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Q&A Q1 2024 System Demo

Date: 26 March 2024

Location: Online, 09:00 - 13:30 Amsterdam time (CET)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2024

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. Where it was clear that a question asked in the "Plenary" room referred to a specific IT product it was moved to the appropriate product room. Wherever this happened, if anywhere, this is indicated in the question text below.

In principle this document will not be updated. 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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Product Lifecycle Management Value Stream

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Electronic Application Form (eAF)

Question	Reply
There will be constant changes in the future - isn't there a better release management other than stopping all eAF services (Web & PDF) for an entire week? What about lower environments, and updates during week-end?	The PMS go-live is an exceptional downtime as data is being changed. Future releases will be independent of PMS uptime as well as done without a downtime
Can you already estimate when it will not ne possible to use any eAF. It would be useful to plan submissions.	The downtime period time for both, the interactive pdf eAF and the PLM Portal web based eAF will be between 11-16th April 2023. Additionally, with immediate effect, we are asking all applicants to use the interactive pdf eAF for their submissions until 26th April. This is to avoid any validation issues/delays due to changes in the CAPs product data after the new CAPs product load.
Can you please explain what the package feature consists of	The package feature mentioned in the presentation on planned work for eAF enables the use of the web based eAF for variations that add a new presentation i.e. adding a new pack size. Currently this is not possible in the web based eAF and the interactive form must be used for these types of variations.
Can you please remind the timelines for the GoLive in the use of eAF for NAPs?	The load of National MRP and DCP products is planned for Q4 this year which will enable us to start a public UAT early 2024
Can you please update us on the possible tiimeline for a veterinary eAF?	We are currently concentrating on improving the performance and stabilising the functionalities for the human variation form. Once we have ensured that the human variation form is ready for mandatory use, we will move on to work on the Human MAA form. We do not have a firm timeline for these epics as of yet, however, what we know today is that due to the new VMP-Reg which means that 'extensions' are now variations, we will need to make significant changes to the veterinary variation form and bring majority of the MAA form fields to facilitate this it is planned that the Vet variation form will be done after the MAA forms for both, human and veterinary domains have been developed.
Could you please give some news regarding veterinary product?	We are currently concentrating on improving the performance and stabilising the functionalities for the human variation form. Once we have ensured that the human variation form is ready for mandatory use, we will move on to work on the Human MAA form. We do not have

Question	Reply
	a firm timeline for these epics as of yet, however, what we know today is that due to the new VMP-Reg which means that 'extensions' are now variations, we will need to make significant changes to the veterinary variation form and bring majority of the MAA form fields to facilitate this it is planned that the Vet variation form will be done after the MAA forms for both, human and veterinary domains have been developed.
Do I understand it correctly, that during downtime of the webbased eAFsand the interactive PDFs, it makes sense to fill in the interactive PDFs before the 11th of April if we need to submitt variations during downtime?	Yes, this is correct, if you do need to submit a variation application form during the downtime period, for any human or veterinary procedure (variation, MAA, renewal), please fill in the interactive pdf eAF form prior to the 11th April. The submission process to the NCAs is not impacted. Also submission process to EMA should not be impacted during this period of time. It is expected that the interactive pdf eAF will start working as normal on the 16th of April (exact time not confirmed as of yet).
For NAPs: is it possible to use the pdf eaf in the longtime or is it necessary to Switch to the „new eaf“?	Eventually, it will become mandatory to use the new, PLM Portal web based eAF for all products, including the NAPs. We will first make the NAPs available in the web based form, then after a period of time during which the use is optional, we will run an external UAT (of all features) and once that UAT is succesfully passed for centralised procedure, MRP/DCP and purely national procedures, we will announce a transitional period towards mandatory use. After the end of the transitional period, the interactive pdf will no longer be available and only the web based form can be used.
If a pack is added, will the information then be transferred by EMA to the other systems (PMS, xEVMPD, SIAMED)?	Add Package will only enable the functionality to request a new presentation for a CAP. Only the full release of the structured changes will be taken back to PMS.
is it possible that once I finalize the eAF on the portal and validate everything in the finalization phase the system gives an error on a field that is actually filled in?	If you have encountered an unexpected behaviour of the system not inline with our user guides or an error please don't hesitate to submit an EMA service ticket and we will happily look into the issue.
What about Chapter 2 updated version previously announced for Q2? When is EMA planning to publish it?	As far as the eAF team is aware, our colleagues plan to publish version 2.2 of chapter 2 as soon as the final mapping to FHIR are aligned. For further details please pose the question in the PMS channel.
What are the timelines for structured data changes using the eAF?	The structured data changes are still heavily being worked on. It is too early to estimate a release for the feature. Parts of the productUI that will also be used for the structured eAF is going to assist industry users in enriching Products for ESMP end of the year.
What exactly is the "add package" feature?	"Add Package" Is the way to add a new presentation to the same strength/form combination of a Central Authorised Product (CAP) in the web Portal

Question	Reply
Will with the addition of a pack in eAF, a unique identifier of this pack be generated in PMS?	The unique identifier for the Packages in PMS will only be generated once the data reaches PMS (after the end of procedure with the ART57 submission). A temporary identifier is assigned by the PLM portal while the package is not yet authorised.

Product Management Services (PMS)

Question	Reply
There is no “pack size” in XEVMPD. There’s a package description which is taken from the SmPC which may cover multiple pack sizes. I think this will be a significant challenge to implement.	As explained, this is already in place in XEVMPD.
How is it planned to bring the details of the packaging sizes for CAPs and NAPs into PMS/ESMP?	With the deltas between XEMVPD and PMS.
Is it now confirmed that the enrichment of Manufacturer and Package information will go through PMS (and not via XEVMPD, or any other manual way)?	As explained: Manufacturers through PMS API or Product UI and pack size through XEVMPD.
Multiplying xEVMPD entries over pack size: how will EMA ensure 3rd ACK review for the batch of EVCodes belonging together (DE-5 pack sizes = 5 EV Codes). Otherwise synchronization for MAH is near impossible due changes EMA implements	As explained, we are improving the validation process.
Can you tell when the PMS Product UI will be live (read only) . Is it in May too for CAPs?	Yes. End of May for CAPs.
Is there any plan to publish the consolidated xEVMPD – RMS mappings?	yes, we will try to publish them as soon as possible.
After the golive, if a date change will occur in xEVMPD do this will be automatically reflected in PMS as well? how often the sync between xEVMPD and PMS will occur?	Yes, through the deltas. As explained, this will happen almost real time.
Are pack sizes supposed to go into "Package description" field in Xevmpd and should it only consist of the size and not the full packaging text from SmPC?	Package description is a free text. We recommend to include the pack size only as this will help you to identify your pack sizes in ESMP.

Question	Reply
Based on the timeline slide, should we expect to reach PMS go-live without a final version of Chapters 3 or 4?	As explained during the Demo: No, because there is no impact on the process or validation. These chapters will be updated as soon as they are impacted.
Can users give recommendations on resolving issues mentioned in IG ch7? If so, how should these be submitted?	You can either contact the Industry/NCAs SMEs for PMS or open a ticket in Service Now.
Even when you populate pack sizes in xEVMPD, migration is near impossible, e.g. 4 x 500 ml bottle Glass I . Pack size is 4 bottles, how you want to extract that? All in national language	We are not going to extract it from XEVMPD. Pack size in a structure way (i.e.: value and unit of presentation) will have to be provided in a second step through PMS API or Product UI. In the meantime, package description from XEVMPD will be used to identify pack sizes.
how do we will submit Manufacturer info in PMS?	We will open the PMS API for write and the write pages of the Product UI.
How pack sizes must look like in xEVMPD? Should be like IDMP definition for example "30 Tablets"?	Package description in XEVMPD is a free text. Our recommendation is to include this text in a way that can help you to identify your pack size in an easy way.
How to understand on Slide 18 'Analysis of API with public data only' : please explain more in detail this 'analysis' step. May it mean there is a prerequisite to be completed by the PMS team, before industry can start using the PMS API ?	The Agency aims to release the public PMS API (and PUI) to support HCP/Patients and other Organisations. In order to release it the publicly accessible data and their use cases need to be agreed. This release is independent from granting Industry access to PMS API as this is executed under registration to EMA account management portal.
Is it planned to publish a New version of chapter 2 . I understood this was planned in previous presentations	Yes, we are working with the SMEs to provide an updated version of Chapter 2 and Chapter 8.
Is RMS/OMS-xEVMPD mapping exercise really finalised? There are still a number locations that have not been mapped with xEVMPD location identifiers. What should be done with this gap?	Please, open a ticket in Service Now for OMS requesting the mapping ASAP.
it could be possible to create an interface with Company RIMS and PMS as currently is possible via Gateway with xEVMPD? this would be very usefull for Manufacturer submission	This will be the write PMS API that I explained. For the moment we will open PMS API read only in May. But this will be the first step to connect your RIM to PMS.
Should the XEVMPD submission continue via Gateway in the downtime?	Yes, XEVMPD is not affected by the go-live of PMS.
We are not reporting on pack size level yet, as it was not mandatory before. Can you give a timeline, when this becomes mandatory via xEVMPD?	You are already reporting on pack size level in XEVMPD for CAPs and for some other countries such as Italy. Therefore, no timeline to become mandatory as it is already mandatory. The difference is that, for some products, MAHs will have to submit pack sizes that are not already in XEVMPD. We will provide additional information on the Info Day as it depends on the product.

Question	Reply
We are typically quick here, but developing a client for the PMS API may take a few weeks. When will we get a specification (chapter 6) and a test system available to start this work to be ready by the end of May?	We are planning to release updates to Chapter 6 and the process to get the credentials to access the PMS API during Q2 and for sure before May. We will prioritise this work after the go-live.
What about Chapter 2 updated version previously announced for Q2? When is EMA planning to publish it?	We are finalizing this Chapter with the SMEs. Hopefully we will be able to update Chapter 2 and 8 during Q2.
When it is supposed to have the PMS API available not only in READ mode but also in WRITE mode?	The plan is to have it available in Q4 2024 or Q1 2025. But only for specific fields to support ESMP. XEVMPD submissions will still be applicable.
Which data element in XEVMPD will be dedicated to enter the pack size for some NAPs	Those pack sizes will have to be submitted as normal EV records. The difference between pack sizes will be only the package description (and in some cases the Authorisation number).
Why are you allowing to add manufacturers for PMS enrichment and pack size goes over xEVMPD. Both could be enriched via PMS only	Not really. Manufacturers are part of PMS but not of XEVMPD so that is why we can include them directly in PMS without impact on XEVMPD. But pack sizes are part of both XEVMPD and PMS. As the synchronization between PMS and XEVMPD is not in place but it is the one between XEVMPD and PMS, any value that is part of both data models should be submitted through XEVMPD.
Will Ev web and Ev post be down during 11- 16 April 2024 ?	No. XEVMPD will no be impacted by the PMS go live.
Will the PMS IDs also be available in the corresponding ePI Record? Same question concerning the SPOR identifiers in the ePI Record?	PMS and ePI team are exploring any possibility to streamline the relationships across the two products. This point is also considered.
In the following response, provided here, you are recommending to include the pack size only (in xEVMPD for package description field) as this will help you to identify your pack sizes in ESMP. Shouldn't be as per SmPC section 6.5?	Yes, as reported in Chapter 3.II XEVMPRM user guide at page 14 MAH can submit the pack size information in the XEVMPD package description data element. This will support the creation of PMS entity to be reused in EMSP.

Product User Interface (UI)

Question	Reply
With the Go Live dates (PMS, Product UI read) and the coming activities (enrich pack size, enrich manufacturers) to support ESMP (by Feb-2025?), is it possible to build and share a roadmap for the next 9-12 months?	Yes, you can already find this information in the PMS Deep dive webinar. However a detailed roadmap will be released as result of the coordination with multiple POs involved.

Question	Reply
PMS PUI Go-Live will be both for CAPs and NAPs?	PMS PUI go live scheduled at the end of May 2024 will allow users accessing CAP data. Due to the significant volume of non-CAP data in comparison to CAP, the need to improve performances of PUI portal as well as allow IRIS data verse to receive high volume of data, non-CAP data will be accessible in Q3 2024. EMA will release dedicated communication via the official EMA channels.
What happens if fields are "edited" in PUI although they are xEVMPD fields, e.g. name. Will there be a backward migration into xEVMPD? Or is it foreseen - 1st edit in PMS, you stay with update/enrichment in PMS	*Question answered verbally during the demo.*
Can you estimate when it will be possible to upload date via RIMS instead of WEB UI?	We don't have this information yet as we have not prioritized the EPIC for the decommission of XEVMPD. Nevertheless, as explained during the demo, there will be some fields such as manufacturers that could be submitted through the RIMS. Otherwise, XEVMPD submissions are still in place.
Will the "edit" functionality be released together with API "edit" specifications in order to allow MAH to edit data in their preferred way? Or will there be a time difference, PUI first ?	We aim to release the API write/edit between Q4 2024 and Q1 2025. While the PUI write/edit is foreseen to be released in Q4 2024 to allow ESMP Team to meet their legal deadline (Feb 2025).
Does the document PI sunmitted in Xevprm will be migrated in the UI as attached document ?	Documents itself as attached to XEVMPD are not migrated to PMS and therefore made available in API / PUI. While document IDs and dates are migrated from XEVMPD. For further information please access EU IG Chapter 7: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/products-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-7_en.pdf
For 2nd round Product UI UAT, will all NAPs be available in the PMS ?	Yes, please also note that some non-CAP data were also available in the 1st round of UAT.
For the 2nd UAT, will there be a "new" data load from PMS or still the data from November 2023 available?	Yes, a new data load will be made available to support the 2nd round of UAT in PUI.
if we request access for different MAHs, will it be possible to view products from different MAHs on the same screen or will it be necessary to change access based on the MAH as is done today in xEVMPD?	We have implemented the access policies in the entire PLM Portal that products are aggregated by user by looking at all locations of all organisations that the user is affiliated to

Question	Reply
the Edit function will be available for all the fields or only for those not reported in xEVMPD?	In the first hand the release of the edit functionality will focus on ESMP-PMS shared elements to enable users to submit the ESMP required data. In this case most of the fields are not shared with XEVMPD except for the pack size (requested to be reported in the package description in XEVMDP as per guidance).This capability is planned to be released in Q4 2024. More information will be shared at the PMS info day event (16 April 2024). Additional functionalities are also foreseen to be released to support the product data enrichment on the non-shared XVEMPD fields resulting empty in PMS.
the SmPC updated version currently upload in xEVMPD would be then available also here?	Documents itself as attached to XEVMPD are not migrated to PMS and therefore made available in API / PUI. While document IDs and dates are migrated from XEVMPD. For further information please access EU IG Chapter 7: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/products-management-services-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-7_en.pdf
What in case there is one user representative for two organisations, can the user see union of product from both organisations or is organisation preselected?	We have implemented the access policies in the entire PLM Portal that products are aggregated by user by looking at all locations of all organisations that the user is affiliated to. A filter is available for each MAH the user is associated to
When the products you can view depend on the ORD ID, is it possible to clarify in your account profile when you are responsible for several ORG ID, i.e. affiliates under the same HQ?	The screen "Products of my organisations" contains a product list of all your associated MAHs. In case you do not filter on a particular one you will be able to see all.
Will it be the same testers for the 2nd UAT as for the first 1st UAT? Is there already a fix timeline in July?	The Agency is targeting Q3 2024 (July) to run the 2nd round of UAT as there will be a new data load (CAPs and non-CAPs) in UAT environment that will allow beta PUI UAT testers to confirm the bugs have been fixed and in particular non-CAP data are correctly exposed. Testers will be contacted as soon as the date to perform the data load is confirmed.
would be PMS sync to CTIS as today xEVMPD is?	PMS is not in synch with CTIS database.
would be PMS UI applicable both for AMPs and DMPs?	PMS PUI as well as PMS API only refers to authorised medicinal products.
would be possible to perform batch updates for all the PMS ID products such as QPPV change as in xEVMPD today?	Yes, this will be developed as part of the Notification process.

Question	Reply
Can you estimate when it will be possible to upload date via RIMS instead of WEB UI?	We don't have this information yet as we have not prioritized the EPIC for the decommission of XEVMPD. Nevertheless, as explained during the demo, there will be some fields such as manufacturers that could be submitted through the RIMS. Otherwise, XEVMPD submissions are still in place.

Electronic Product Information (ePI)

Question	Reply
will the ePI completely replace the PI upload in eCTD sequences?	PI will still be uploaded in eCTD in parallel. For more details, see the pilot procedural guidance: https://plm-portal.ema.europa.eu/Guidance/article/KA-01025/en-us
Will the ePI replace the word file (working document) and section 1.3.1, or will it have to be supplied additionally?	The Word and pdf files will need to be provided additionally. For details, see the pilot procedural guidance: https://plm-portal.ema.europa.eu/Guidance/article/KA-01025/en-us
Congratulations on the progress you've made to date! Could you give your thoughts about how you expect ePI to interact with the PMS (what kind of data, how the process might look)?	PMS and ePI team are exploring any possibility to streamline the relationships across the two products. Further information will be shared in due time.
would be track changes available?	It is not currently planned to implement track changes. This could be considered as an advanced functionality in the future.
As ePI is still in pilot phase, is it the right moment to investigate a link from Product UI to ePI, or is it premature?	PMS and ePI team are exploring any possibility to streamline the relationships across the two products. Further information will be shared in due time.
How can you import your labeling documents in the EPI portal....is their a batch upload functionality	In the coming PI, we will work on FHIR upload by language. Batch upload can be considered as a future advanced functionality.
how would be managed the amendements by CA during a procedure? directly in the portal?	For details, please see the pilot procedural guidance: https://plm-portal.ema.europa.eu/Guidance/article/KA-01025/en-us
If the pharmaceutical companies themselves have to look for vendors who offer programmes for importing word-documents, how can they find suitable ones?	It will be up to the pharmaceutical companies who they would want to work with. For example, pharmaceutical companies will be able to create and upload draft ePIs into the PLM portal if they wish to test ePIs provided by vendors.
it would be possible to retreive the previous versions of each ePI managed in the portal?	Yes. Previous versions will have the status 'Archived'. Please see the December 2023 system demo, where this was demoed.
it would be possible to save draft in the portal?	Yes, it is possible to save drafts. For full information, please see the user guide for applicants: https://plm-portal.ema.europa.eu/Guidance/article/KA-01024/en-us

Question	Reply
Please can you outline what consideration and/or planning has been given to a veterinary ePI.	While the initial focus will be on human products, the standards and technologies developed can all be applicable for veterinary ePI in the future.
there would be a link with PMS ID and eAF ID to link the ePI version to a specific product and to a specific procedure submission?	PMS, eAF and ePI teams will be working together to realise the synergies between the products, such as the links mentioned. Further information will be shared in due time.
When will the import-function for word-documents be available? This is an absolute important functionality for many pharmaceutical companies!	It will be possible to import FHIR or to create ePI in the portal editor, but import Word functionality is not planned.
Will filling in the ePI online be mandatory?	The implementation of the revised pharmaceutical legislation may impact the obligation to submit ePI.
Will it be possible to use in-house/vendor systems to create the ePI in FHIR format and load the ePI as a whole to the PLM portal?	Yes. In the coming ePI we will develop this functionality. It will be possible to upload an entire ePI for one language at a time.

Regulatory Procedure Management (RPM)

Question	Reply
Will the PSUR menu you're presenting only be agency view, or will it be possible to upload PSUR directly to the platform, replacing eCTD?	The view in the Demo was the agency view. The submission process of the product lifecycle procedures remains unchanged.
would be here link of info with PMS ID?	The feature is not yet enabled, however this enhancement will be explored for future implementation.
are there different access roles in IRIS?	For industry and network user access information, including roles, please refer to the guidance on the IRIS website https://iris.ema.europa.eu/access/
Can you give advice how organisations will have to redirect/forward notifications to functional mailboxes, if the rapporteur is from outside an organisation (NCA)?	The email notifications from the EMA IRIS case management always come from the same email address (ema-iris@id.ema.europa.eu), therefore it should be possible to set up auto-forward of messages if required.
could you please publish a document with the answer to the question here reported even if they have been managed during the session?	A Q&A document will be published shortly after the Demo.
In the demo we could see that applicants / MA holders etc are listed with their "SAP number". Is IRIS not integrated with OMS?	IRIS in integrated with OMS. In the case management some information on the organisations are displayed, for quality-check purpose.

Question	Reply
it could be possible to activate a Gateway between IRIS and Company RIMS as currently happen for xEVMPD?	The submission process for all the EMA-led procedures will remain unchanged, for the moment. This means submission of the PSUR will take place on the PSUR Repository or, for the other procedures, via the Gateway.
Meaning also the MAH for a NAP will receive information on the PSUSA procedure via IRIS? No longer via email/Eudralink?	Document sharing with the affected MAH will happen via the EMA Iris case form to the Industry portal. At certain key stages of the procedure email notifications will be sent to the relevant stakeholders similar to current processes.
Will CP Nr. (starting with EMEA/H/C/) remain the same after introduction of RPM for all CAP products?	The EMA product number will be used for products migrated from SIAMED to IRIS in addition to the PRD number.
would these activities in IRIS replace the eCTD submission for PSURs?	The submission process will remain unchanged.

Union Product Database (UPD)

Question	Reply
For PMS UI, a part is a reporting section. Will something similar be developed for veterinary products, or will veterinary products be included in the PMS UI reports?	UPD will not be included in the PMS UI reports, but something similar might be developed in the future via the UPD Data Quality Framework (DQF). Please note that at present the DQF is available for NCAs only.
Could you please confirm if the URLs for the national PI translations of the CAPs published in the UPD remain constant and unaffected by new PI versions?	UPD does not have URLs related to documents since all the documents in UPD are stored in SharePoint and the system does not have direct access to them.
Will the super-grouping also allow to select different implementation dates, per procedure included and even per registration part of MRP/DCP?	MAH can select different implementation dates for the different procedures included in the submission.
Will the system be adapted to receive also VRA?	VRAs are not within the scope of UPD. For CAPs the VRAs are managed via IRIS

Managing the Agency Value Stream

New Fee Regulation (NFR)

Question	Reply
Today the PV fees for Human products are partly based on Art57 chargeable Units. Will the PV fees be based in the future on PMS records?	Regarding the changes foreseen in Regulation 2024/568 (New Fee Regulation), it's important to note that while adjustments are being made on the procedures and fees, the main database used for calculating chargeable units remains the same, and it is Article 57. Even though PMS data may align with Article 57 content and could be considered by the system, the fundamental regulatory data source is not intended to change. The process of accessing Article 57 data remains as it was with the previous regulation. This ensures consistency in regulatory procedures while incorporating potential updates within established parameters. We may consider in the future to migrate the regulatory database for the Pharmacovigilance to PMS.
Please expand on the vet chargeable unit algorithm	The process and implementation of the veterinary chargeable unit algorithm is described in the regulatory frameworks. This algorithm follows a structured approach based on different aspects relevant to the veterinary product's authorization data stored in UPD database as per analogy Article 57 stores the data for the Human's Pharmacovigilance fees. The details on how to calculate the chargeable units are outlined in Regulation 2024/568 (New Fee Regulation), and the veterinary algorithm is implemented based on those regulatory requirements. Within the project implementation EMA is setting the interface connection to the UPD database to extract the products list and calculate the chargeable units that are then used to calculate the fee.
Do you know when the EMA guidance about fees will be released ? Thank you	Work on updating EMA's regulatory documents, user guides, web pages and FAQ documents is progressing incrementally during the course of the year. Publication of final material is planned for Q4 2024.
When we a PSUR has a datalock point end of december 2024, with submit date in 2025, will we fall under new fee regulation ?	Please kindly note that the EURD data lock point date determines the fee amount, the legal entity to be charged and the applicable fee incentive(s), if any.
Will the payment methods remain the same?	1. With the exception of the items outlined in1 point 2, fees and charges for services shall be payable in their entirety in accordance with Article 7(3) of the Fee Regulation within 30 days from the date of the request for payment (invoice) issued by the Agency. 2. The following services shall be provided only after the fee or charge has been paid in its entirety in accordance with Article 71 of the Agency's Financial Regulation and

Question	Reply
	Article 7(3) of the Fee Regulation: Parallel distribution (Annex IV, point 6.3 of the Fee Regulation) Certificates of medicinal products (Annex IV, point 6.2 of the Fee Regulation) Scientific advice (Annex I, point 1 and Annex II, point 1 of the Fee Regulation 3. Link to new fee regulation https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32024R0568
[Moved from ESMP room] Which Industry Forum did Paola refer to in her answer to the question about the update EMA explanatory note on fees ?	The forum we refer to was the ISG meeting on 25th March (link to EMA website https://www.ema.europa.eu/en/events/eighth-industry-standing-group-isg-meeting). in that instance we informed the audience that work on updating EMA's regulatory documents, user guides, web pages and FAQ documents is progressing incrementally during the course of the year. Publication of final material is planned for Q4 2024.
If there will be no fee for Type IA, will it be allowed to maintain Product Information via data submission only (as per ROG)?	*Answer added to Rev. 1 of this document.* As outlined during the public system demo directly, there won't be a separate fee for Type I variations under Regulation 2024/568 (New Fee Regulation), rather services related to Type I variations are included in the annual fee. Please kindly note that the regulatory requirements to provide the data as per the designated procedure are applicable independently from the levied fee or fee type. If the proposed product information change is to be submitted to the regulators via a variation request (as per Variation regulation and Variation Guidelines), the marketing authorisation holder is requested to submit the change via the relevant variation procedure.

Monitoring Value Stream

European Shortages Monitoring Platform (ESMP)

Question	Reply
Could you make the distinction between the data that will be submitted (by MAHs) to ESMP, from the data collected via data integration (using PMS)?	*Question answered verbally during the demo.*
It's been mentioned that information about manufacturers needs to be provided in PMS for ESMP. Could you specify which manufacturers would be in scope?	*Question answered verbally during the demo.*
Is the manufacturing site status (in activity yes/no) a data that would have to be maintained specifically in ESMP ? What are the criteria for a manufacturing site to be considered as active ?	*Question answered verbally during the demo.*
Regulation expects a fully operational ESMP by Feb 2025 - does that mean: the system, data for CAPs only, under crisis only, CAPs and NAPs under crisis only, all CAPs and NAPs...? What is expected?	*Question answered verbally during the demo.*
The list of critical medicines only lists substances. Are all dose forms relevant, or only specific forms (e.g. use in hospitals ICU, only injectables,...)?	Indeed, the critical medicines lists only contain substances, pharmaceutical forms and routes of administration. During crises, the EMA would identify which exact products would fall under those particular categories and ensure the relevant MAHs owning them are informed of their new reporting requirements. The ESMP will be listing all those relevant products, tailored specifically for each MAH and pre-populate their templates with the relevant product information.
Looking at the timeline, would the use of the platform become mandatory at Go-Live or will there be an "optional use" period?	*Question answered verbally in the system demo.*
How do you define y crisis?	The MSSG was recently established under Regulation (EU) 2022/123, which assigns a reinforced role to the Agency in crisis preparedness and management for medicines and medical devices to monitor shortages and ensure a robust response to major events or public health emergencies, and to coordinate urgent actions on the supply of medicines within the EU. The Regulation formalises and strengthens the governance structures EMA had put in place to ensure swift and coordinated action during the COVID-19

Question	Reply
	pandemic. One of the MSSG's tasks is to establish lists of critical medicines needed during a public health emergency that require close monitoring because of a possible increased risk of shortages. As soon as the MSSG adopts a list of critical medicines for the management of a particular public health emergency or major event, are the "crisis" reporting requirements triggered.
Do MAHs have to report on the whole product portfolio, although no shortage is actual? What about critical medicines of the list, still report although no shortage is actual?	When there is a public health emergency or a major event (such as covid-19 and mpox) or when an MSSG-led preparedness exercise is triggered (such as the close monitoring of antibiotics in 2023), MAHs need to report information on shortages and supply of their CAP and NAP medicines in scope of that particular crisis/MSSG-led preparedness, regardless of the fact whether they are experiencing a shortage or not. Outside of these situations, MAHs need to report to the EMA all potential and actual shortages of their Centrally authorised products.
To your point worded over slide 12 "MAH to ensure that data through IRIS are accurate": can you confirm that the MAHs have to ensure that product data are accurate in PMS via PUI/API? Otherwise please provide more information.	Here I was specifically referring to the information on the Marketing status of CAPs submitted through IRIS. The ESMP is using this information to ensure MAHs are not requested to provide information on shortages, stocks, etc for products that are not marketed. Therefore MAHs will have to ensure the information on the marketing status of CAPs in IRIS is entered correctly and is up-to-date. Information on the master data on products in PMS will indeed he handled through the respective PMS user interface.
About prearedness, Could you clarify which event should trigger an ESMP submission from the Industry? Is it correct to say that industries must submit data only when they have visibility of potential or actual shortage?	For MSSG-preparedness activities there is no distinct trigger besides the decision of the MSSG that these activities need to be triggered. When this happens the relevant MAHs will be contacted to submit data through the ESMP. These activities need to be seen as distinct from the routine CAP shortage reporting. For CAP shortage reporting the MAH must submit data when they are confronted by a potential or actual shortage.
Are all registered manufacturers relevant for ESMP (e.g. also testing sites, intermediate manufacturers), or only the final active substance manufacturer, bulk manufacturer, batch releaser?	The EMA will be monitoring issues at all points of the supply chain, which includes all points in the manufacturing process, as if an issue occurs in any of them, this may result in lack of supply.
Are there different processes for critical medication in crisis and "standard" shortages?	Indeed, when a "crisis", i.e. a public health emergency/major event or a MSSG-led preparedness exercise is triggered, then MAHs need to provide a wider range of information and submit it at a frequency defined by the MSSG. The routine shortage reporting is an obligation MAHs of CAPs have towards the EMA at all times.

Question	Reply
Could you please clarify for which medicines we'll use the ESMP? All medicines or only reported in a list? Are we going to use it only in case of shortage? only during a crisis?	Not all medicines will be monitored using ESMP. Which medicines are in scope will depend on whether there is an ongoing crisis or not: During a crisis (i.e. public health emergency (PHE) or major event (ME)) EMA will monitor the supply, demand, and availability of critical medicines as defined by a list of critical medicines published for that crisis. Outside of a crisis phase, EMA will monitor relevant medicines upon request by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) or as defined in the upcoming legislation to prevent and manage shortages which might lead to a PHE or ME (i.e. preparedness activities). ESMP will also be used for the routine reporting of shortages of centrally authorised products by MAHs.
could yuu please clarify which are the field to be reported by MAH in ESMP if there is no crisis and when a crisis is happening?	This was answered verbally in the system demo for MAH routine shortage reporting. For crisis reporting please consult the previous system demos where we demonstrated what data elements need to be inserted during a crisis. Additionally, we will be publishing all the datasets in scope of each reporting phase, so MAHs have full visibility of data to be reported.
during a crisis, MAH should submit info even if a shortage is not ongoing for a specific product?	During a crisis, if the MAH owns critical medicines as defined by a list of critical medicines published for that crisis, they will indeed have to submit data to the ESMP regardless of the fact if they are experiencing a shortage. The frequency of those submissions will be defined by the MSSG specifically for each crisis.
For reporting of shortages for CAPs, the new ESMP will replace the current process to send a filled form to a dedicated EMA email address?	Thank you for your question. Indeed, that is the intention.
How does EMA plan to increase quality on the NAP data that is being loaded into PMS? Currently the data is in XEVMPD and data quality is unfortunately average at best	XEVMPD team is planning to improve the validation process we currently have implemented. This way, records in XEVMPD belonging to the same product will be validated at the same time and by the same person reducing discrepancies in the validation. These improvements will be discussed with the PMS SMEs. Nevertheless,, we will need MAHs' support to review 3rd AcKs making sure they agree with the validations we perform.

Question	Reply
How much time do we have to deliver our data in case of a crisis?	The MSSG defines the reporting requirements and data submission frequency of data on shortages, supply and demand during crises. However, the MAHs will also need to ensure all their product data is inserted at pack size level of granularity and if a crisis occurs, MAHs would need to ensure all their packs of medicines in scope of crisis reporting are inserted into xEVMPD (PMS once available for NAPs) within two weeks.
how much time MAH have to communicate shortage in ESMP from when a shortage occurs?	For routine shortage reporting, MAHs need to report to the EMA as soon as they are aware of a potential or actual shortage of a CAP. During crises the frequency of reporting will be set by the MSSG and will be specific to each crisis.
how will be tracked the marketing status for NAPs?	The marketing status of NAPs will be requested from MAHs only in a crisis/MSSG-led preparedness exercise for critical medicines as defined by a list of critical medicines published for that crisis/MSSG-led preparedness exercise. This data will be submitted via ESMP and will be demoed in the next system demo.
if the info on ESPM are taken per Country how this differences in the Marketing status are kept from PMS since we'll have info on Europe basis?	Data on marketing status of CAPs is already gathered via IRIS for each pack and each country. This data is currently not in scope of PMS. Data on the marketing status of a particular set of NAPs will be collected via the ESMP only if there is a crisis or an MSSG-led preparedness exercise has been triggered.
In case of crisis, are the industries required to submit data also if there is not a shortage for the medicinal they own? How often should the industry update their data in case of shortage?	During a crisis, if the MAH owns critical medicines as defined by a list of critical medicines published for that crisis, they will indeed have to submit data to the ESMP regardless of the fact if they are experiencing a shortage. The frequency of those submissions will be defined by the MSSG specifically for each crisis.
interoperability requirements to what is referred to?	The roadmap for the ESMP accounts for the submission of data in spreadsheets through the web UI, but also, post-MVP for some datasets through a REST-like API, which will allow for a machine-to-machine interaction. We refer to this as system-to-system interoperability.
Is the excel file the only way for the MAHs to upload information in the system?	Machine-to-machine (M2M) interaction for submission of data is the goal of the interoperability features the ESMP will be working on. Therefore MAHs will be able to choose whether they want to submit data via spreadsheets in the user interface, or communicate via M2M interaction. Please consult the end part of the ESMP system demo for timelines on this.
Is there any plan to stop the marketing status reporting in IRIS and include the information in PMS instead?	Current ambitious development plans on the ESMP and PMS side do not allow for this, however both teams will be exploring this option in the future.

Question	Reply
it could be possible to have a list of all the fields\requirements reported in the ESMP and have an indication of those that will be taken by PMS and those that need to be entered by MAH?	This was answered verbally in the system demo for MAH routine shortage reporting. For crisis reporting please consult the previous system demos where we demonstrated what data elements need to be inserted during a crisis. Additionally, we will be publishing all the datasets in scope of each reporting phase, so MAHs have full visibility of data to be reported.
Regulation expects a fully operational ESMP by Feb 2025 - does that mean: the system, data for CAPs only, under crisis only, CAPs and NAPs under crisis only, all CAPs and NAPs...? What is expected?	*Question answered verbally during the demo.*
starting from Feb 25 MAH need to be ready to use ESMP for all CAPs as mandatory in case of a shortage even if there is not a crisis?	Indeed, the ESMP will allow MAHs to report shortages of CAPs via the platform from Q4 2024, which will replace the current way of working via email communication. There will be a transition period in place as well, as explained in the demo, and there will be guidances, webinars and other relevant content to ensure MAHs are supported in this change.
Submission of data will never be possible through a gateway from a Company RIMS?	The roadmap for the ESMP accounts for the submission of data in spreadsheets through the web UI, but also, post-MVP for some datasets through a REST-like API, with which a company RIM system can interoperate.
supply forecast e demand forecast would be in scope to ESMP? these need to be communicated for all CAPs or only in case of a crisis?	This is indeed in scope of the ESMP and would need to be provided for a specific set of medicines only of there is a crisis or an MSSG-led preparedness exercise.
there would be different access roles for MAH to ESMP?	All MAH users will have the same access roles for ESMP.
What is the legal basis (the legislation) stating that the EMA owns the manufacturing details ?	EMA currently owns the data on the manufacturing sites of centrally authorised products which are submitted by the Industry when applying for a marketing authorisation. They also need to keep this information up-to-date and submit a variation when there is a change in this data.
What would be the legal basis (the legislation) stating that the EMA owns the manufacturing details for NAPs ?	Regulation (EU) 2022/123 sets out the legal basis for requesting information on manufacturing sites from marketing authorisation holders. The EMA already holds the data on manufacturing sites of CAPs, however the MAHs will have to submit this information pertaining to NAPs. For the time being we have restricted the scope and will be requesting this data (to be submitted Feb-Dec 2025 via PMS) only for the NAPs included in the scope of the Union list of critical medicines, to ensure preparedness for a potential crisis.

Question	Reply
Will all the data fields tracked in ESMP be included in the EU PMS IG Chapter 2 expected in Q2/2024 and all RMS lists created before Jan 2025?	The RMS lists required for the ESMP are already created. ESMP-related data fields which are not part of EMA master data on products will not be part of the PMS IG. ESMP will be releasing our own implementation guides in Q2 and Q3.
Will NCA have access (in ESMP) only to data for product related to procedures where they are stakeholder (RMS/CMS) or will they have access all data regardless of their involvement?	In the ESMP, NCAs will have visibility of product information of all products authorised in their countries in scope of reporting requirements, in order to report the relevant data on national need and demand in a crisis situation/MSSG-led preparedness exercise against the products defined in the scope of that particular crisis/exercise.

Research & Development Value Stream

Paediatrics Procedure

Question	Reply
Can you please be clear on all the paediatric submissions which will be included? Initial, modification, annual, waiver? All rolled out at same time ?	On 4 June 2024 we will go live with the following processes: Application for Initial Paediatric Investigation Plan, Modification of Paediatric Investigation Plan, Compliance Check, Product Specific Waiver, Annual report on deferred measures, Confirmation of the applicability of the Agency decision on class waivers, Discontinuation of the paediatric medicine development as agreed in a PIP.
Will the paedriatric information on IRIS replace the rudimentary information in xEVMPD?	The new development in IRIS relates to pre-authorisation procedures and research products namely: Application for Initial Paediatric Investigation Plan, Modification of Paediatric Investigation Plan, Compliance Check, Product Specific Waiver, Annual report on deferred measures, Confirmation of the applicability of the Agency decision on class waivers, Discontinuation of the paediatric medicine development as agreed in a PIP. Any data on the research product provided via these applications is not meant to replace any information in the xEVMPD