SPOR & XEVMPD status update webinar – Questions and Answers

Date: 09/07/2025

Location: Online, 10:00 - 12:30 Amsterdam time (CEST)

Disclaimer

This **document contains a direct record** only of questions asked & answered **in writing** through Slido.com during the webinar. The **most voted questions were answered orally** – please find the **recording of the Q&A session here**. In principle this document will not be updated. The responses represent the expert view of the SPOR team at the time of the webinar and are not official statements by the European Medicines Agency nor its partners.

#	Category	Question	Reply
1	OMS	I am not sure I understand whether the change in OMS business rules implies a revision of the choice of reference systems on which the Address Doctor automatic processing is based. It poses major consistency issues between the legal requirements for accurate addresses and the contents of OMS.	Unlike "small" changes to the OMS Business rules the choice of reference sources such as National Business Registry and specifically Address doctor has data quality/policy and also system/cost implications and therefore would be one that requires significant consultation and Network escalation (NDSG/MB, HMA). We do not envisage that to happen soon.
2	OMS	OMS not having totally sync with other EMA system is a blocker currently for PMS data verification and remediation, web eAF testing and usage, IRIS PSUSA submission error.	Thank you for your comment. The roots causes might be different on a case by case basis and depending of the supported application. The involved teams are working on it.
3	OMS, PMS	When EMA plans to release the annex to Chapter II, which defines the LOC-ID to be used for each Regulatory Authority for the enrichment of MBOs?	There is already a question for this topic. So archiving this question.
4	PMS	Do you really expect to map ALL NCA data by the end of 2025 (I don't think it is feasible at package level, do you mean at Product level + for critical substance list medicines only?)	the mapping focuses on medicinal products on the Union List of critical Medicinal products and the intention is to map at product and package level. We understand the success of package level mapping depends on whether Industry have created all packages or not and we will be liaising with NCAs on issues we encounter.
5	PMS	During the enrichment process regarding manufacturers, do we have to include only the manufacturers and functions reflected in section 32p31 of module 3 or do we also have to	Please refer to EU IG Chapter 3 Link : https://www.ema.europa.eu/en/documents/other/process-electronic-submission-medicinal-product-information-chapter-3_en.pdf pag 13 (6th paragraph).

		include the active substance manufacturers? Thank you	
6	PMS	Enrichment for pack sizes and MBOs: PMS API is not yet delivered and review of manufacturing activity is still pending from EMA. Since these are pending, whether EMA will change the existing dec 2025 deadlines for PMS enrichment process?	This is a duplicate question. We will reply verbally to the same top voted question.
7	PMS	For Non-CAPs, both conc(required) & presentation strength(not required) are present under PHP. Our understanding is that only one type of strength either conc or presentation strength should be included. Is this known issue (unable to find in FAQ) or should we raise ticket to remove prsnt strength?	Please refer to EU IG Chapter 8 from page 32 onwards. Link: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-service-pms-implementation-international-organization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-8_en.pdf In this document and in Chapter 2 you can see that depending on the type of products the presentation and/or concentration strength might be required to be structured at PhP level. Please note that the edit functionality does not yet allow to structure such data. At the moment this information is loaded from XEVMPD ref. Ch 7. Please check first if the product data between XEVMPD and PMS are aligned.
8	PMS	Full product name requirement in IG chap 2 and in EV chap3.II are inconsistent. Please, ensure the requirement on 1:1 field EV to PMS are same. Thanks	PMS has more name part elements in comparison to XEVMPD. In Ch 7 you can find which xevmpd name parts are aligned and mapped to PMS name parts, however several are still empty because there is no 1:1 match with PMS.
9	PMS	Given all these technical delays with the portal, will the EMA be push the current deadline of December 2025? i.e. PMS portal unable to pull the current data to submit even after pressing the refresh button. Validation always fails.	That question is already in slido. We will reply to this one in the Q&A.
10	PMS	How MAHs can keep track of recent PMS system changes—both in product data (With respect to own products data) and system functionality wise.	You are welcome to join the quarterly System Demo hosted to keep users up to date on the progresses of the EMA projects including PMS. We hosted the last SD in June and in September we will host the Q3 2025 SD. Link: https://www.ema.europa.eu/en/events/upcoming-events Link to Q2 2025 SD: https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2025 In addition you can subscribe to PLM Newsletter and register to PMS Q&A clinics.

11	PMS	Is it mandatory to send Medical Device Manufacturers and MBOs until the end of 2025?	Please refer to Chapter 3 page 13 https://www.ema.europa.eu/en/documents/other/process-electronic-submission-medicinal-product-information-chapter-3_en.pdf here you can find information on what is required.
12	PMS	Is it possible to publish a one slider on how to update/enrich PMS data? While following video presentations, it is not possible to conduct the steps shown.	Please refer to the PUI Navigation guide:https://plm-portal.ema.europa.eu/Guidance/article/KA-01048/en-us/ for the step by step guide.
13	PMS	Is needed to sent Medical Devices Manufacturers to PMS until Dec2025?	Please refer to Chapter 3 page 13 https://www.ema.europa.eu/en/documents/other/process-electronic-submission-medicinal-product-information-chapter-3_en.pdf here you can find information on what is required.
14	PMS	Non-CAPS: We have products with two different authorised pharmaceutical forms. Both authorised pharmaceutical forms are included in XEVMPD, but only one is displayed in PMS — the second one is missing. Should we contact ServiceNow, or will this be automatically corrected by EMA?	PUI does not receive the second authorised dose form because IRIS does not have such functionality. PUI and IRIS DV teams will work over this Q3 to implement the functionality and align products data.
15	PMS	Just confirm MAHs only need to perform data enrichments for products on Critical Medicines List by end of this year?	Yes, as mentioned in several events and communications including PMS info day session 4 slides. Link: https://www.ema.europa.eu/en/events/product-management-service-pms-information-day-2025
16	PMS	PMS API - what is the request limit per client? I am getting too many requests error.	Thank for this question however to provide you the most complete answers we need the technical team. Also if you are experiencing issues please open a SNOW incident ticket type reporting as much details as possible. PMS read API is available in production since July 2024 and has no limit as long as users are registered.
17	PMS	SmPC/ Section Excipients with known effect: Due to authority request an Excipient (Sorbitol) is listed which is contained in another excipient (Maltitol liquid). Sorbitol itself is not part of the composition (only Maltitol), but appears in PMS in composition. Can this be changed (delete Sorbitol)?	This is a specific question for a specific product. Not in the scope of this session. Please, open a ticket in Service Now so we can check the specific scenario. Thanks.
18	PMS	There are 2 documents PMS FAQ and PMS Q and A but currently I can no longer see PMS Q and A document on PLM portal. Is this an issue?	Please refer to the PMS FAQ for most up to date questions and answers on PMS: https://www.ema.europa.eu/en/documents/other/product-management-service-pms-frequently-asked-questions-faqs_en.pdf

19	PMS	There is disparity in Ch.3 and Ch.2 IDMP defniton for Confidentiality indicator. Chapter 2 says only one MBO type "Manufacturer responsible for batch certification" is public. Chapter 3 says two MBO types " Batch Releaser" and "Manufacturer of the biological active substance" is public. Clarify.	Only batch release MBO RMS term is public. This will be corrected in Ch 3. Thanks for your message.
20	PMS	Under the PMS Current Operating Model, following PMS data enrichment, if data in the scope of the PMS enrichment (manufacturers, pack size) are impacted by a CMC change, MAHs should maintain PMS data via PUI, soon API. When will the eAF structured data be available to submit manufacturers data?	Thank you for this valid question. However the timelines to introduce the eAF structured changes can only be agreed and announced by eAF team not PMS. We kindly advise you to submit this question to the eAF team via SNOW ticket.
21	PMS	When will the discrepancies regarding certificate data between Chapter II and Chapter III be aligned or clarified?	Can you please clarify which discrepancies?
22	RMS	At the last SPOR status update you mentioned the possibility of an RMS pilot to help NCAs map to RMS lists. Is this not in scope anymore?	Due to other priorities we cannot offer this service at the moment for all NCAs. Please contact us (HoS: Isabel.chicharo@ema.europa.eu) to see if/what we can do to help with any specific mapping.
23	RMS	Do the corrections/updates for UCUM terms also lead to changes of the UCUM list that is used in EudraVigilance for ICSR submissions? This UCUM list is published separately as excel file on the EMA website under the Eudravigilance EU Implementation Guidance section.	The RMS team only maintains the data (including UCUM codes) within the RMS list and it doesn´t maintain any data outside of SPOR. Therefore, these updates did not result in changes of the UCUM list used in Eudravigilance.
24	SMS	By when will we have to change the invalid substances and duplicates in our systems? Will this cause variations if there are text updates/changes necessary?	There are currently no estimated timelines for addressing the SVG 0 Invalids. The SVG flag 0 Duplicates will not be addressed before 2026 and the Invalids will only be started afterwards. For both Duplicates and Invalids, the exercise only impact substance and product records. No changes on labelling are deemed required for now
25	SMS	Creating an API for a Master data solution to synchronize sms data. Is it recomendable? And then feeding RIM?	You can connect to the already available SMS API, which allows access to all public substance data in SMS. Further details are available in the SMS Guidance, section 4.3
26	SMS	Replacement of Substances (from Flag 0 to Flag 1) that needs to be taken care from MAH's doesn't have any specific deadlines set by EMA but mentioned by end 2025, can we have some clarity on this? Also, please can you let me know	I heard now, this is paused, how many days/months/years... but still MAH's need to carry out the cleansing right? Also, please answer question about variations ..

		if MAH's need to create variations in order to capture these changes?	
27	SMS	There is no defined timeline of sms list updates. We have to regularly check the SMS list on regular basis. Is it possible to change SMS list (current) to a monthly update so that MAH's also check it only on monthly basis? Right now changes are being on any dates within the SMS list.	The SMS export available in the SPOR portal is automatically updated on the daily basis. It contains all public substances and substance names available in SMS. Currently, there are no plans to create a separate export containing only the changes performed in the previous month. The best way to monitor this delta would be by connecting to the SMS API instead of using the SMS export
28	SMS	When fungus and fungi will be formally examined by the substance validation group?	This data cleasing exercise is expected to be completed within Q3
29	SPOR	Can you share youtube channel link	Please find the link to EMA's youtube channel: https://www.youtube.com/@emainfo/playlists
30	SPOR, PMS	Are you able to share a link to the PMS newsletter that was mentioned earlier in the presentation?	In the event webpage you can access the presentation and all links: https://www.ema.europa.eu/en/events/spor-xevmpd-status-update-webinar-1 Including the newsletter subscription:https://ec.europa.eu/newsroom/ema/user-subscriptions/3638/create
31	XEVMPD/ Art. 57	If we change fully to use M3 document instead of SmPC for active substance and excipients will this be in accepted also in the future when future IDMP steps are implemented?	One of the reasons why we accepted composition to be submitted as per Module 3 is because this is IDMP compliant.
32	XEVMPD/ Art. 57	Is that correct that the information on composition should be populated based on Mod. 3 Dossier and not SmPC?	As explained verbally and as stated in the latest version of Chapter 3.II: XEVPRM user guidance, the composition can be submitted either as it is stated in the SmPC OR as it is stated in Module 3
33	XEVMPD/ Art. 57	Is there a date agreed for decommissioning of XEVMPD, as the parallel feeding of 2 databases and related match and merge issues is highly time consuming, confusing and unpractical? Also SNOW tickets to solve issues last long and do not solve the problems in many cases.	No specific date has been agreed yet, this will be communicated in due course
34	XEVMPD/ Art. 57	Regarding German standard authorisations and their composition: We do not have a SmPC or module 3 dossier for this special products. How can entries in xEVMPD be validated without such documents available? Should	Yes, you can, providing that these documents can support the validation of the information that you submitted for that product in the XEVMPD (i.e. the document references the information submitted in the XEVMPD)

		we provide German standard authorisation texts then?	
35	XEVMPD/ Art. 57	Will upgraded UI will also need upgrades in MAH's RIMS gateway for xEVMPD submission?	The XEVMPD UI upgrade will have no effect on Gateway submissions from Gateway users. The submission rules or XEVPRM schema are not changing. Only the user interface that is used for submissions by WebTrader users will be updated
36	XEVMPD/ Art. 57	How/where can we see if a substance is Flag 0 or Flag 1?	You can check the SMS portal and the list of current and non-current substances https://spor.ema.europa.eu/smswi/#/
37	xEVMPD/Art.57	There is some issues logging into EVWeb/ Export download in terms of Active xcontrol elements.Is this a known issue?	There are issues, especially after upgrade to Windows 11 when the provided workarounds stop working. You must continue to use ActiveX and IE tab extension to access the current XEVMPD user interface (EVWEB) and the Bulk Update and Bulk Export tools. If you experience technical issues accessing either of those, please submit a ticket via ServiceNow, with detailed description and supporting
38	xEVMPD/Art.57, PMS	You are changing element data substance reference for xevmpd as per M3. How will this reflect allready submiltted products? What MAH should do?	If you referenced your AMPs the composition as it is in the SmPC and you attached the SmPC to the product entry, the validation of the data was performed on that data. If you wish to update the composition so that the composition is reflected as it is in Module 3, you can do so by performing an UPDATE of the AMP and attaching the extract from Module 3. The product information following such update will be validated in due course. It is up to you to decide if you wish to perform this update, the EMA accepts both