full interoperability to be established between the ESMP and national systems one on side, and a fully populated and reliable product data on pack sizes of all products in the EU/EEA in PMS on the other, to establish product data standardisation and mapping across national product systems and PMS.
While Pack size submissions are completed on MAH side, by the end of January 2025 it seems a really short time to expect that industry completes the QC all the AMP records migrated by EMA to the Product DB PMS in approximately 4 months only	*Answer added to Rev. 1 of this document.* There is no need to perform a full data quality (DQ) check of all AMPs migrated to PMS and the PMS team has not established a deadline for this activity. This activity should be performed by MAHs overtime and as they perform the enrichment of their products from Q1 2025 or when these products will be used in eAF, or based on strategies defined internally.
Adding to my previous comment: 4 months applicable to NAPs (non-CAPs) when these are made read-only by the EMA in September 2024	
Is there a deadline to submit marketing status value for critical medicine in PMS or IRIS or in other system (marketing status field as reported in chapter 2 of IDMP IG)?	*Answer added to Rev. 1 of this document.* Information on the marketing status of all CAPs must be populated in IRIS and kept up-to-date at all times. This requirement is already in place. Furthermore, there are procedural deadlines to provide updates to the marketing status for centrally authorised products to EMA. Please refer to the webpage "Notifying a change of marketing status": https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/notifying-change-marketing-status and the IRIS guide for applicants: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf. Information on the marketing status is not captured in PMS at this time.
To use ESMP, will you have request a new role via account management? If yes, which one.	*Answer added to Rev. 1 of this document.* An ESMP user access role will be requested through the EMA account management portal, which will be approved by the organisations' User Administrator. These steps will be further described in the ESMP User guide for MAHs which will be published in before the release of the functionality for Routine Shortage reporting of CAPs. Multiple users can be registered for a single MAH and submit on behalf of that MAH, and users submitting data in the ESMP can be different from the i-SPOC. Trainings for users will be organised before the launch of the ESMP for MAHs in Q4 2024. Please also refer to: Guidance and training section of the ESMP

Question	Reply
	webpage: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform#guidance-and-training-materials-69020.
What are the timelines for MAH to report shortages in ESMP?	*Answer added to Rev. 1 of this document.* For routine shortage reporting of CAPs to EMA, the same timelines apply as currently in place. Please refer to: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/medicine-shortages-availability-issues-guidance-companies and https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-and-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs-union-eea_en.pdf.
The ESMP reporting to NCAs: will an API be available?	*Answer added to Rev. 1 of this document.* At least one machine-to-machine dataset will be available with the launch of the ESMP MVP in February 2025. Then, depending on the usage of this API and depending on the interest to use more APIs, EMA will develop additional APIs. EMA engaged in numerous discussions with all relevant stakeholders about the messaging format and requirements and reached an agreement to use an open technology based on XML and HTTPS. This will be available from February 2025. EMA will inform relevant stakeholders when it becomes available. That option will be made available for NCAs who want to use the API and adapt internal systems to the API to submit data to the ESMP.
Are we to implement alternative therapies for all alternative therapies on the market or is it only our own alternative substances related to our own MAs?	*Answer added to Rev. 1 of this document.* The MAHs are requested to report information on any known alternative therapies they are aware of, to the best of their knowledge, whether held by their MAH or others. In the routine shortage reporting functionality MAH can decide to enter substances or product data in the Alternative therapy field.
Which field in PMS will populate the information active substance strength? If there are many active substances in the same product, will all substances and their amounts be stated or will the strength of the drug product be stated?	*Answer added to Rev. 1 of this document.* The data element pertaining to the active substance strength in the ESMP will be showing the strengths of each active substance.
Is the PMS ID the same for a specific medicine on every Excel sheet and is it always 8 numbers in length? In a prefilled Excel template I downloaded, there were PMS IDs of different lengths and I was not able to upload it again.	*Answer added to Rev. 1 of this document.* We assume from your question pertains to the NCA UAT exercise. In the UAT environment we assigned the PMS identifiers randomly and they do not necessarily reflect the structure of PMS products as they will appear in production. Any issue related to UAT needs to be reported to the EMA ESMP team according to the processes in place so we can investigate the issue in-depth.

Question	Reply
Is the ESMP webpage down at the moment?	The ESMP webpage can be accessed with this link: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform
Can NCA's see routine shortage reporting data from MAH's in the MCT dashboards?	*Answer revised in Rev. 1 of this document.* The MCT dashboard is only to be used during PHE or ME. Currently, the shortages reported during routine shortage reporting cannot be seen in the MCT tool and this will not be implemented for the go live in February. EMA aims to implement this functionality in the future, post minimum viable product (MVP).
Will NCA's be obligated to share data from the MCT dashboards with MAH's regularly or is it only in request from MAH?	*Answer revised in Rev. 1 of this document.* The MCT tool is meant to assist in effective decision-making during crisis on a national level. This is not meant to be shared with MAHs as it could represent a breach of policies on confidentiality.
dashboard: now one needs to select a specific product. how about the possibility to look for a certain substance + strength (+ form)?	By selecting the aggregation key that you are interested in (4.1 or 3.1) the aggregation key is adjusted. In the drop down menu of the aggregation key there is a search bar where you can select the active substance and pharmaceutical form (+ strength).
Is the only scope for submission of data to ESMP post Feb those within the ULCM in the case of a critical incident? or can that scope be expanded depending upon the situation?	*Answer added to Rev. 1 of this document.* There are currently no direct or immediate reporting requirements to the ESMP for products in the ULCM, unless the same products are present within a list of critical medicines for a specific MSSG-led preparedness exercise or crisis, which is defined ad-hoc for each particular situation. Starting from February 2025, products in scope of reporting can vary based on three different instances: normal circumstances (i.e., no public health emergency or major event), MSSG-led preparedness, and Crisis. Routine shortage reporting in normal circumstances (which will be made available from end of November 2024) requires early reporting of shortages from marketing authorisation holders (MAHs) to help prevent or manage shortages of specific products. This applies to all centrally authorised products (CAPs) and must take place when an MAH is made aware of a potential or actual shortage of any CAP. During a crisis situation, EMA publishes a list of critical medicines it monitors for that particular crisis via the ESMP. Similarly, MSSG-led preparedness reporting will be triggered in the ESMP for a sub-set of both centrally and nationally authorised medicines included in a list created for that particular activity.
Can you download templates from ESMP without needing to know the PMS id? Can you download template based on other data elements?	*Answer added to Rev. 1 of this document.* Yes, users will be able to download all templates for the products affiliated to their MAH/NCA without knowing the PMS ID.

Question	Reply
	For routine shortage reporting, the user will be presented with all CAPs affiliated with their organisation and they will only need to select the product name for which they wish to submit information. The system will then automatically pre-populated the reporting template with the relevant product information of those products, including its marketing status from IRIS, for products which are marketed or temporary unavailable. For crisis and MSSG-led preparedness activity reporting, the platform will generate templates which you can download, compile, and upload, which will be tailored to the user's affiliation and include the specific products in scope of reporting requirements for a particular crisis or MSSG-led preparedness exercise. The templates will be pre-populated with information previously submitted to the EMA through different systems. Should products not appear in the pre-filled template, please ensure all your product data is up to date in IRIS (i.e. marketing status) and PMS.
Is the interface enabled for mouseless operation?	*Answer added to Rev. 1 of this document.* Most of ESMP is enabled for mouseless operation. Every page can be accessed, every template can be downloaded, and every submission can be completed from start to finish with only a keyboard. The only exception is Alternative therapies data submission flow to be used in Crisis or MSSG-led preparedness scenarios. Without a mouse, the page can be accessed, but it is not possible to add or remove therapies. The overall experience on the usage of the platform aims to be easy and quick. However, sometimes user cannot skip generic content (primarily the side navigation). This means they have to tab through every option in the navigation before they can access the page content. For people with vision impairment, most of the application is compatible with assistive technology (AT), which reads the page contents out loud. Some exceptions exist, such as when selecting products for MAH Routine shortage reporting. Here, the AT will not read the product that is related to a checkbox in that list.
Does the marketing status (IDMP field) need to be submitted for ULCM? What is the deadline?	*Answer added to Rev. 1 of this document.* Information on the marketing status for all CAPs needs to be submitted and kept up to date at all times via an existing process in the IRIS platform. This information will be used in the ESMP for CAPs in scope of the reporting requirements to the ESMP, but it cannot be modified there. If marketing status details for CAPs in IRIS are out of date or incorrect, changes need to be implemented directly in the IRIS platform, after which they will be automatically reflected in the ESMP. Please also refer to: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/notifying-change-marketing-status. Information on the marketing status of nationally authorised products (NAPs) will only be requested for a specific group of products in scope of crisis or MSSG-led preparedness reporting,

Question	Reply
	when this is triggered by the MSSG, and submitted via a standalone reporting data flow directly in the ESMP. There are currently no direct or immediate reporting requirements to the ESMP for products in the ULCM, unless the same products are present within a list of critical medicines for a specific MSSG-led preparedness exercise or crisis, which is defined ad-hoc for each particular situation.

Technology Lifecycle Management and Information Security Value Stream

EMA Account Management – Authentication to EMA systems using email address

Question	Reply
When you work in a company which covers a lot of MAH's which are located in different countries, how can you request roles for all of them in one go. At the moment this is not possible in the system.	Please join us on Friday, we will show how to request access for multiple organisations. https://www.ema.europa.eu/en/events/ema-account-management-whats-new
will this change apply to all the systems/applications (IRIS, PLM portal, UPD, etc..) where you have to introduce EMA credentials?	Yes, we still have few systems not capable of modern authentication and multi factor authentication, we are working with the different teams to change this. All the systems mentioned above are affected by this change.
What are the legacy applications that will still require username and password?	The main applications are: Clinical Data Publication Portal, SPOR (OMS and RMS), EPITT Human, Common Repository and PSUR, we are working with the different teams to change this.
Will the email authentication also work with EMA applications like UPD?	Yes, most of EMA applications supports this change.
Do you currently have plans to enable single sign on for EMA systems.	Single sign on for EMA systems is already in place for all the systems using modern authentication. With this change, if your company is integrated with Azure AD and has single sign on implemented, you will not be prompted for further authentication.
After typing the User Name and the password, we do have to confirm logging-in via MS-Authenticator. I do not remember if that step has been set up from our company or if it is mandatory. What happens to this step?	The Multi Factor Authentication step remains in place, we omitted that step to speed up the demo.
How will this work if you are a service based company and working for multiple clients	It depends on your account is set up, if you are using your are using the service provider email address you will authenticate with that, if the company you are working for provided you an email address you will be using the company email address.
I do face some issue when want to change device for authentication via Authenticator app. This change will solve the issue?	Not for now, you will still be prompted for Multi Factor Authentication.

Question	Reply
Is there a method for automatically changing all users in an organisation to this authentication method rather than allowing them the opportunity to opt in I would hope we could force the change and oblige them to convert.	Yes, please open a ticket for the Service Desk and we can convert all the users of a specific email domain.
Is this change also impacting the usage of the API?	No, API using modern authentication are not affected unless you are prompted for interactive sigin.
We are told functional/group mailboxes are no longer allowed. if a user has an individual mailbox linked in EAM, I understand a group mailbox can still be notified for the role « contact person after authorization ». Thanks for confirming	Yes group mailboxes are allowed in contact fields for notifications but not anymore for authentication.
Where is the definition of a Federation being documented ?	Federation is the ability to rely on another identity provider based on SAML or WS-FED standards. Organisation using Azure AD (aka Entra ID) are automatically federated.

Managing the Agency Value Stream

New Fee Regulation (NFR)

Question	Reply
Do I understand correctly that MAH gets invoice for SA appr. 1 week before SWAP and if not paid in time, slot will move to next SAWP? It will be a big challenge for MAH to pay in time. Can invoice sharing be accelerated?	*Answer added to Rev. 1 of this document* Yes, the invoice will be issued after the administrative validation which will be approximately one week before the start of procedure. If the payment is not received by the start of procedure it will automatically be moved to the next available. We recommend that you pay the invoice as soon as possible upon receipt, for your request to be included in the next available start of procedure date.
Can you confirm : the system waits for 30 days after the payment deadline before canceling the workflow ?	The system will cancel the invoice at day 31 from the invoice date.
CPPs will go in IRIS?	*Question answered verbally during the demo.*
For SA, in case the fees are not paid within 30 days and the procedure is cancelled, are additional costs applied for the validation process?	*Question answered verbally during the demo.*
How much time does industry have to pay EMA after we have received the invoice?	The payment due date is 30 days from the invoice date, this will be clarified later on in the presentation.
If the invoice for Scientific Advice will be made available in IRIS, will it still be visible in the EMA invoicing system ? Aim of the question: identify if a given Org can receive the same invoice twice by different systems. Thanks	The pdf invoice will not be available in IRIS. In IRIS you will only see the invoice number and the amount. The invoice will be available in the EMA invoicing portal if you are portal user and/or it will be sent by email to the email address registered in our financial system for receiving invoices.
Thank you for the demo, but CPPs requests are not managed in IRIS. How will that work then ? Specifically when the EMA identifies that adjustments to the initial request are needed. Thanks	The CPP requests system is currently being finalised, and we will be able to provide further details in the coming months. We will provide an instruction email to use the system, and we will organise a dedicated demo.

Product Lifecycle Management Value Stream

You can subscribe to the quarterly PLM Highlights Newsletter at
https://ec.europa.eu/newsroom/ema/user-subscriptions/3638/create

Veterinary Union Product Database (UPD)

Question	Reply
What advice can EMA give to MAH for dealing with NCAs that are totally unresponsive? Please do not quote the contact list again	The MAH may wish to escalate such issues at CMDv-Interested parties meetings or write directly to HMA.
Is it forseen tech./product data quality issues on UK NI products will be resolved before end of free QPPV email update period? MAHs are certainly not willing to submit C.1 VNRA and pay VNRA fees on product with tech./product data quality.	Only authorised users can amend the UK NI products. These products have not been updated since 2022! Recently the EC has allowed EMA to make changes to the UK NI products, but discussions about the details are ongoing and therefore no action has been taken so far for any UK NI product. All stakeholders will be informed as soon as process starts. Due to enormous backlog of UK NI products requiring updates it will not be possible to complete the task before end of free QPPV email update period.
If UPD UI is idle for less than 1 hour, a user has to login again, despite the clock displayed not having reached 0 minutes. Are you aware of this?	We are not aware of such issue, please open a ticket in ServiceNow and the team will investigate it.
In administration, the principle of providing information only once has been put forward to reduce burden for users. Are you making efforts to make sure to follow this principle?	Please note that EMA has an aspiration to follow the "Design for User Centricity" principle where we design services to support the entire user journey, ensuring a seamless experience from start to finish. Users should provide data only once, with administrations retrieving and sharing this data as needed, in compliance with data protection rules. This minimizes repetitive data entry and streamlines the user journey. We aspire to follow this principle, yet we recognise this is not always fully possible.
Is API available for this MRP creation after SPC harmonisation?	The creation of an MRP after SPC harmonisation will be available for UI and API users on the 3rd of October.
The option to save a draft VNRA does not work. When will this problem be resolved?	We are not aware of such issue, please open a ticket in ServiceNow and the team will investigate it.
What about the email notifications? Will this be fixed in the next release in October 2024?	As soon as the root cause is identified a hotfix will be applied in PROD but it is very unlikely that will go under the next release on 3rd of October.

Question	Reply
Why MAH needs to ask RMS and/or CMS and/or NCA to raise a ticket when the ticket has already been raised for UPD issues? Would not be better that EMA Support would just add needed stakeholders to WatchList?	When a ticket is raised, the UPD Service Now team conducts an investigation to determine the root cause of the issue/problem. A detailed analysis and next steps are always provided in writing in the ticket. These next steps may include instructions to contact the relevant national competent authority for cross-checking purposes. Duplication of tickets by different stakeholders for the same issue affecting the same product is discouraged. As for the suggestion that EMA Support unilaterally adds stakeholders to the "watchlist," this may result in confusion, administrative burden and breach of confidentiality.

Product Management Services (PMS)

Question	Reply
Can you provide information on what type of manufacturing data needs to be submitted on package for ESMP by December 2025?	This will be provided in a specific manufacturers webinar in Q4.
When will the PMS API be publicly available? When will the nationally authorised product be added?	*Question answered verbally during the demo.*
What is the estimated target timelines for the completion of this moving of products records within PMS?	*Question answered verbally during the demo.*
In PMS I find medicinal products in status "current", but also "provisional". What is the meaning of the latter? I did not find any documentation on the status.	*Question answered verbally during the demo.*
We we're referred to the PMS demo regarding information as to what manufacturing information exactly is expected by December? And how it is supposed to be entered into PMS?	*Question answered verbally during the demo.*
Can you give an outlook as to when pending MRP, DCP and national registrations must be transmitted via xEVMPD in order to be integrated into PMS and which data exactly is required or where further information can be found?	Submission of pending MPRs and DCPs will be available in XEVMPD by beginning of Q1 2025. Please, take into account that pending pure NAPs should not be submitted to XEVMPD. Only pending MRPs and DCPs after they have been approved by the Reference Member State should be submitted so they can be used in eAF in case there is a need to submit a variation for these products.
How will companies be able to submit Manufacturing data in bulk to support ESMP?	*Question answered verbally during the demo.*

Question	Reply
Since you are merging pack sizes for CAPS will there be one product in PMS for CAP including EU/NO/ICS/LI or will it be one separate product for EU/NO/ICS/LI (4 in total, like it is currently in xEVMPD)?	We will merge all of them under the same medicinal product. At the end, it is the same medicinal product and we only need one for eAF, shortages, and the rest of use cases consuming data from PMS.
When will the API to update/enrich the manufacturing data in PMS? As currently this looks as the only "bulk update" function possible.	We are working to have it ready by Q1 2024. Nevertheless, we also need MAHs to be ready to submit to the PMS API. That is why during Q4 we will be hosting some sessions to provide additional information on this.
If MAH's change the data in xEVMPD after initial migration with data quality issue, will the logic provided still apply?	*Question answered verbally during the demo.*
Does the marketing status (IDMP field) need to be submitted for ULCM? What is the deadline?	This is a question for the ESMP team. Please, raise the question there.
If I use the Product(s) of my Organisation(s) in PMS I found verry strange issues, what are the fields that take in the migration. itis not only the Full Name.	Please, review Chapter 7 to understand the business rules of the migration.
Is this Package ID the national ID coming from individual NCAs? Are all the NCAs having these Package IDs? Will these be used to generate PCIDs?	No. This is a technical ID generated by PMS. They will not be used to generate PCIDs, it is just a technical package ID that never changes and that should be used to map against MAHs or NCAs databases/RIMS.
The match and merge protocol is still not working appropriately even after latest correct submissions to xEVMPD. Also sometimes the M&M has hpnd and pack has been merged with correct PMS ID record but previous duplicate PMSID is nt nulfied	We are investigating this issue as we have found some duplicates created in PMS. This is a priority for Q4.
We have been talking a lot about manufacturing data and package size. But is there a full list/overview of what type of data you're able to support and by when?	During the PMS Info day we provided all the information. The information is available in the event page. Moreover, we hosted a webinar on pack sizes and there is also an event page with all the info and we will host another webinar for manufacturers with all the info.
What do you use as source of truth to know that an entry contains a mistake (comprimido->comprimidos)?	*Question answered verbally during the demo.*
Why does PMS have duplicates of the same product for example Divigel 1 mg? All are the exact same product but with different PMS id and with different language for Pharmaceutical form.	We will have a look at this issue and address any possible bug. Thanks for letting us know.

Question	Reply
Will the NCA's LOC "own" the authorisation or the ORG? Currently all of Finlands products belong to an old Location and in the UI it says [INACTIVE] Finnish Medicines Agency.	We will have a look at this issue and solve any possible bug. Thanks for letting us know.
In the example we have seen ....Once the pack size moved to correct medicinal product ..what is the status of Excisting PMS ID ?	The former product that loses the packaged medicinal product will become nullified as we can't have medicinal products without packaged medicinal products.
Having the timeline Feb 2025 for Critical Medicins in mind, when are the XEVMPD product data fully imported to PMS also for DCP/MRP/National so that we can check the correctness.	All products from XEVMPD are already in the PMS API and Product UI.

Product User Interface (PUI)

Question	Reply
Is there any way to download the public data for analysis (example: cross-references in "my" products)? Right now I see a power bi report which has been completely locked down and I can look, but not export.	*Question answered verbally during the demo.*
Will EMA consider holding a webinar related to further explain beyond the current Ch2 guidance (when expected?) about "PMS ID unicity/construct/data element's dependency and its cardinality/relationship with PMS structured data elements"?	EU IG Chapter 2 is expected to be released at the end of October. We are not planning to host a webinar to touch on the mentioned point however we are open to any suggestion. We would be very grateful if you could please submit a ticket in EMS Service Now as ask a question to SPOR/PMS to further detail your proposal.
There are many products in PMS PUI having data related to ingredients incorrectly migrated (does not match with EV export and RIM data latest submitted): some are also missing the active substance. Could you please advise?	Please, open a ticket in Service Now so we can investigate. Please, provide the PMS IDs, EV codes, etc.
Why does the "Friendly Name" need to be individual everytime? Can I not just go with "Erich" and nothing more as the user performing the change is surely locked in the Audit Trail. Or is there a specific reason?	This is similar to the XEVPRM message name. There is a friendly name so the user can identify later which is the form they are working with.

Question	Reply
Can EMA kindly communicate when both the EU IG Ch 3 and 4 publication can be expected please?	EU IG chapter 3 is expected in Q4 2024 to describe how to submit the limited set of product data in PMS PUI. While the timelines for the publication of EU IG chapter 4 is not yet available. We will announce it as soon as we have a clearer view of the timelines.
Will EMA consider adding PRD EV Codes to 1)All Ingredients Dynamic Product Reports and 2)All Manufacturing Operations related reports? The PMS ID-PRD EV code Mapping exercise's proving tobe challenging particularly when data incl M&M issues	We can consider this and deploy it based on the capacity we have. Right now we are focused on the enrichment process so only we have left capacity to improve the dynamic reports we will release this improvement.
Can we do bulk updates to product records for modifying the data in PMS	You will be able to do it. For the moment we are working on the MVP which does not allow bulk update (making same changes to multiple products)
Will it be possible to add the manufacturer and information common to the whole product family instead of Medicinal Product per Medicinal Product - thus will it be possible to update the information in bulk?	Yes, we are currently working on the bulk update functionality. This is the MVP for the moment.
When adding information on manufacturers, does this have to be performed on MA level, or can information be added to the manufacturer, as this organisation acts, e.g. only as intermediate manufacturer for a number of product.	The submission of manufacturer product data can be performed only at Medicinal Product (MA) level at the moment.
When will entire non-CAPs data get loaded in PMS as currently we partly see the products with a lot of issues (multiple PhPs, incorrect active substances, only one MPFN for BE, FI, multiple PMS IDs for 1 MPFN) though coorect in xEVMPD.	The non-CAP data load in PUI is completed. If you are experiencing issue please notify this to EMA via the Service Now. Guidance is available in the PLM portal under the PMS section. Please make sure the incident is as much detailed as possible to facilitate the investigation.
Is versioning and who made what edit in PMS UI foreseen?	Yes, as displayed during the demo.
Are PhPIDs expected in PMS? If yes, when?	They are expected but not for the moment. There is a discussion ongoing on who is responsible to create these IDs and how to manage this. So for the moment we don't have timelines that we can share.
Are RMS, SMS and OMS IDs expected display in PMS PUI?	No. Only the terms will be shown in the product UI.
Can EMA confirm "PMS ID" is meant to be unique for each PMP record within PMS PUI/API?	Yes, PMS ID is a unique and stable identifier for the identification of the medicinal product entity. The same ID is available in both systems PMS API and PMS PUI.

Question	Reply
Does PUI edit pages mean that you can modify the data in PMS?	Correct. But for the moment only manufacturers, MBOs, structured data on pack sizes and data carriers. Which are fields that we don't have in XEVMPD.
From your presentation it sounds as if it is possible to duplicate entries by mistake while editing a data set. Would there be a warning?	We are putting business and validation rules in place to avoid duplicates.
In PMS not all valid product entries from xEVMPD are imported. What can be the reason – is there any guidance available and what are the next steps to do? Is the import of all data is completed?	Not valid records from XEVMPD have been migrated if they meet the requirements explained in Chapter 7 of the EU IG. You need to make sure that the MAH is correct. It might happen that invalid records had an old MAH in XEVMPD and that is why you are not able to see them.
Information about manufacturer must be per entry manually are is there a bulk import possibility.	Yes, we are working to develop it however for the first release only single updates will be possible. We aim to release the bulk functionality soon after.
The match and merge protocol is still not working appropriately even after latest correct submissions to xEVMPD. Also sometimes the M&M has hpnd and pack has been merged with correct PMS ID record but previous duplicate PMSID is nt nulfied	Kindly notify EMA by submitting a ticket to Service Now as incident type in PUI.
What are the timelines for updating the fields Manufacturer's, MBO's and Structured pack sizes?	As explained during the PMS Info Day, manufacturers, MBOs and structured pack sizes are supposed to be included by Dec 2025 for those products under the Union List of Critical Medicines. Keep in mind that this data has to be maintained as well.
What if a product is old, and we do not know the exact manufacturing operation start date?	We are discussing this with the ESMP team and we are hosting a webinar in Q4 to reply to all these questions. Please, bare with us until we host the webinar to reply to all this questions.
What if we have more than one data carrier for a pack in the country? Can we differentiate them? Like add a description?	User can add as many data carrier identifier (ID and Type) as needed for the same package. However as per EU IG Chapter 2 there is no field that enable user to enter a description.
When the EDIT DATA feature will be available?	At the very beginning of Q1 2025.
When will the API go live?	It is already live for MAHs. Please, check Chapter 1 of the EU IG to understand how to get access.
Will additionnal Dynamic Reports be added to cover ALL xEVMPD data? Currently there is several missing so we can't QC everything about our CAP/NAP import into PMS.	No, for the moment there will no be additional dynamic reports.

Electronic Product Information (ePI)

Question	Reply
Is there any news about the import functionality for Word documents? This is an absolute must-have for many pharmaceutical companies!	Word conversion functionality will not be developed by ePI team in the foreseeable future, but it is expected that there will be options from third-party providers.
Will there be a bulkupload functionality ?	Yes, in the future there will be way to import multiple FHIR files simultaneously. This feature will be developed in a step wise approach.
If phasing-out of paper PL is not desired by NCAs, ePI key benefits (ecol. footprint, speed, flexib., lower cost) would be negated. How can EMA counteract such nationally divergent developments and promote the phasing-out of the paper form?	Regarding use of the paper form, electronic or both, this will be determined by legislation. The main goal of the ePI product is to make available an electronic format so that the patient/healthcare professional can receive timely up-to-date information in their chosen format at the point of need.
From whatching Evinn's presentation, I think we will need colleagues who are familiar with XML coding to understand validation reports and FHIR. Or are there plans to redesign the processes so that normal labelling/RA staff can handle it?	FHIR is indeed a technical format, and technical expertise will be needed at some point if the applicant wishes to create their own FHIR ePI and upload it. Alternatively, the editor can be used to create and submit ePI, in this case familiarity with XML is not needed.
Do we need to submit local language SPCs and english language SPCs for national procedures?	There are no new language requirements. ePI will be submitted for the same languages as the Word/pdf PI.
Can MAH create ePI in english language and translate it to other languages in portal?	Translating an ePI in the portal is not a functionality that will be provided. However, all translations can be created in the portal via the editor, or translations can be imported via the import FHIR functionality
Can MAH draft SmPC's in ePI portal?	Yes, there is an editor in the PLM portal-ePI where the MAH can draft PI and later submit to the regulator.
ePI does not allow tracking of changes, Word working files are still required. Can additional work involved in maintaining ePIs be minimised for all by only having to submit the updated ePI once at the end of variations?	Yes, this is how we anticipate ePI will be implemented in the regulatory process throughout Europe. ePI will only be submitted at the end of the procedure once the text has been agreed upon and approved.
Is a plugin for Word currently being developed to export ePIs directly in the FHIR standard? Or are there any software vendors working on such a solution?	The ePI team will not be working on a word plugin that exports to FHIR. However, there are software vendors that are currently developing this technology.
Is it the intention of EMA that MAH needs to submit Product information (SmPC, PIL etc.,) in PLM portal in FHIR Format?	This is one option for the MAH. Alternatively, ePI can be created in the editor at the portal. Creation and submission at the portal will be in addition to the submission of Word/PDF PI in eCTD.

Question	Reply
How can a complete set of multiple languages be imported?	This is not currently possible, but will likely be developed in future. It is currently only possible to import language by language.
How can users partecipate to ongoing activities? Is it a requirement to held MA to gain access to the ePI portal to help with UAT and other upcoming development tasks?	In the coming months, we will be having another UAT that will allow MAHs access to the ePI portal to test out the ePI functionalities. Be on the lookout for the UAT announcement

Regulatory Procedure Management (RPM)

Question	Reply
Where can we obtain the list of point of contacts for all our products? The ServiceDesk has not given feedback after 2 months.	Obtaining the list of points of contact is indeed a common request that we have been working on to address. That is still in progress, the expectation is to be able to provide this by end of October. Service Desk is principle point of contact. However, please share your ticket number with the Product Owner or plm.valuestream(at)ema.europa.eu and we will investigate.
What is the standard timeline after the submission for EMA to create the case management in IRIS ?	The procedural timelines themselves don't change. We do not yet have full details on any system driven delays. You may find this webinar useful for further details: https://www.ema.europa.eu/en/events/industry-update-webinar-regulatory-procedure-management-product-lifecycle-management-iris
When the procedure is approved but a closing sequence needs to be submitted what is the status in IRIS ?	The status in IRIS should be "completed", as the ECTD sequence is outside of the IRIS system at this time.
What is the escalation pathway when ServiceDesk is not responding?	Service Desk itself remains principle point of contact. However, please share your ticket number with the Product Owner or plm.valuestream(at)ema.europa.eu and we will investigate.
Which are the RPM submission type EMA is planning to remove the generation of an application form? While this form may not be of use for the EMA, it is used by applicant to be able to send the form for team review and also for archiving.	
When are training webinars for industry planned?	Training webinars for industry are planned for November. They will be announced on the EMA events page. https://www.ema.europa.eu/en/events/upcoming-events
the form that is possible to generate from IRIS	

Question	Reply
We have a recent example of a case management via IRIS, whereby the variation has been closed as completed in IRIS but no CVMP opinion document was uploaded and no e-mail notification has been received up to 5 days after completion.	This is not expected behaviour. Please raise a ticket for this issue via Service Desk.
The need for an individual email address for the EMA account is well understood. However this should not prevent the MAH from communicating a functional mailbox for the « contact person after authorization »	Individual e-mail addresses are required due to the constraints of the system itself, which imposes them for security reasons.
Is the submission contact in IRIS for a case management the person who will receive notification email in case of question or approval ? EMA contact will not receive notification email.	The product contact is the default case contact and manager as well. As manager you can set additional colleagues as case contacts and managers.
How easy will it be to change the contact person in case the person is out of office or left the company? What will be the process?	Each MAH has an IRIS administrator that can change rights as needed.
Why does it have to be an individual email address, while a generic address is allowed for the QPPV email?	Individual e-mail addresses are required due to the constraints of the system itself, which imposes them for security reasons. QPPV is based on a different system that does not (yet) have this constraint.
Will linguistic review be part of IRIS-RPM in EMA?	
IRIS PSUR scope expansion. Question 1: Can EMA confirm that invoices will continue to be sent to MAHs, according to the existing fee process? e.g. via EMA Invoicing portal and using the existing Customer account number	Yes, confirmed.
IRIS PSUR scope exp. Q2: Will the procedure management process (e.g. milestones like Submission, RSI and EOP) continue to be handled separately from invoicing for PSURs? e.g. lead product/MAH in the PSUR CL does not impact invoice process	

Electronic Application Form (eAF)

Question	Reply
Any update of the timelines when the eAF will start the transition phase for the use for NAPs before becoming mandatory?	We are hoping to publish an updated timeline slide after the next PI planning event has taken place next week, however, we are not yet in a position to announce a date for the mandatory use. Our next, more reliably anticipated major timeline event will be the release of the non-CAPs in the eAF. We are hoping that to take place within the next couple of weeks as we can see significant performance improvements in the system. Before we can launch the transitional period leading to mandatory use, we have multiple well documented milestones that we need to reach, these include an external UAT of all eAF functionalities.
Any visibility EMA can share about UAT timelines (which half/quarter) in 2025?	We had hoped to start the UAT in the first half of 2025, however, due to recently discovered OMS related issues we will have to review if this is still possible.
Can the present and proposed tables in eAF be added as landscape page? Currently its portrait and everything looks squeezed inside tiny space. an you change the interface to landscape in future?	The new design (to be implemented during Q4 2024) will also enable enlarging of the working area.
Can you please inform of the status on the improvement of the eAF in order to be able to choose alternative company names from OMS?	This functionality is planned to be implemented in Q4 2024.
How many of the new eAF forms are being created in the Portal vs created in Acrobat? Do you track this?	We are tracking the usage and are pleased to see the number of active users going up and we can see a clear trend where users are opting to use the web based form more and more. We do not yet have statistics comparing the number of web based forms to the total number of application forms, however, this is something that might start doing to better understand the usage levels.
Please provide the timelines for when the web based eAFs become available for veterinary medicines?	The EMA should be in a better position to provide more clarity on this by the end of this year once the Portfolio planning exercise for prioritising different epics across the agency is concluded.
Please remind us when CAP eAF will become mandatory	The timelines for mandatory use for CAPs and non-CAPs are expected to be the same. We are currently reviewing the timelines and there are number of steps that need to be taken before we are able to announce the start of the transitional period towards mandatory use of the web based eAF. It should be noted however, that the use of the PLM Portal eAF for CAPs is strongly recommended since May 2024. Although, the use is not yet mandatory, we are hoping

Question	Reply
	to see the majority of CAP MAHs to use the web based for for their applications.
Please share the DCP/MRP eAF timelines	The release of the 'NAPs' in the eAF does indeed also include the MRP/DCP products, hence we tend to use word non-CAPs to ensure that all products are included. It is hoped that these products will be available through the eAF in very near future.
When you mention non-CAPs, do you forsee for purely national products to undergo variations through eAF as well or only MRP/DCPs?	Yes, the PLM Portal eAF will replace the interactive pdf eAF which is currently used for all types of variation applications, pure NAPs, MRP/DCP and CAPs. We are using the term non-CAPs to ensure that we also include MRP/DCP and not only NAPs which can be sometimes understood as the purely national products.
There are some NCAs that necessitate that values for MAH on the AF be identical(verbatim) to that printed on the packaging/labelling. What are the plans to onboard the NCAs to the principles of OMS to prevent obstacles in assessment?	We are currently looking at the use of OMS in the eAFs in detail. This is something that we will need to also raise with the OMS colleagues to ensure that all NCAs are fully aware of the OMS data rules, but also on the specificities in relation to the use of OMS in the web based eAF where it is mandatory unlike in the interactive pdf eAFs. Additionally, we have planned the functionality to display 'alternative names' from OMS in eAF for Q4 2024.
we are facing difficulties in adding the present and proposed (P&P) information to the eAF. The tables are overlapping and its not easy to add the tables within the margins. Is there is tutorial or guidance how we can add the P&P tables?	We are aware that the current design and functionality of the Present and Proposed section is less than ideal and in practice, a large number of users is actually providing information in a separate annex. As this is of course less than ideal we have been working very hard during the past previous quarters on improving the design of the present and proposed section (as well as the PLM Portal eAF overall) and I'm really pleased to confirm that we will be implementing the new design during the next quarter (Q4 2024). This will bring quite significant changes, including ability to expand the working area, into that particular section.
When adding a new packaging, will it be possible to add the Package Description at time of the variation? Users are confused that the information cannot be provided as part of the variation	The information to be included in the pack size field is expected to be similar that would be included in section 2 of the interactive pdf i.e. short description. The proposed package description can be provided in the proposed field.
When entering data in xevmpd, how long it will take until it is visible in the eAF?	The synchronisation routine is running every two hours, however, how long this routine will take depends on the number of products being updated (and of other factors too), in general it should be expected that updates from xEVMPD are normally displayed in eAF within the same working day, sometimes very quickly, sometimes taking several hours. We are constantly monitoring this and make adjustments where necessary.

Question	Reply
When migrating the marketing authorisation status from IRIS to PLM the update date was wrong if the last action was re-introducing a product to the market, as the update date is end date of marketing. Is there a solution?	We noticed that we were pointing to an incorrect field in the dataverse in the section which relates to Orphan exclusivity, the correct actual first authorisation date is now displayed. This was a simple bug which has been fixed and the fix has been detailed in the release notes.
when talking about IRIS, are you referring to IRIS platform or IRIS dataverse?	Would you be able to clarify the question? If this question refers to my eAF presentation, I believe I mentioned IRIS in the context of OMS and in this particular case it was related to use of OMS data in IRIS dataverse.
When you showed the selection of Pack size in the system - it will be a pick list of all available pack sizes or free text still?	The feature in the demo was the 'add pack size' functionality which enables the web based form to be used for variations that add a new pack size. This is a specific feature as the web based eAF doesn't allow the users to directly type the new pack size details in section 2 of the variation form. In general, for CAPs, all approved pack sizes are already available in the web based form and the user must link the relevant variation classification scopes and impacted presentations (packages) in present and proposed section. For non-CAP products, where packages are not yet available, the MAHs are invited to enrich their medicinal products with package information. More details on this enrichment process is provided through the PMS/PUI communications.