SPOR & XEVMPD status update webinar – Questions and Answers

Date: 28/01/2026

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

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	Export of OMS in the SPOR Portal seems not to be working. Any update on this?	We are working towards have them back at the end of this quarter.
2	OMS	Could you please clarify the process within the SPOR platform for a distributor to upload the updated regulatory documents (such as GDP Certificates or WDA) for an entity to which it's user is linked with a Super User Role?	If you are trying to update an OMS record, please use the Service Desk forms (OMS change request) and attached the referent document.
3	OMS	Is it possible to already request organisation "alternative names"?	Yes, please use Service Desk > Request OMS Service form to do so.
4	OMS	Will it be possible at some point to have relationship between organisation available? (HQ, Affiliate, etc)	This has not been planned as some of those details may be confidential and may change from procedure to procedure.
5	OMS	Are there some criteria for companies in order to be able to register in OMS, or any kind of company could do this?	Yes, OMS manages legal entities that are registered with the local authorities and are needed to certain regulatory procedures. Any user can propose a change to our OMS dictionary. The requirements if a company must be registered in OMS are stablished by different regulatory procedures.
6	OMS	What measures could be taken against a company that has registered with the OMS (being associated with an EudraGMDP Number) but is neither an authorised manufacturer, importer nor wholesaler of medicines, so misleading their customers?	The EudraGMDP number presented in OMS it refers to an internal key, meaning when we created OMS dictionary we used EudraGMDP as one of the sources to help us building our dictionary and this is where that key comes from - there is no relationship between the presence of this key in OMS and the existence of a valid certificate. The existence of a valid certificate need to be verified using EudraGMDP database.

7	OMS	Which are the controlled vocabularies used by OMS? Do you mean the CV's used for XEVMPD & SPOR until now?	No, controlled vocabulary mentioned today refers to a document stating the definition of the categories used in the OMS dictionary - this document is available in our OMS portal.
8	PMS	Could you please explain that information about inactive CROs must be provided and that enrichment is required?	replied live - duplicate ueston -- inactive CRO are not needed in PMS
9	PMS	When will the functionality for product to be entered into SPOR/ OMS be effective instead of manually creating it into EV production?	Timelines are not yet available. This depends on the plan to decommission XEVMPD and re-point all consuming systems to PMS.
10	PMS	For the manufacturer enrichment via PMS API when the same MBO is defined for different Substances (with potentially different start dates), shall we submit both? Or only one (i.e. with earliest date)?	You can submit only one MBO as the relationship between MBO and substances is not yet implemented.
11	PMS	PMS MBO enrichment: as importation site is not mandatory in dossier anymore should we exclude this manufacturing operation during MBO enrichment in PMS even if it is mentioned in some dossiers? Or should we follow submission as approved?	We are discussing this aspect with eAF team. In principle any product data which is authorised shall be reported in PMS. We will update PMS FAQ document with clearer information.
12	PMS	PMS MBO enrichment: how to deal with "older" CRO sites that are listed in our MA dossiers but no longer exist and are not registered in OMS? Do we have to register these sites in OMS? How to prove their existence? Question also asked during Q&A clinic on PMS on 13.01.2026, but still is unsolved.	Please note that inactive CRO data are not required in PMS.
13	PMS	PMS- Where can one apply for the PMS SME group?	If you are an Industry representative, via your Industry Trade Organisation. If you are from the Network, via HMA and network portfolio group.
14	PMS	Changes done in OMS are not reflected in PMS. PUI, Dynamic Reports, and XML extract displays a manufacturer in different ways, which is confusing.	Changes to OMS product data submitted to XEVMPD reflects in PMS API. If you access PMS API you will notice that the LOC ID and ORG name are correct according to OMS and EV data due to the data mapping performed. However due to defect in OMS data synch at IRIS level these information may result outdated in PMS PUI. It is intention of EMA to fix this multi-system issue automatically however since discussions are ongoing on the best strategy to follow, for the moment users can open snow tickets so PMS data stewards can investigate and request any eventual data fix in IRIS accordingly.
15	PMS	When will PUI be fixed to display Manufacturer and MBO records of a "[MERGED]" site?	This is not a PMS issue. The issue is caused by IRIS data sync not taking the updated OMS record. Please open a ticket listing the products impacted so they can manually fix it in IRIS.

16	PMS	The EU IG chapter 8 in not updated as per chapter 2, when will this document be updated ?	The PMS SME group is working on the update. Publication timelines are not available at the moment.
17	PMS	We are currently in the process of updating PMS with MBOs. However, we have issues with the PUI and the dynamic reports not showing up the MBOs despite the XML output has all the manually entered/enriched MBOs.	Please note that usually there is a delay to sync MBO to IRIS and then to PUI. To properly investigate we kindly ask you to submit a SNOW ticket.
18	PMS	We have recently added UK product records due to requirements from MHRA to report UK QPPV and UK location of PSMF. Please confirm these records are out of scope for QPPVs associated with virtual affiliates.	Please note that it is no longer technically possible to reference a VA linked QPPV in any AMP in the XEVMPD. If your product references such QPPV, when you are performing your next update of the product information, you will receive a negative ACK asking you to reference HQ of affiliate associate QPPV Code
19	PMS	What does " PMS Public API" mean?	Application programming Interface ref. https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services#eu-idmp-implementation-guide-12045
20	PMS	When will Latest MedDRA versions be updated in PMS?	MedDra list is updated in RMS. PMS reads SOR and XEVMPD data.
21	PMS	When there are discrepancies between XEVMPD and PMS, where do we need to submit our ticket for correction? If we have a big amount of corrections to establish, is there a way to group all of them in one request?	You can submit an Incident ticket type assigned to PMS via EMA Service Desk. If you have more products data impacted, you can attach a file listing all issues, PMS ID, EV codes, MAH data, MA NR.
22	PMS	When will PMS be mandatory?	The data submission of non cap MBO and pack size data is already mandatory based on Ch 2 rules ref.https://plm-portal.ema.europa.eu/Guidance/article/KA-01134/en-us/
23	PMS	Where can the news about the call for PMS SMEs open till 31st January be found?	If you are representing Industry, via your Industry Trade Organisation. If you are from the Network, via HMA and Network portfolio group.
24	RMS	Is is mandatory to incorporate EDQM terminology list in Safety Database for safety case (ICSR) processing whenever this list is updated?	EDQM is mandatory for ICSR submissions, for the field dosage form and route of administration. The RMS list should be updated weekly over the weekend and on the Monday the EDQM terms should be available for use in EV.
25	RMS	Related to EDQM terminology: is it possible to receive a notification whenever the lists are updated?	Unfortunately, the Subscription functionality is not available anymore. Our suggestion is that you do an "Advanced Search" in RMS, that you select the relevant lists and that you specify a date range to see what terms have been updated during that time interval.

26	SMS	Can you please let us know what actions are to be taken from MAH as per new updates w.r.t SSG1?	The general recommendation also applies for SSG1: avoid substances with SVG flag 0 and, if possible, refer to substance records with SVG flag 1.
27	SMS	For a medicinal product including 2 active substances, could we consider in sms list only one single SMS ID including both active substances. It will ease the identification of the product in IRIS	SMS is a list of substances, not products. Combinations of two active substances are considered invalid substances and will not be registered in SMS. This information will be kept at product record level in each relevant system (e.g. IRIS, XEVMPD/PMS, UPD, etc.)
28	SMS	Is the SVG flag correction exercise also in UPD? You only mentioned PMS and XEVMPD.	"SSG1 - solutions" are almost exclusively used as excipients. Since UPD only has active substances, the impacts of the SSG1 recleansing exercise on veterinary products are expected to be very low or even zero
29	SMS	When we have Ph.Eur mismatch in substance comment, what action needs to be taken?	These substance records should be used with caution. Further information is available on the SMS Guidance, section 8.3 Data Cleansing - Scenario 3.
30	SMS	When will the SMS cleansing (duplicates; SVG Flag 0) be implemented in XEVMPD?	There is no defined timeline at the moment.
31	SMS	Why are some substances translations not added in SMS, in case if the correct substances in SVG0 and duplicate SUB is provided? However, substance translation is not avaliable even we have requested the substance translation via Service Desk.	Some translations/aliases are considered redundant to already registered substance names (e.g. just differ by an extra space or additional special characters), so they are not registered. Also, if the translation contains unnecessary levels of granularly, they might also not be registered.
32	SPOR	Do we need to register distributors?	The answer to this question it depends on where do you need to use the distributors details *e.g. Q: do you need an EudraGMDP document or for PMS? A: yes, data needs to be registered in OMS.*
33	SPOR	Please define non-EMA Users (referring to slide 41). Does a Company as MAH as non-EMA User? Is a EMA-User someone from EMA?	EMA users = EMA staff registered under EMA HQ ID. Non-EMA users = MAH, sponsor, NCA users registered under their MAH, sponsor, NCA organisation profiles.
34	XEVMPD	Can you access all the substances in EVWEB tool?	All substances records with domain "Human use" are available via EVWEB. The only substance records not available as the ones with "Veterinary use", since they are not relevant for activities in Eudravigilance/XEVMPD. However, in IRIS, it is possible to see substances from both domains.
35	XEVMPD	For XEVMPD submission of a medicinal product including 2 active substances, could we consider one single EV code assigned for both active substances to ease the identification of the product?	If the pharmaceutical product has 2 active substances, then the product will reference 2 substances, where each substance has its own substance EV Code assigned.

36	XEVMPD	From this Monday 26/01, the XEVMPD database seems unable to download or upload XMLs, can we have an update regarding the issue?	A similar question was already answered live, we are aware of the issue and in the process of fixing the root cause of the issue. Downtime is planned for production and XCOMP for Saturday.
37	XEVMPD	From which date the new EVWEB interface will be available? The current one is not working fine anymore.	We will make this new UI available in February.
38	XEVMPD	How/where can an "additional QPPV" add his/her 24/7 number?	In your 'Manage your contact details'/'Manage your profile' in the EudraVigilance restricted area.
39	XEVMPD	The phone number added on the 'Manage your contact details' for an additional QPPV is automatically an additional 24/7 number, even if it is not named as such?	In "Manage your Profile" only the main QPPV number can be added currently. There is no possibility to add for additional QPPVs a number.
40	XEVMPD	If a add a Virtual Affiliate to my HQ. Will i be able to retrieve the PSMF EV Code and QPPV EV code created by the VA's HQ	Yes; data submitted in the XEVMPD from an affiliate profile is always owned in the XEVMPD by the HQ profile. Affiliates never own any data in XEVMPD
41	XEVMPD	if we have already the xEVMPD certificate, do we need to do the training again for the new interface?	No, the interface is not gonna change drastically. The same functionality and buttons will appear, so no need to be re-trained.
42	XEVMPD	Is it necessary to complete a new training certificate for the use of the new XEVMPD web interface?	No, it is not.
43	XEVMPD	Is it possible to have all AMP data of an MAH & affiliates provided, before the bulk download is available?	The Bulk Update tool allows users to download information for all products owned in the XEVMPD by the MAH's HQ organisation. Affiliates do not own any data in the XEVMPD, they can submit data, but the data is always owned in the XEVMPD by the HQ organisation, under which they are registered in EV.
44	XEVMPD	Is there any deadline to submit pack size for non-CAPs to XEVMPD (which are not included in ULCM list)?	30.06.2027
45	XEVMPD	Is there any plans to add a "Save" fonctionnality in XEVMPD?	No, there is no plan to include this functionality for the moment.
46	XEVMPD	Our QPPV is HQ profile. The product records in XEVMPD are created and maintained via virtual affilate profiles. Is this acceptable? Or would the product data in XEVMP also need to be maintained via HQ profile?	Yes, this is acceptable. You can maintain the data via a VA, the data is owned in the XEVMPD by the HQ and references the QPPV linked to the HQ or regular affiliate.
47	XEVMPD	Please clarify if Gateway users can submit to Xevmpd as usual and that it is not affected by the new UI?	The new UI has no impact on gateway users submissions.
48	XEVMPD	Recently EMA announced a change of transfer protocoll from http to https für ICSRs and ACKs. Does this change affect ACKs (1st, 2nd Level or 3rd ACKs) we receive for xEVPRMs?	This change will have no impact on XEVMPD submissions.

49	XEVMPD	Recently there is an update for ULCM medicines where each pack size should have separate EV code and it was mentioned as for all the products also this should be followed. Is this a requirement to follow for all the products?	It is a recommendation to submit one product report per pack size. See Annex in Chapter 3.II for related information.
50	XEVMPD	Regarding 3rd Level Acknowledgement, is it mandatory to archive this ACK for Compliance purpose?	It is not needed. These AcK can be retreived in the user interface.
51	XEVMPD	There's a product that has valid-trasbferred MA AS This product has been transferred again can we perform the invalidation with the reakted submission status and after the insert with the reakted status with the new holder?	If the product references a 'valid-transferred MA status' and the MA is transferred to another MAH (different HQ), then the old MAH invalidates the product (referencing 'not valid due to MA transfer' MA status) and the new MAH enters it as new, referencing 'Valid - Transferred MA' status.
52	XEVMPD	What is the difference between 3rd acknowledgements and Valid Versions visible in EVWEB as information and date validated are always different. Also, suggest which one we should refer to update our database?	You should always user the latest validated version of your AMP to update the data in your internal database.
53	XEVMPD	When will became use MedDRA Preferred Terms mandatory?	It is not a mandatory action. MAHs are allowed to submit PT instead of LLT in case they want.
54	XEVMPD	Will the EMA does update the PTs based on the current LLTs available for the existing data?	No, MAHs are responsible for this update whenever and if they want to do it.
55	XEVMPD	Will the new UI be applicable for for all activites done in EVWeb, including ISCR submissions?	The EVWEB for submissions of ICSRs and the XEVMPD user interface will remain separate UIs, as it is now. They will not be combined together.
56	XEVMPD	Will there be any new data fields in XEVMPD, or will all future data enrichments go into PMS?	There is currently no plan to include new data fields in XEVMPD.
57	XEVMPD	How should we register DMPs that are prepared in a hospital in accordance with a magistral formula or pharmacopoeial prescriptions? Do we need to enter them into the XEVMPD, if they are compendial, but non-authorised (e.g. DMP is administered together with a non-marketed compendial product)?	If this type of product is not authorised and it will be used in a clinical trial, then you must enter the product information in the XEVMPD as a DMP, so you can register the clinical trial for this product
58	XEVMPD	How should we enter a combinational DMP which consists of 2 or more separate products (with different API)? In case of a multiple pharm. products submission in 1 message, what's the difference between the submission of a combinational DMP and of totally different DMPs entered in 1 message?	If the product is a combination product, you should insert 1 DMP referencing 2 pharmaceutical products in the XEVMPD. In one XEVPRM, you can insert up to 100 DMPs.

59	XEVMPD	How we should enter a DMP consists of 2 separate products: 1st contains an API, 2nd – an adjuvant: 1) as 2 pharm.products in one message or as 1 administrable pharmaceutical form nevertheless the product is physically available in two or more different pharmaceutical forms/formulations?	If it is a combination product (KIT), then 1 DMP referencing two pharmaceutical products. If it is not a combination product, then 1 DMP, each referencing the respective pharmaceutical product. See Process map 2 of https://www.ema.europa.eu/en/documents/other/guidance-electronic-submission-information-investigational-medicinal-products-human-use-extended-eudravigilance-medicinal-product-dictionary-xevmpd_en.pdf for related information
60	XEVMPD	Once the updating of AMPs referencing QPPVs associated with VA has been completed, are we expect to inform EMA, respectively (e.g. replying to the email as received from EMA on this request)?	No, it is not required to follow-up by replying to my email.
61	XEVMPD	XEVMPD: Pls kindly confirm: The usage of PTs instead of LLTs for NEW product submission to XEVMPD is currently NOT mandated. I.e. we would not receive an invalidation if we were to submit new product entries using LLTs this or next week. Thank you	If your AMPs do not reference PTs, you will not receive a negative ACK or a follow-up communication from the EMA to add the PTs
62	XEVMPD	Should all APs from VA now receive the QPPV code from HQ?	Any product submitted in the XEVMPD from a VA profile is owned in the XEVMPD by the HQ, never the affiliate (virtual or regular). You can reference in that product the QPPV registered at the HQ level or at an affiliate level (regular, not virtual).
63	XEVMPD	What is the exact date of new web UI implementation?	It is foreseen to be a date in February.
64	XEVMPD	When will XEVMPD be accessible without the Internet Explorer extension?	As soon as the new UI is live, you can access it without ActiveX and IE tab extension. You will however need to use those, if you want to use the Bulk Export/Bulk Update too (until Q3)
65	XEVMPD	Where can we find the Q&A document from the monthly clinics?	Please note that the Q&A from the monthly clinic sessions are not documented/published. It is an interactive session, questions are answered live only.
66	XEVMPD	Which MedDRA Version should be indicated? Reference to currently valid version 28.1 was changed (3rd ACK) to other versions. Change to these versions (e.g. 20.1) initiated 3rd ACKs concerning MedDRA Version for other MAs, when 20.1 was again not correct. Though evweb/PMS UIs show 20.1.	The latest version available (so 28.1). If the MedDRA Version was changed as part of the validation, please log this via the EMA Service Desk, so we can investigate.
67	XEVMPD	Will MAHs and Sponsors be required to re-take XEVMPD evaluation training if they already hold XEVMPD certificate, due to change of the interface and implementation of the XEVMPDweb?	No, there's no need for re-training. Please refer to the Article in ServiceNow for related information: https://support.ema.europa.eu/esc?id=kb_article&sysparm_article=KB0014045&table=kb_knowledge

68	XEVMPD	Will MAHs and Sponsors organizations be required to create VA profile after implementation of the new XEVMPD UI (XEVMPDweb) in same manner it was required with old (current) XEVMPD interface, when organizations have registered HQ profile for Gateway submissions?	Yes. If your HQ is registered in EV as a gateway user and you wish to use the XEVMPD user interface, then you will need to create a virtual affiliate to allow users to submit data via XEVMPDweb.
69	XEVMPD	Will the current EVweb interface still be usable in parallel with the new xEVMPDweb?	Yes, there will be a transitional period for 3 months since the go live date, where both UIs (old and new) will work. See https://support.ema.europa.eu/esc?id=kb_article&sysparm_article=KB0014045&table=kb_knowledge for further information.
70	XEVMPD	Should the MedDRA terms LLT be updated to a PT term, since EMA will only perform validation on PT terms from now on?	No dedicated update is required. You can continue to reference LLTs in your AMPs and add PTs during the next update of your AMP information. Both, LLTs and PTs can be referenced in an AMP entity.