



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Q&A Q4 2024 System Demo

Date: 12 December 2024

Location: Online, 09:00 - 12:00 Amsterdam time (CET)

Link: <https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2024>

### 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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# Managing the Agency Value Stream

## New Fee Regulation (NFR)

Question	Reply
Is the CPS interlinked with the SPOR services? Will the Product information be taken from PMS, and the Manufacturer details from OMS?	The CPS is currently a Minimum Viable Product (MVP) and requires manual input, as it is not yet integrated with SPOR services. Historically, the process for requesting certificates involved downloading a PDF form, completing it, and emailing it to the certificate assessment team. We are actively working to streamline and improve this process and system.
Why MAHs need to enter data over and over again, why CPS does not get data from other EMA systems?	The CPS is currently a Minimum Viable Product (MVP) and requires manual input, as it is not yet integrated with SPOR services. Historically, the process for requesting certificates involved downloading a PDF form, completing it, and emailing it to the certificate assessment team. We are actively working to streamline and improve this process and system.
it is clear that the current process as explained is a huge increase in admin burden for industry : not able to save the data for a future request, add all manufacturing address manually and not using OMS data.	Please note that historically, the process for requesting certificates involved downloading a PDF form, completing it, and emailing it to the certificate assessment team. We are actively working to streamline and improve this process and system.
Are there fees associated with parrallel Joint Scientific Consultation from HTAbodies ? How EMA will apply it's own fees ?	For guidance on Parallel joint scientific consultation, please consult this <a href="#">webpage</a> . Please note that EMA's scope and fees for this procedure are the same as for standard <a href="#">scientific advice</a> . For more information regarding the fees applicable from 1 <sup>st</sup> January 2025, see <a href="#">Fees payable to EMA</a> , and specifically the Q&As available on our NFR dedicated <a href="#">webpage</a> (New fee regulation: General questions and answers - Annex I). Moreover, from 1 <sup>st</sup> January 2025 Scientific Advice procedures will be subjected to prepayment, for more information please refer to the presentation/recording of the webinar held on 24 <sup>th</sup> October (available in the " <a href="#">information events</a> " section). Some HTA bodies may charge fees for participating in the parallel consultation procedure. The <a href="#">EUnetHTA JSC secretariat</a> can provide information on HTA associated fees.
Can we track the status of our request?	Not as such on the system, but you will receive emails at every step of the process (submission, invoice generation, etc.) that will allow you to track the status of the request.
Is this CPS also applicable for Veterinary sector?	Yes, both for human and veterinary certificates.

Question	Reply
Did you plan to update the document "Explanatory note on general fees payable to the European Medicines Agency" for NFR	No, the explanatory note document will not be updated. However the new documentation that substitutes the explanatory note are the working arrangements (WA).The WA plus Fee Q&A have been published on the new NFR dedicated webpage which you can find at this link <a href="https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025">https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/new-fee-regulation-1-january-2025</a>
During the demo it was not clear if you can add a Purchase order nr. (PO) to appear on the invoice. It happens sometimes that EMA sends invoices without the PO nr. which delays payment. Please note the PO nr. on invoice is a must.	Yes, the PO field is available on the application and when filled in it will appear on the invoice. Please refer to the guidance on our website: How to pay   European Medicines Agency (europa.eu) <a href="https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/how-pay">https://www.ema.europa.eu/en/about-us/fees-payable-european-medicines-agency/how-pay</a>
For the certificates be issued as soon as paid ? Or after 30days ?	The timeline will be calculated starting the business day after full payment is received and the issuance date depends on whether they are requested as per Standard or Urgent procedure (e.g. 2 or 10 working days).
How long will it take to get the invoice for certificates after request submission in the portal ?	The invoice is issued in a matter of minutes and sent to the customer as per current process.
Is there a 'save template'option to avoid repeating the same fields populated over and over again?	There isn't such option at the moment. The CPS is currently a Minimum Viable Product (MVP) and requires manual input. Historically, the process for requesting certificates involved downloading a PDF form, completing it, and emailing it to the certificate assessment team. We are actively working to streamline and improve this process and system.
Is there a change in the certificates process on the payment end? I.e. invoicing aspects Vs current arrangements (e.g. invoices on both portal and email notification)	There is no change in the process.
Regarding the CPS, is there an option to view ongoing requests? Can we have multiple customer account numbers linked to the same login? Will there be an option to create a template and or use a previous application as a template? Thank you.	You won't be able to track the request status on the system, but you will receive emails at every step of the process (submission, invoice generation, etc.) that will allow you to track the status of the request. Yes, it is possible to request CPS Industry User roles for multiple organisations, therefore multiple customer account numbers. For complete information on how to register please consult this notice. The CPS is currently a Minimum Viable Product (MVP) and requires manual input; it is not possible to save templates.
Which email contact will receive annual fees on MA VET invoices? Will be different from the one for PhV fees?	EMA issues invoices to the applicant or marketing authorisation holder's legal address held on the Agency's file at the applicable fee level date.

# 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>

## Product Management Services (PMS)

Question	Reply
Most of our members are reporting issues with PMS data quality in over 50% of their products, such as additional substances added, wrong information migrated, duplication, etc. Are you planning to fix the xEVMPD migration and fix the data?	In 2025 the PMS team plans to raise the level of data quality, where applicable. Please refer to the <a href="#">Q&amp;A PMS document</a> published. Please be aware that a new version is due to be released on 19/Dec.
Will you please confirm if manufacturers for NAPs should be uploaded in PMS for products listed on the critical products list before February 2nd 2025?	<i>Question answered verbally during the demo.</i>
Can you perform a dummy update for all your active XEVMPD registrations? E.G. via bulk update?	<i>Question answered verbally during the demo.</i>
For Luxembourg can we choose any other dummy update? With our system we would have more options than the dot in the comment.	You need to update something that is not impacting the data of your product. You can also update the package description for example.
Why, instead of adding a dot or any dummy data, we can't just resubmit to sync the data?	XEVMPD doesn't allow the submission of a new version with the same data as the previous one.
Any timeline for Luxembourg EV codes update?	<i>Question answered verbally during the demo.</i>
Almost 40% of our ESMP non caps products were not migrated in PMS and others migrated with missed values as dosage form, package.. ticket: INCO100798, will it be solved before the write Access to the PUI to add pack size?	The investigation of the opened ticket is in progress. Please allow us the time to complete it. Thanks
If the initial documentation on Write API is released still in December, when will it go live or will be allowed to use to enrich PMS product data?	Chapter 6 and technical specification for PMS API is not planned to be released in December. To support the Go live of the MVP enrichment process in PUI (end of Jan 2025) Chapter 1,2,3,5, and 9 will be released on 19/Dec. PMS API edit will be made available at later stage.
Let me rephrase then: when is the Write API specification expected?	The exact date is not available at the moment. We do expect this to be released in 2025.
Adding a dummy data, event just a dot, would lead to a 3rdACK correction?	No. Because we don't make changes to dots entered in this section.

Question	Reply
If for a MRP procedure the full name of the product name is not in SmPC section 1 (local guideline) it is at the top of the SmPC page How can the MAH get the correct name registered in PLM as in XEVMPD they check against section 1.	PMS will take the data as submitted in XEVMPD.
Which report allows to Check the short name in PMS? as the previous one doesn't exist anymore, as this field needs to be checked to support the ESMP go live	<i>Question answered verbally during the demo.</i>
the PMS API webinar on January will be held inside the EU NTC platform or through EMA website? is it published?	The virtual event is hosted on the EU-NTC platform as this is for NCAs only. Title: Webinar on NCAs read-only access to Product Management Service (PMS) Application Programming Interface (API): 15 January 2025, 14:00 – 15:30 CET
What will happen for LU if there are different MA numbers without Procedure number?	We will use the other fields we used for grouping as explained in Chapter 7 and 9 such as active substance, strength, MAH, authorised dose form, etc
I do not understand for lux, we have been asked to enter national Numbers in xempd to identify the pack presentation, does that mean that all what i did was wrong??	No. This data is still relevant and will be shown in the package description. Remember that the national IDs must be entered in the package description field. This data will still be shown, but now the packages will be grouped in the correct medicinal product.
Does this mean, we have to do a manual dummy update for all Luxembourg Entries (NAPs and MRP/DCPs)? Shall we also check, that for all the other countries, where we have different MA numbers per pack size, have the correct grouping rule?	No. You just need to submit a dummy update on the impacted products. If you just have a package, there is no impact. If you have the same MA number for these packs, there is no impact. It is only for packs with different MA numbers per pack. For the other products, in principle the business rules are correct. Nevertheless, as we have always said, one of the checks you need to perform is that we have migrated the EV Codes under the correct product in case different EV Codes belong to the same product.
(1) Human NCA API access can be requested. Should Human + Vet NCA do the request again, or is the granted token still working? This question because a Hum + Vet NCA is experiencing problems.	The NCA API users who have already received access to PMS API production do not need to re request the same role. Only NCA not yet having access to PMS API needs to request it via IAM. If you are experiencing issues in accessing PMS API please be aware that we have identified a bug and an hotfix is planned for tomorrow. We recommend you to try again on Monday.
(2) When trying to retrieve everything information through API, for a product which is definitely in the scope of the country, the following error is shown: 403 APIM. Product is NOT in user affiliations. Ticket RITM0171359.	We will review the ticket. But it seems you don't have the correct role for the company under which this product is authorised. Make sure you have selected in IAM the correct ORG.

Question	Reply
Is there a deadline for VET only NAP products? thank you	PMS is not managing Vet products. Please, contact the UPD team
Will EMA still consider Feb 2025 for XEVMPD pack size submission or any changes expected on the timelines?	This is still the date. But you will still need to continue submitting this data if you have new products or packs authorised after Feb 2025
We do not see any entries for LU in PMS, what to do?	Make sure you have read Ch 7 to understand how the migration is done and if there is any data issue in XEVMPD. Make sure you have requested the correct role for the correct MAH in Product UI. If you still don't see them, raise a ticket. Maybe there is an issue with these EV Codes.
When user should raise the change request?, is it only for data enrichment in PMS or in future the change request will be raised on the basis of variation Post approval or new registrations approval?	As soon as you need to enter or amend data in the scope of the enrichment you need to submit a change request to provide to PMS the updated data.
When will PMS-IDs for CAP human products be stable? Recently 600001880693 replaced 600000100259 for EMEA/H/C/005642/001...	Please note that the PMS ID never changes. The product with PMS ID 600000100259 refers to the product name Vabysmo 120 mg/mL solution for injection and is linked to the relevant PRD while the product with PMS ID 600001880693 refers to the product name Vabysmo 120 mg/ml - Solution for injection (slightly different from the one above) and therefore not matching with any PRD available in XEVMPD. Ref. EU IG Chapter 7 grouping rules. Please open a ticket in service now to receive the full analysis.
Does the duplicate ID problem have relevance for products authorised in Norway too? I have found different PMS-ID's for the same product in data downloaded from PMS in PLM-portal	Not in principle. If you have found discrepancies, please, check CH 7 and 9 to make sure you understand how the data is migrated and see if you have any data discrepancy in XEVMPD. If you don't find any issue, please, send a service Desk ticket.
Does Chapter 3 describe the process for updating PMS with regard to marketing status declarations for non-CAPs ? Have discussions been held on this subject ?	Marketing status is not reported via PMS so Ch 3 does not describe this process. Marketing status for non-CAPs is to be reported via ESMP.
With current API update, the client ID associated with the ORG ID can be used to retrieve data from the API. Before that, it was possible with one client ID to retrieve all the data from the ORG Ds that I have access to. Why this was changed	It was an unintended behavior, as our documentation stated you need to request 1 client id per ORG ID, and also use each for each ORG ID.
Please can the EMA release a list of the required manufacturer business operations for which manufacturers should be enriched	We will include the information in Ch 3 but as we announced during the webinar, all manufacturers submitted through the eAF are the ones required in PMS.

Question	Reply
<p>Once edit access is enabled in PUI end Jan-25, is there a requirement to enrich any data at that time? Pack sizes will come from Xevmpd and manufacturer data is to be added by Dec 2025. What data needs to be enriched in PUI Q1-Q1 2025?</p>	<p>Please refer to the attached link of the webinar hosted in November:  <a href="https://www.ema.europa.eu/en/events/submission-manufacturers-manufacturing-business-operations-mbos-structured-pack-size-data-product-management-service-pms">https://www.ema.europa.eu/en/events/submission-manufacturers-manufacturing-business-operations-mbos-structured-pack-size-data-product-management-service-pms</a></p> <p>As of end of January 2025 structured manufactured data, structured pack size data and data carrier identifiers for NON-CAP products can be submitted to PMS based on the impacted products mentioned in ULCM list.</p>

## Product User Interface (PUI)

Question	Reply
<p>After I enriched the manufacturers in PUI, but I realize that I have to change some information given for a psecific manufacturer. Shall I still call it "enrichment" or when will "Update" be available?</p>	<p>Enrichment. This information will be provided in Ch 3.</p>
<p>How the enrichment process of Manufacturers will be linked with eAF process? Ex: In case of new manufacturer addition, which one to submitted first, eAF or PLM PUI enrichment process?</p>	<p>PMS should only be updated with authorised data. So only when the manufacturer or MBO is authorised, then, the data should be provided to PMS.</p>
<p>Whether Industry need to submit manufacturer for excipient also? Can you please confirm. Because RMS term is not available for Excipient manufacturer.</p>	<p>You need to submit the manufacturers as submitted in the eAF.</p>
<p>Will EMA still consider Feb 2025 for XEVMPD pack size submission or any changes expected on the timelines?</p>	<p>No changes.</p>
<p>Can MAHs please have a Read only role to PUI?</p>	<p>This is prioritised for Q2 2025</p>
<p>What is the timeline for the go live of Industry to use the eAF for NAPs in PLM portal?</p>	<p>As you see, this is a question for eAF. Please, ask this question in the eAF group, not the PMS one. Thanks.</p>
<p>Is there any bulk update feature available to edit and submit change requests?</p>	<p>It will be released later in Q1 2025. It is under development.</p>
<p>How to enroll for Product UI UAT from Industry side?</p>	<p>The UAT is already ongoing with the PMS SMEs and other members of the PMS support team.</p>

Question	Reply
The demo used a product authorised in Northern Ireland (XI): is it required to enrich PMS with the MBO also for NAPs authorised by the MHRA and valid in XI? My understanding was that only for QPPV and PSMF the EU legislation applies.	This is a demo with a random product. Products in XI are out of scope of ESMP.
What actions are MAH expected to perform from end of January when PUI edit functionality is live?	Submit pack size structured data and manufacturers and MBOs for products under the ULCM.
When the "Change Request" function in PMS-PUI will be available? Is this function dedicated to the "enrichment" of data not available in XEVMPD and will this replace the modifications to be made through XEVMPD?	Change request is linked to the enrichment process. So only for manufacturers and structured pack size data. XEVMPD is still in place.
Once I submit a change request it disappears from the workspace (modified tab) and does not appear anywhere anymore. After days it re-appears as "completed". Where can I find it in the meantime?	Not a question for here. We are improving the work space to show more status of the CR like incomplete or failed.
Can I enrich PLM data using my RIMS software instead of done it on the PLM portal? How can I proceed?	It will depend on your RIMS and if it is ready to submit to the PMS API. This is why we will release the write PMS API later in 2025.
Is there a way to view or track what specific changes or edits were made through a particular change request ?	User can list all changes in the description CR fields and when submitted and clicking in the PMS ID link the product will display the new version (progressive number) and updates included. Nevertheless we will plan new user stories to improve such functionality.
Could you please clarify the scope for the Northern Ireland XEVMPD products migration to PMS? The EU legislation applies only for the QPPV and PSMF information already available in XEVMPD. No need for any enrichment correct?	Correct. We have migrated all the products from XEVMPD to PMS, also those authorised outside EU but that were submitted to XEVMPD. But the enrichment process does not apply to them.
Products in XI are out of scope of ESMP. What about to enrich the data in general in PMS, are in scope?	As they are out of scope of ESMP, they are out of the scope of the enrichment for the moment.
Does this system apply also for VET marketing authorisations MRP / DCP / NAP?	No. PMS is only for Human products.

Question	Reply
How to enroll as PMS SMEs?	There was a call for interest and now the group is closed until end of 2025 (if I am not mistaken). If there is a need to change the SMEs, then, a new call will be opened and communicated.
Can you confirm if pack sizes need to be submitted to Xevmpd -> PMS for Northern Ireland or not?	Northern Ireland is out of scope of ESMP, so if the authorisation is provided at product level, there is no need to submit the pack sizes to XEVMPD. If the authorisation is provided at package level, then, pack sizes should be submitted to XEVMPD.
How to enroll for Write PMS API software UAT process? How software vendors can contact EMA? Can you please explain the process.	The PMS API UAT process will be defined at later stage in 2025. When defined we will inform all involved stakeholders via Industry trade organizations including vendor companies as well as the NCAs.
Is there plans to update the ULCM list?	Yes, an updated version of the ULCM list will be released next Monday.
According to new variation regulation IA variations shall be submitted as annual reports. Is the update of a new manufacturer in PMS/PUI then linked to the implementation date or the annual report approval notifications of the agencies?	This question is pending for RA team's feedback as this question is related to the new variation regulation. If you do not see answer by tomorrow please raise a ticket to the attention of the Regulatory Affairs Office.
Is the manufacturer list from initial marketing authorisation application or latest 3.2.P.3.1 is enough	As explained in the enrichment webinar, manufacturers submitted within the eAF are the ones to be provided to PMS. Not only those submitted during the initial MAA, but also those ones added during the life cycle of the product. <a href="https://www.ema.europa.eu/en/events/submission-manufacturers-manufacturing-business-operations-mbos-structured-pack-size-data-product-management-service-pms">https://www.ema.europa.eu/en/events/submission-manufacturers-manufacturing-business-operations-mbos-structured-pack-size-data-product-management-service-pms</a>
For submitting new or updated manufacturer information how is this then going to be related to SIAMED? Is data not flowing from SIAMED back to PMS for this data?	Enrichment process is only for Non-CAPs. For CAPs, the data will be coming from SIAMED.
Regarding the data to enter for manufacturers, the manufacturing operation start date is mandatory : why it is not possible to enter a manufacturer without that date , which could be completed later ?	This is the design. If you don't know the date, you can include the same date as the approval of the medicinal product.
Can a colleague see my CRs in "My workspace" or in his/her workspace or is it limited for the user who submitted the CR?	Yes, if both are able to see the products, then both can see CRs for these products.

## Electronic Product Information (ePI)

Question	Reply
What are the urgent priorities and actions that must be undertaken by Marketing Authorization Holders (MAHs)? Additionally, could you outline the general timelines for these activities?	<i>Question answered verbally during the demo.</i>
in the near future will more structured data elements from PMS - product name, excipients, MAH name/address - be incorporated into the FHIR message?	<i>Question answered verbally during the demo.</i>
Is there any news about the import functionality for Word documents? This is an absolute must-have for many pharmaceutical companies!	<i>Question answered verbally during the demo.</i>
If you are linking the PMS ID directly, is the Data Carrier info still necessary in PMS?	<i>Question answered verbally during the demo.</i>
How will patients be able to scan the GTIN? will there be a QR code required?	<i>Question answered verbally during the demo.</i>
Which identifiers are included in the ePI, for example for substances? (To support cross border use)	<i>Question answered verbally during the demo.</i>
Please give us an overview of which software manufacturers are working on extended functions for simplified ePI creation and maintenance. Word export to ePI, for example. What is the current status in this regard? What is in the pipeline?	We do not have such an overview. It is for pharmaceutical companies to do their own research on this topic.
Will there be available uat environments to try these functionalities?	<i>Question answered verbally during the demo.</i>
will there be UATs or ongoing (voluntary) opportunities for MAHs to create and maintain ePI starting in next 1-2 years?	<i>Question answered verbally during the demo.</i>
Does your work include efforts on the scanning tech for the matrix? E.g. mobile apps?	<i>Question answered verbally during the demo.</i>
Will there be an updated roadmap for PLM released soon?	<i>Question answered verbally during the demo.</i>
In the epi pilot, have the documents been uploaded using fhir standard or manually created in the portal?	<i>Question answered verbally during the demo.</i>

## Regulatory Procedure Management (RPM)

Question	Reply
For CAPs contact data has to be updated via a form. What about NAPs undergoing PSUR/PSUSA? How is the contact information submitted/updated for these cases?	<i>Question answered verbally during the demo.</i>
IRIS is not a messaging tool, how can it replace eudralink ? If we want to send a quick message, do we need to write in a document?	<i>Question answered verbally during the demo.</i>
If in XEVMPD the email address provided is a generic address, this should be updated with a personal one?	<i>Question answered verbally during the demo.</i>
In eAF there is possibility to have 2 contacts, once the Iris case is created, will it be assigned to both contacts mentioned in eAF ?	<i>Question answered verbally during the demo.</i>
regardind the question that was asked about the email address in xEVMPD: do you mean the pharmacovigilance enquiry email??	<i>Question answered verbally during the demo.</i>
How can we download all documents of a specific case in one go for archiving purposes? (Not one by one)	<i>Question answered verbally during the demo.</i>
We currently have as "first email" a specific email and as "alternative email" a generic mailboxes. Do we have to also modify the alternative email?Thank you	<i>Question answered verbally during the demo.</i>
Do the contac persons under eAF section 2.4.5 and 2.5.1.11 need an EMA-account? Will they be contacted by the EMA through IRIS?	<i>Question answered verbally during the demo.</i>
Who is notified in the case of inspections, the QPPV or the contact person?	<i>Question answered verbally during the demo.</i>
Do the email address to receive invoice also have to be a personal email?	<i>Question answered verbally during the demo.</i>
Can also a person with IRIS coordinator role be used as contact persons? Will this person be shown also in the search list for the managers to chose from?	<i>Question answered verbally during the demo.</i>
Can you have more than one contact person on a procedure in Iris?	<i>Question answered verbally during the demo.</i>

<b>Question</b>	<b>Reply</b>
Where can we find information to update the PhV enquiry email in XEVMPD with a personal one? In the past this email address was required to change to a generic one in order data protection issues.	<i>Question answered verbally during the demo.</i>
Iris guidance mentions we can reply to email without changing subject. In which cases we can do that?	<i>Question answered verbally during the demo.</i>
who is the contact person for a NAP involved in EMA-led referral? - who will be notified when the referral is initiated and their product is in scope	<i>Question answered verbally during the demo.</i>
Are EU PIs for linguistic review on D+5 and D+25 to be submitted via IRIS starting January 2025?	<i>Question answered verbally during the demo.</i>
Some PIPs are missing from our MAH listings in IRIS due to a migration issue. What is the best method to compare and report this discrepancy?	<i>Question answered verbally during the demo.</i>
As download is not that easy how long are closed cases going to be available in IRIS? I.e is the archived submissions /communication available indefinitely?	<i>Question answered verbally during the demo.</i>
If the contact person added another manager for the procedure as advised, will this additional manager receive email notification?	<i>Question answered verbally during the demo.</i>
Who will be the contact person fo refrrals? QPPV? What if this person will be on vacation in time of referral? How we can dedicate another person for referral in advance?	<i>Question answered verbally during the demo.</i>
Is it correctly understood that only one email address per contact type can be handled by IRIS ?	<i>Question answered verbally during the demo.</i>
The contact registered in IRIS on the MAA is that the general contact for questions?	<i>Question answered verbally during the demo.</i>
Does the procedure variation number need to be added into the eAF with the IRIS submission ID when available	<i>Question answered verbally during the demo.</i>
Do the contact persons mentioned in eAF 2.4.5 and 2.5.1.11 (responsible for scientific service and for product defect)	<i>Question answered verbally during the demo.</i>

Question	Reply
need an EMA-account too? Will they be contacted by EMA through IRIS?	
Which contact will receive annual fees on MA VET invoices?	<i>Question answered verbally during the demo.</i>
Who is the contact person for psurs? QPPV mentioned in psur the document? Or person mentioned in Cover letter?	<i>Question answered verbally during the demo.</i>

## Electronic Application Form (eAF)

Question	Reply
Would it be possible to receive an updated roadmap for eAF with expected recommended use, UAT, transition period and mandatory implementation?	The Network Portfolio Roadmap, including eAF is available on the EMA website. This is reviewed quarterly. Detailed planning for Q1 will take place next week during our Planning Interval (PI) ceremony and should any update be needed, this will be shared at the start of 2025. <a href="https://www.ema.europa.eu/en/documents/other/network-portfolio-roadmap_en.pdf">https://www.ema.europa.eu/en/documents/other/network-portfolio-roadmap_en.pdf</a>
Missing a timeline for the mandatory use of the eAF for NAPs? From 1st of Feb 2025 is that the beginning of the transition period for use of eAF for NAPs?	We have a slight delay in the start of the strongly recommended use of the web-based form for non-CAP variations due to pending data cleansing exercise in PMS. We anticipated that this cleansing will be finalised by the end of January so that we can start the strongly recommended use for non-CAPs from February 2025. This is not yet the start of the official transitional period towards mandatory use. In line with what EMA has shared previously, the steps towards mandatory use are: create a system that is ready for mandatory use; conduct public testing, announced at least 2 months in advance; address critical topics identified during testing before announcing the start of the transition period at least 3 months in advance; a transition period of 6 months. At this time EMA is not yet ready to announce the UAT.
How to best check if the all the products are correctly available in eAF, any export function suggested?	It is possible to check the products prior to starting an eAF using the Product UI Dynamic Product Report, or in the PLM Portal SPOR menu, select the option Medicinal Products. To ensure that all products needed are available, we recommend to create an eAF and perform a product search.
Will the use of the eAF also be mandatory for registered homeopathic medicinal products, national procedure? And if yes, when?	The interactive pdf eAF will be fully replaced by the web based in eAF in future. Detailed timelines will be published in future.

Question	Reply
Will the 61.3 notification form also become an electronic one in PLM future?	The roadmap of the future improvements for procedures in IRIS RPM has not yet been finalised and it will be determined at a later stage if there will be an eAF or an IRIS process.
Granting coauthors access to the electronic Application Form (eAF) does not track their changes, making it hard to identify modifications. This is a significant drawback. Is there a solution or workaround to track changes?	Indeed, this is correct. Tracking of changes in the web UI has not been highlighted or mentioned as a requirement previously. This is also aligned with the interactive pdf eAAF where it is not possible to show track changes.
In what period after completion of an RUP will the new authorisations be visible? EoP was at the end of September. The additional CMS authorisations are not visible yet.	The products will be available in the eAF after the MAH has submitted the information to XEVMPD. Only after the xEVMPD submission the products will become available in eAF. If you have problems finding your products, please contact the PMS team with the relevant info (including the EV Code) so we can check if the record has been migrated.
When should be used as mandatory the Eaf for the Naps products ? Will the curent eaf be inactive immediately once the new web based eaf is effective or will there be a parallel use possible for both?	<p>In line with what EMA has shared previously, the steps towards mandatory use are:</p> <ol style="list-style-type: none"> <li>1. create a system that is ready for mandatory use</li> <li>2. conduct public testing, announced at least 2 months in advance</li> <li>3. address critical topics identified during testing before announcing the start of the transition period at least 3 months in advance.</li> </ol> <p>There will be a transition period of 6 months during which, both the web based form and the interactive pdf eAF can be used.</p> <p>At this time EMA is not yet ready to announce the UAT. As mentioned during the demo, there will be a slight delay of the start of the previously announced 'strongly recommended use of the web based eAF for non-CAP variations. It is now anticipated that the use can be started (submissions to the NCAs) in February 2025 on critical data issues and eAF functionalities have been fixed.</p>
In the last Q/A it was mentioned, that it possible to include more than one present/proposed row per category, as it is possible in the eAF currently. Could you please explain how?	Yes, with this new updated present and proposed section it is possible by adding multiple 'sections'. There is currently an error as the 'section label' is mandatory, however, this will be changed to optional in a future release. Also, it is currently a bit cumbersome to add multiple sections and move between them however, the saving and navigation as well as viewing of the multiple sections in parallel will come with the fixes in Q1. The user guide will be updated to reflect the corrected functionality.
In xEvmpd there is only 1 email entered and so generic ONE .. So ??	In eAF you can include the MAH email address and the contact person email address. For non-CAP variations, it is possible to include multiple contact persons.

Question	Reply
Is an annex A still being accepted to list a huge number of products involved for a variation?	We are currently looking at potential solutions for very large variations. Currently the Annex A (for CAPs) and Annex B (for non-CAPs) are in use with interactive pdf eAF. As the web based eAF works differently, we are not yet in a position to confirm if an annex can replace the product listing. If for the time being you have a huge variation and you wish to use the interactive pdf this is still possible.
Will there also be changes in the pdf Version of the eAF (e.g. the present/ proposed section)	We are not anticipating changes to the interactive pdf eAF present and proposed section as there have been no change requests to change this and as we are aiming to concentrate on improving the web based eAF. The interactive pdf eAF is still updated in line with the new variation regulation and other regulatory requirements.
Is there an import functionality for PLM eAF on the roadmap?	An import functionality has been discussed as a requirement for the web based eAF however, implementation is not in the short-term roadmap at the moment.
How long do you expect the transition period to be?	The official transitional period is expected to last for 6 months during which the use of both, the interactive pdf eAF and the web-based eAF is possible.
After completing a DCP/MRP (EoP), the new CMS cannot immediately be sent to xEVMPD as long as the national approval is not yet received. How can I include these MAs in the eAF?	The xEVMPD is implementing a feature to allow xEVMPD updates for products pending national approval. This will allow the 'pending products' to become available for use in the PLM Portal web based eAF.
<p><i>[Moved from PMS room]</i>  Did Kristiina say that eAF for non-CAPs will be strongly recommended from Feb 25? At the same time the transition period doesn't start? Can you clarify further around these dates please? lease include a link to the eAF roadmap too.</p>	<p>In line with what EMA has shared previously, the steps towards mandatory use are:</p> <ol style="list-style-type: none"> <li>1. create a system that is ready for mandatory use</li> <li>2. conduct public testing, announced at least 2 months in advance</li> <li>3. address critical topics identified during testing before announcing the start of the transition period at least 3 months in advance.</li> </ol> <p>There will be a transition period of 6 months during which, both the web based form and the interactive pdf eAF can be used. At this time EMA is not yet ready to announce the UAT. However, as I mentioned during the demo, there will be a slight delay of the start of the previously announced 'strongly recommended use of the web based eAF for non-CAP variations. It is now anticipated that the use can be started (submissions to the NCAs) in February 2025 when critical data issues and eAF functionalities have been fixed. Updated eAF roadmap will be published once planning for the first quarter of 2025 has been finalised.</p>

## Veterinary Union Product Database (UPD)

Question	Reply
<p>What is EMA doing to make NCAs aware that accidental data changes in their systems (probably done by NCA API) have huge impact on data and MAH work process. Meaning today data might be alright and correct, but not tomorrow due to a mistake.</p>	<p>When we are made aware by MAHs that such instances occur, we liaise directly with API users but we would also encourage you to liaise with them directly so that they can review the data and revert accidental actions that caused issues.</p>
<p>When MAH API is foreseen to be available for use.</p>	<p>The API for MAHs is foreseen to become available in 2025</p>
<p>In regards to NCA accidental changes: constantly checking the whole MAH portfolio in UPD using UI to catch accidental changes is and would be HUGE administrative burden.</p>	
<p>Considering the fact that the UPD team already gained some experience with data quality and overall implementation, is there a plan to discuss with the human medicines team for some knowledge sharing? Did this already happen?</p>	<p>Of course, the knowledge and experienced gained in the last 1.5 years is available and we will work with PMS colleagues to share such knowledge.</p>
<p>What is EMA plan to resolve technical and data quality issues on last (5) percent's of UPD products that are blocking NCAs and MAHs business processes.</p>	<p>There are certain mandatory fields that can only be updated by Member States; we can provide such information on how to best populate these but unfortunately, we cannot carry out these updates ourselves.</p>
<p>The automatic update of non-current substances: will this also process the non-current substances still present in UQF (25 with alternative substance), or only for the substances which have become non-current since last update of UPD?</p>	<p>The automatic update of non-current substances will apply only since last update of UPD.</p>