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Q&A Q2 2024 System Demo

Date: 26 June 2024

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

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2024

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.

This document is expected to be updated in mid-July to provide the missing answers. 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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Table of Contents

Managing the Agency Value Stream

New Fee Regulation (NFR)

Question	Reply
[Moved from UPD room] Concerning the new fee regulation, can you explain why provisional products in UPD are included in the calculation of the fees?	*Answer added to Rev. 1 of this document.* Unfortunately, we are not yet in a position to answer this question as the technical implementation is still work in progress. Further details will be communicated in due course.

Experts Management Tool (EMT)

Question	Reply
Is a 'EMA Activity' defined somewhere?	The Activities that are in scope for the call for expression of interest will be defined in the Call for expression of interest documents to be published on the EMA webpage in the coming weeks.

Monitoring Value Stream

European Shortages Monitoring Platform (ESMP)

Question	Reply
Do MAHs have to report the baseline on Marketing Status for each pack size for union list products until Feb25 even if there is no shortage?	*Question answered verbally during the demo.*
How will the MAHs be informed, if a crisis appear, in order they can timely react?	*Question answered verbally during the demo.*
In the latest on ESMP webinar, the PCID was stated as the data used from PMS. However, this data is not yet available in PMS. Is it planned to have this identifier created before ESMP's MVP go live?	*Question answered verbally during the demo.*
To clarify maintenance/update on data fields: xEVMPD via xEVMPD, Manufacturers via PMS, Marketing Status (CAP via IRIS; NAPs via Excel in ESMP -visible in PMS?), Pack size (CAP - SIAMED, NAP via xEVMPDcode multiplication). Can you confirm.	*Question answered verbally during the demo.*
We already provide marketing status to the NCAs. For us, it is now double work. If you do not have the marketed status beforehand, all products (also the not marketed ones) will appear in your template initially, right?	*Question answered verbally during the demo.* *Addition added to Rev. 1 of this document.* The scope of data submission for NAPs to ESMP is limited to a specific set of products during crises or MSSG-led preparedness activities. When a list of medicines that are critical for a crisis or a list of medicines that are identified for an MSSG-led preparedness activity gets published, all NAPs from the MAH according to that specific list will appear in the ESMP template for marketing status of NAPs. If then the marketing status of a NAP is submitted as 'not marketed' or 'never marketed', the respective product will not appear in the subsequent templates generated by the ESMP. Once the ESMP becomes interoperable with NCA systems, EMA will work to reduce the manual workload for submissions to the ESMP.
Thank you for your answer regarding Marketing status NAPs. 2 remarks: Limited scope depends on your portfolio of critical medicines; it is still several hundred packs for most; your process breaks if non marketed products do not further appear as a MAH can decide later to start amrketing of the formeer non marketed product	*Answer added to Rev. 1 of this document.* Thank you for your remarks. The submission of information for NAPs will only be triggered in crises or MSSG-led preparedness activities as per the specific list of products for that crisis or activity. In those situations, the marketing status for NAPs needs to be submitted via the marketing status template in the ESMP and updated in the ESMP if the MAH starts to market the product. Then the respective subsequent templates will automatically start including the entries for this product and also then all other information for this product will need to be submitted in the ESMP.

Question	Reply
For CAPs, EMA already has marketing status info. Should the MAH maintain shortage info for both marketed and non-marketed packages of products listed on the list of critical medicines, or only the ones 'marketed' or 'non available' in IRIS?	*Answer added to Rev. 1 of this document.* Marketing status information for all CAPs needs to be continuously maintained in IRIS, as per the current process. Shortages and further shortage information for CAPs shall routinely be reported through the ESMP as soon as the MAH is made aware of a (potential) shortage of a CAP or changes to its shortage situation, as soon as this functionality goes live. If a CAP is not marketed in a country it is not possible to report a shortage of the CAP in that country. However, shortage information needs to be submitted through ESMP for each country in which a product is marketed and in which a shortage occurs.
Are marketing status related fields in IDMP IG Chapter II v2.1.1 ' 4.6.5. Risk of supply shortage, 4.6.6 Risk of supply shortage comment, 4.6.7.1 Reason' currently not part of ESMP? Will these be required at a later stage in ESMP or PMS?	*Answer added to Rev. 1 of this document.* The information related to the marketing status is currently captured through IRIS for CAPs and through ESMP for NAPs (limited to a specific set of products during crises or MSSG-led preparedness activities). Therefore, for the moment, EMA is not requesting this information via PMS. If there is any change in this strategy EMA will inform their stakeholders. The ESMP does not require submission of these specific fields mentioned in the question. The data elements regarding shortage details that will be submitted through ESMP, to be found in the ESMP MAH Implementation guide which will soon be published on the ESMP webpage: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform
RMS list related to the Marketing status, it was supposed to be updated and definition should have been added to define better the terms. It did not happen, please clarify when definitions will make available.	*Answer added to Rev. 1 of this document.* Please note that the update of this list has not been prioritised due to other activities to be delivered. In order to update the term description of the current terms of the Marketing status lists, the text needs to be agreed among the involved teams using this list. We will follow up with the relevant teams to explore when an agreement can be achieved.
Routine shortage reporting (slide 24) only for CAPs? No double reporting for national products (NCA + EMA) except during a crisis?	*Answer added to Rev. 1 of this document.* Yes, routine reporting of shortages to EMA applies only to CAPs. Shortages of NAPs have to be reported nationally as per national requirements. However, in MSSG-led preparedness exercises and in crises, availability and supply information is to be reported for both CAPs and NAPs that are in scope (defined by a specific list of medicines that will be published at that time) through ESMP to EMA.
When a variation impacting on the manufacturers takes place, do we have timelines to be followed for the updates in PMS for the critical medicines? And how frequently does the additional manufacturer information need to be updated on ESMP?	*Answer added to Rev. 1 of this document.* For CAPs, as soon as the change is authorised, this will be updated in SIAMED and from SIAMED in PMS. For non-CAPs, this information has to be maintained by MAHs and EMA needs to discuss how much time is given to applicants to perform this update. As the edit process is not in place yet EMA will engage for these discussions in the near future.
How will NCAs be informed about the marketing status of CAP products in their country from ESMP/PMS?	*Answer added to Rev. 1 of this document.* NCAs can access the marketing status of CAPs in their country in IRIS.

Question	Reply
If NAPs that are "not-marketed or "never-markted" not needed for ESMP, do we still need to multiply the pack sizes in xEVMPD? Or can we wait for the PMS field enrichment in PMS directly?	*Answer added to Rev. 1 of this document.* In normal circumstances (and now for the products in the Union list of critical medicines) there is no strict requirement to submit the pack sizes for non-marketed products. As EMA progresses forward with the submission of pack sizes for all products, you might want to expand the scope to all products. However, if a crisis or MSSG-led preparedness activity is announced, ESMP will be asking for the pack sizes of all authorised products in scope of the crisis or activity, regardless of their marketing status, to be submitted within 2 weeks. The reason is that the marketing status can change quite quickly, and EMA needs to have an overview of all the authorised pack sizes in a crisis or MSSG-led preparedness activity.
Please clarify the definition of 'Not Marketed' - e.g. if product has been distributed and expiration date has not past, is the product considered to be 'Marketed'?	*Answer added to Rev. 1 of this document.* Please refer to the IRIS guide for applicants (https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf) for all definitions related to the marketing status, including 'not marketed'. These definitions should be read in conjunction with the definitions on the webpage 'Notifying a change of marketing status' (https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/notifying-change-marketing-status). Regarding the last part of the question: The date of marketing cessation shall be the date of the last release into the distribution chain.
How is EMA validating the manual upload of the data?	*Answer added to Rev. 1 of this document.* The ESMP processes the submission of data according to validation rules for each field. If a validation rule is not fulfilled for one or more fields, an error will be triggered, and the submission of the data will not succeed. All validation rules will be explained in the Implementation guide that will be published soon on the ESMP webpage: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform
In the Ecel you showed only the Marketing Status is allowed to change. If MAH changes something else, will the vlaidation catch it and report it as an error?	*Answer added to Rev. 1 of this document.* Yes, we demoed only that specific part of the data submission process for NAPs Marketing status. The PMS ID will be processed by the system and an error message appears if the PMS ID was altered. The other product data fields are included in the template only to support users to refer to the correct product while inserting the relevant information requested in the template. Any change or addition to other data elements holding descriptive information on the product (product name, active substance, country) will not be processed by the ESMP. If changes need to be applied to these data elements, changes must be done in directly in PMS.
Could the availability status information for national products be retrieved directly from the UPD, as it is already available here, or is it necessary to submit it separately via ESMP?	*Answer added to Rev. 1 of this document.* UPD is a single source of information on all authorised veterinary medicines and their availability. The scope of the ESMP are medicines for human use. Therefore, data from UPD is not relevant for the ESMP.

Question	Reply
How are the products listed if the products are not available by pack size in the PMS but by MA?	*Answer added to Rev. 1 of this document.* Products that are not available by pack size will not be listed. Therefore, the submission of the information on the pack size in PMS is needed.
How do you expect the file to be compiled when there are multiple alternative sites for a manufacturing operation? will the file be set up with multiple lines or will the manuf info be collapsed into a single cell?	*Answer added to Rev. 1 of this document.* Currently the validation only allows for a single value to be entered, but thank you for this suggestion, we will ensure this is implemented as an improvement after the minimum viable product is delivered.
Will it be possible to populate information in ESMP itself or are data only used from PMS, eg pack size and package description?	*Answer added to Rev. 1 of this document.* Pack size and package description are populated in PMS and cannot be adjusted in ESMP or ESMP templates. Even if these fields are changed in the ESMP templates, it will not be processed during the upload of the filled file and submission of the data, as PMS is the system for managing master data on products in the EU/EEA, and the ESMP is simply a user of that data.
Thus, for clarifications purposes; the submission of this information/template will be mandatory for NAPs only at times declared by EMA as preparedness situation/crisis situation?	*Answer added to Rev. 1 of this document.* Yes, the submission of the filled templates on the marketing status for NAPs will only be mandatory at times of crises or MSSG-led preparedness activities.
Could you please make the slides shown available?	*Answer added to Rev. 1 of this document.* Slides from this system demos have been published on the event page. Here is also the link to the ESMP Essentials and Industry Reporting Requirements webinar (https://www.ema.europa.eu/en/events/european-shortages-monitoring-platform-essentials-industry-reporting-requirements), held on 24 June 2024, and the published slides form that webinar. These contain the same information as shown on the slides during the system demo.
Are MAHs being requested by the EMA to submit marketing status information in multiple places e.g. ESMP, PMS, IRIS? Which application is considered the source of truth/primary source for this data?	*Answer added to Rev. 1 of this document.* Information the marketing status for CAPs needs to be inserted and kept up to date at all times via an existing process in the IRIS platform. This information will be used in 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. 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, when this is triggered by the MSSG, and submitted via a standalone reporting data flow directly in the ESMP. EMA will also work on the long-term strategy for reporting the information on the marketing status of all products via a single submission flow.

Question	Reply
Can the proposed template used for the upload be modified adding new rows? If not, how we can specify that for a specific site (specific row in the template) there are more than one alternative site?	*Answer added to Rev. 1 of this document.* Currently the validation only allows for a single value to be entered for alternative sites, but thank you for this suggestion, EMA will ensure this is implemented as an improvement after the minimum viable product is delivered. However, additional rows should never be inserted in the file.
Will the technical guideline specify which of the Manufacturing details fields are mandatory or not? Are they all mandatory? Which is the frequency EMA indicates to refresh them?	*Answer added to Rev. 1 of this document.* The Implementation guide, which will be published on the ESMP webpage (https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform), will specify which fields are mandatory. The MSSG will define the frequency of reporting specifically for each crisis or MSSG-led preparedness activity.
If "not marketed" NAPs products will no longer be visible on your ESMP extract, how can I change the status if they are marketed. Your extract always showed ALL products and just some were tagged "not marketed". Will this remain like this?	*Answer added to Rev. 1 of this document.* Yes, the marketing status for NAPs has to be amended in the NAPs marketing status template. If a NAP has the marketing status of "not marketed" it will still appear in the NAPs marketing status template but will not appear in other templates, e.g., the availability information template. If the marketing status is changed with the submission of the edited NAPs marketing status file to e.g., "marketed", the NAP will then appear in the other templates.

Antimicrobial Sales and Use (ASU) Platform

Question	Reply
ASU:why do NCAs have to upload a sales dataset if MAHs already uploaded sales in the UPD ?	As per Article 57 of Reg. (EU) 2019/6, Member States are responsible for reporting antimicrobial sales and use data to the Agency. As per Article 11.1 of Delegated Regulation (EU) 2021/578, Member States can choose to obtain their antimicrobial sales data from any of the following data providers: marketing authorisation holders (MAHs), wholesalers, retailers, feed mills, pharmacies or veterinarians. The ASU sales templates are prefilled with the volume of sales data submitted by MAHs in the UPD, in case Member Staes wish to use MAHs as their data providers. However, if they decide to use a different data provider due to the characteristics of their national collection system they may do so and replace the MAH data with the data from their selected provider.
And: please kindly confirm there is no overwriting by NCAs of the sales uploaded by MAHs	The ASU sales templates are prefilled with the volume of sales data submitted by MAHs in the UPD. Member States are responsible for reporting antimicrobial sales data to the Agency (as per Article 57 of Reg. EU 2019/6) and can choose to overwrite this information only in the ASU sales template if: a) they wish to use a different sales data provider (as contemplated in Article 11.1 of Delegated Regulation EU 2021/578) or b) if they need to correct the MAH volume of sales data for movements of products across their borders as part of parallel trade and/or complete them with that of other data providers when appropriate (as mentioned in Article 11.2 of Delegated Regulation EU 2021/578). This is to avoid instances, for example, of double reporting of sales between countries.

Veterinary Union Pharmacovigilance Database (UPhV)

Question	Reply
When using the Product grouping in DWH, the result show AE not pertaining to the MAH (AE with active substance only) and also reporting AE with active substance of a different form (spray when the MAH product group is a spot on).	Please report any issues found related to Product grouping in DWH via the EMA Service Desk so that our technical team can investigate and fix any problems.
When will the Duplicate Detection Tool be available for the MAH?	The Duplicate Detection tool is intended to be used by the EMA data stewards only. However, a report will be developed in Data Warehouse that will allow MAHs to view the reports for their organisation that have been designated as "duplicate reports"
Which organization will have the possibility classify a duplicate as the master case ? What will happen in case the 2 duplicates are originating from 2 different MAH, and each of them designate a different case as the master case ?	The Duplicate Detection tool is intended to be used by the EMA data stewards only, and not by MAH. The EMA data stewards will be responsible for the duplicate management process in UPhV (EVVET3). Please also note that in UPhV (EVVET3) there is no concept of master case as in EV human. Instead, one of the cases will be classified as the "Principal report", and that case will be used for analysis in DWH, while the other case will be marked as a "Duplicate report".

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
Concerning the new fee regulation, can you explain why provisional products in UPD are included in the calculation of the fees?	*[This question was moved under New Fee Regulation.]*
During the demo of retrieve VNRA, the date of first submission was not today. Is this normal?	The demo was recorded in a test environment and some inconsistencies (e.g. date, product name, MAH, etc) occur since the data was prepared to serve the demo.
Is there an option to select which notification you will receive as MAH?	The email addresses provided by the UPD Super Users for their organisations will receive all the notifications that UPD has triggered as a result of any action performed in the system. It will be the users of this mailbox who will have to filter those notifications they want to see, and this will be possible because the subject of the notification provides the name of the functionality to which it corresponds.
Which types of notifications will be sent by upd.notification@ema.europa.eu?	Email notification will be trigger by the system for any of the following actions performed by a user: creates, updates, upload/updates of documents, VNRAs submitted/approved/rejected, submission of Volume of sales or availability status by MAHs or transfers or ownership.

Electronic Application Form (eAF)

Question	Reply
What happens when you add a new pack in the eAF? Is it added to the PMS at approval?	Yes, indeed, upon approval the new pack size will be included in PMS so that it can be selected in the eAF for the next variation. We are hoping to have this feature available in the eAF very soon. We will organise a training to explain this new feature in detail.
Will the EMEA/H/W products remain in the list on the PLM portal?	Yes, this is the intention to avoid any need to maintain the interactive pdf form for these products.
any update on veterinary timetable for eAF?	We are aiming to start the work on MAA forms (Human and Veterinary) in 2025 and will subsequently work on the veterinary variation form.
Will the eAF also be made available to the veterinary sector?	Yes, the form for veterinary variations will also become available. We are working on replacement of all the current interactive pdf eAFs. We are working in an order that enables us to reuse as much as possible to minimize the development effort and this means that in order to start the work on the veterinary variation form, we ideally would like to have the Veterinary MAA form finalised as the variations that were previously extensions do require large number of fields from the MAA form to be added into the variation form and we would like to reuse the designs and technical development work done for MAA.

Question	Reply
In the report section, if I click on the Package Size, will only medicinal products show up which have already entered package sizes and other products won´t appear?	Currently this list contains only centrally authorised products and all CAPs have pack size information available. More information will be provided for non-CAPs by the PMS team in an upcoming webinar on 11th July 2024 . https://www.ema.europa.eu/en/events/public-webinar-pack-size-submissions-xevmpd-product-management-service-pms
The vet sector is eagerly waiting for changes to the vet variations eAF: integrating the former line extensions + replacement of date field for the implementation date by a free text field. when will they be implemented ?	We really need to work on this in a logical order, first we need to finalise the requirements for the Veterinary MAA form, this is currently ongoing and changes that will be initially implemented in the interactive pdf eAF. Subsequently we will start analysis to look at which fields/sections of the MAA form need to be removed as they are 'moving' to the variation form, subsequently we'll start analysis of the new variation form. We will first update the pdf eAF for vet MAAs (including the special variations). We will then start working on the web eAF for vet MAAs (without the special variations). Once the web based vet MAA form is developed we can start work on the vet variation form as we will need to 're-use' large number of MAA form fields in the variation form. This is considered to be the most efficient way forward. For now we know the sequence of events, however, timelines need to be planned and they will be published according to agency wide priorities.
Will the eAF section cover the latest timelines? I'd like to know when web-forms will become mandatory (human not veterinary)	We have presented a very high level overview of the upcoming events however, this is not an updated timeline. We are currently preparing to expand the use for non-CAP products and subsequently, we will start an external UAT to confirm that all required functionalities are available. Following a successful UAT we will be able to start the transitional period for mandatory use. For now, the use for CAP variations is strongly recommended where possible.

Product Management Services (PMS)

Question	Reply
If NAPs that are "not-marketed" or "never-marketed" are not needed for ESMP reporting, do we still have to multiply pack sizes in xEVMPD? Or can we wait for the PMS enrichment?	In normal circumstances (and now for the products in the Union list of critical medicines) there is no need to submit the pack sizes for non-marketed products. However, if a crisis or MSSG-led preparedness is announced, for the products in scope of reporting, we will be asking for the pack sizes of ALL those products, regardless of marketing status, to be submitted within the mentioned timelines. This is because the marketing status can change quite quickly, and we need to have an overview of all the authorised pack sizes.
Are API credentials related to a specific user, or to defined MAH org´s? What if later the IRIS/PLM admin is onboarded for another MAH - are the API credentials extended to this ORG automatically, or is it required to request a new set?	Please read EU IG chapter 1 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-1_en.pdf section 3.2.1. Registration to PMS Application Programming Interface (API). The current model supports only separate API credentials per OMS Organisation ID.

Question	Reply
The pack description in xEVMPD needs to be given in local language. Will this now change using CV for pack size? What if pack size is identical but filling volume not, e.g. 5 x 2ml vials. Like 5 x 2ml vials (0,9ml) and 5 x 2ml vials (2ml)?	Pack description in XEVMPD is a free text field while the pack size PMS data elements are controlled vocabularies. We recommend to register to the upcoming webinar Public webinar on pack size submissions: from XEVMPD to product management service (PMS). Link: https://www.ema.europa.eu/en/events/public-webinar-pack-size-submissions-xevmpd-product-management-service-pms
When will I be able to register for the API? Still in early July?	Yes in July when API read for registered users will be released. EMA will communicate the exact data in due time.
RMS list related to the Marketing status, it was supposed to be updated and definition should have been added to define better the terms. It did not happen, please clarify when definitions will make available.	The update of this list had a dependency with other teams. It will be updated upon completion of discussion and final agreement.
Discrepancy in chapter 2: section title is "4.6.3. (Marketing status) end date", but the section describes the "marketing end date" (not status). I guess it is the "marketing dates", not "status dates". Correct?	This point is already in our radar. Thank you
Are marketing status related fields in IDMP IG Chapter II v2.1.1 ' 4.6.5. Risk of supply shortage, 4.6.6 Risk of supply shortage comment, 4.6.7.1 Reason' required at a later stage in PMS? Fields do not seem part of ESMP at the moment	These fields are not required to be completed at the moment in PMS to support ESMP.
Could you confirm that for the API account, it needs to be associated to all the MAH organisation IDs so that all the medicinal products are accessible? if authorizations under 10 MAHs, then all need to be assigned to the API account user.	The current model supports only separate API credentials per OMS Organisation ID.
Do MAH need API credentials for each OMS ID? Or can there be a "headquarter" API/OMS relation?	Please read EU IG chapter 1 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-1_en.pdf section 3.2.1. Registration to PMS Application Programming Interface (API). The current model supports only separate API credentials per OMS Organisation ID.
Does for PMS (UI) any certification course / knowledge evaluation will be available?	As stated in EU IG Chapter 1 to read PMS data no certification is required.
if a MAH LOC-ID is changed is enough to submitt the new code in xEVMPD in comment field, or should we have to perform other actions?	Please follow the XEVMPD chapter 3.II guide and OMS operation manual for this situation.

Question	Reply
if applicator is co packaged item , then we considered as component for secondary package or primary package component type	Please raise a question in Service Now. When submitting it please provide the supporting documentation i.e. smpc/dossier to properly evaluate your request of information.
Mapping the SIAMED data for marketing status of CAPs the data field "date of change of marketing status" was migrated to a PLM field named "Marketing status end date". When the last action was re-entering the market, you have a wrong info.	Please submit and incident ticket type in service now to allow the team to properly investigate on the issue. Please also submit all the supporting material and screenshot.
We've seen that there is data visible in the PMS where we assumed there would not be (Marketing Status Dates). According to Chapter 7 there should be no data migrated over. Why is there data here? the data looks to be inaccurate.	This is correct. This information is not stated in EU IG Chapter 7 and it was not expected in PUI pages. We are discussing the data flow of the marketing status data from IRIS to PUI.
What means internal or external users	Internal means EMA user while external registered user means the network MAH / NCA
Will there be any guideline explaining how the pack sizes should be reported to xEVMPD in order to have that data in PMS?	PMS team will host a webinar on Pack Size Submissions: from XEVMPD to PMS. Date: 11 July 2024 Time: 10:00 – 11:30 CEST. If interested you can register at this link: https://www.ema.europa.eu/en/events/public-webinar-pack-size-submissions-xevmpd-product-management-service-pms
Will there be guidelines about manufacturers data that we will need to add for NAPs?	yes, guidance will be made available in due time. For the moment we are focusing on providing guidance to submit pack size in XEVPMPD to PMS in order to support ESMP activities.

Product User Interface (UI)

Question	Reply
Will it be possible to extract a complete dataset of all owned authorised products from PMS in order to perform datacheck?	In PUI data can be exported with different reports and at different level across the PUI pages i.e. ingredients, pack sizes, manufacturers, ATC codes, etc. The full list of PMS dataset is not yet available for users to be exported.
Unit of Presentation field, in PUI, is showing values not related to the correct RMS list. Can you please clarify why the value are not align as per chapter 2?	The Agency will investigate on the issue. Kindly submit an incident type ticket in Service Now (PLM portal – PMS Product Data) as per procedure mentioned in the support section https://plm-portal.ema.europa.eu/Guidance/article/KA-01048/en-us/
Will you allow industry to harmonise data in the PMS where SmPCs are not harmonised (for historical reasons)? There is a lack of clarity in Ch2 about what industry is expected to provide, and this does not support consistent data.	Yes, however this will occur when the enrichment process will be available and in a step based approach.
How is it possibile to view the ESMP report? I don’t find the same table in my profile	On the top row --> Products Management Service --> Dynamic Product Reports there you should have access to the ESMP report

Question	Reply
how long does it take to have data from XEVMPD. I see a product with data coming from SIAMED, the submission in XEVMPD was yesterday: the EV codes are not present this morning . Is is normal?	Data are loaded almost in real time. Depending on the XEVMPD queue generated this might take longer. If data are not yet available please report it in Service Now as incident so the teams can investigate. Thank you
if applicator is co packaged item , then we considered as component for secondary package or primary package component type	Thanks for your question but this is not in the scope of the system demo. Please, raise this question via Service Now so we can reply to it.
If the EVCODE is not present, what does it mean? What should the MAH do?	There is a bug for some products on the match and merge. That means that we have not been able to merge the product with SIAMED (the one you see) with the records from XEVMPD. We are working on this issue and we will solve it during Q3.
Is it necessary to request access to PMS UI in order to view the reports in PMS?	If you want to access the Public report (https://plm-portal.ema.europa.eu/medicinalproductsall/) this is publicly available and no need to register in IAM. If you aim to access your products data dynamics reports with confidential information then the registration is required.
Is it normal that as MAH with NAPs, we cannot access to PLM PUI yet as our products haven't been migrated yet ?	Yes, this is correct. Non Centrally authorised products will be made available in July 2024.
Marketing Status data for CAPs is now available on the UI. Data Quality issues are also found i.e. not aligned with the data on the IRIS portal. Should MAHs do anything about it?	As explained during the PMS demo we are aware of this issue and we are already discussing this topic.
RITM0130496 is the ticket related to UoP and RITM0113804 is the ticket related to pack size discrepancy in PLM/PMS	Thank you, the team will investigate on both tickets raised.
The EV codes are not presented for LI/NO/IS: is it normal ?only EU have been migrated ?	Correct, only EU records are migrated from the moment from XEVMPD. Moreover, during Q3 we will update Chapter 7 as we will not migrate LI, NO and IS records. In PMS, only one record for the CAPs will be present.
The MP Authorisation Status is found to be wrong for multiple CAP products. Is the fix identified and implemented already, if not, what is the current status on this?	PMS team is aware of this issue and we are looking to fix it in production in Q3 2024.
There is currently an issue in displaying in the UI certain data that are present in the XML export ('additional monitoring' for example). When can we expect this to be fixed?	We are working on bug fixes continuously.
We've seen Marketing Status Dates visible in the PUI - Where are the dates migrated from? They don't appear in the Chapter 7 migration guide.	They are coming from IRIS. As explained during the PMS demo we are aware of this issue and we are already discussing this topic.
Will it be possible in future to download data, preferably as excel?	It is already possible to discuss lot of data in Excel format.

Electronic Product Information (ePI)

Question	Reply
Which PMS data will be ingested by ePI ? Is there any plan for a E2E PMS-ePI data pilot ?	As a first step, we will link ePI documents to products in PMS (PMS ID), and we expect to start to work on enabling this towards the end of the year.
When will the import-function for word-documents be available? This is an absolute important functionality for many pharmaceutical companies!	It is not currently planned to develop import for Word.
Are there any documents specifically important for MAH here?	You may wish to browse the ePI guidance section of the PLM portal.
Are there any systems available or in pipeline to prepare ePI xml to upload via FHIR? Will there be a EMA freeware?	There is an editor in the PLM portal that can be used to create ePI. It has been successfully used in the almost-completed pilot.
How do I have to prepare the WORD PI in order to be able to import it to the MVP as FHIR? Will there be detailed guidance for this necessary modification of the WORD document?	If you are working with Word as a starting point, the preferred option would be to create your ePI using the editor. Companies who have their PI in structured documentation systems could make the necessary changes guided by the FHIR IG to export to the ePI FHIR format. Another option could be to use a vendor to generate the FHIR ePI. We expect there to be additional options as the EU ePI standard goes live and becomes adopted.
The most important question for us remains: How can we convert our Word files into the FHIRE standard?	Conversion from Word may be an option offered on the market in future. Alternatively, the editor at the PLM portal can be used to create ePI, which can then be submitted/exported as FHIR.

Regulatory Procedure Management (RPM)

Question	Reply
Who will be the MAH contact point for NAPs?	*Question answered verbally during the demo.*
Will EMA take the contact from the cover letter / eAF as the contact person for non-CAP procedures?	*Question answered verbally during the demo.*
to know the Admin of your organisation, where do I need ask for?	*Question answered verbally during the demo.*
Will EMA's certification of medical product process also go to IRIS / RPM? Or will we continue to request the certificate via email and also receiving the certificate via email?	*Question answered verbally during the demo.*
Can the IRIS administrator grant access to closed submissions to new contact person, in case there was a different contact person registered at the time of submission?	Currently, there is not a possibility to change the contact person once a case is closed. What can be done is to add a new contact as "IRIS Industry Coordinator". However this role will give access to all ongoing/closed submissions from the organisation.
When will this demo be available to rewatch as a recording? How long does it normally take?	*Moved to plenary room and answered there.*