SPOR & XEVMPD status update webinar – Questions and Answers

Date: 09/04/2025

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.

#	Question	Reply
1	Any user can access? but the needs the role permission? now getting 403 SMS role missing	Information on access to the SMS API is available in the Guidance for External Users, section 4.3: https://www.ema.europa.eu/en/documents/other/sms-guidance-external-users_en.pdf
2	Any user can access? but the needs the role permission? now getting 403 SMS role missing	If you still have access issues after following that process, please create a ticket in EMA Service Desk
3	Are all documents submitted to Article57/xEVMPD public?	No. They are not public.
4	Are MAHs required to review the data in the SMS? In the case where it is a generic product that has a well established substance that is already on the xEVMPD	Any MAH can review their products in XEVMPD for substances with SVG flag 0. However, if this is not possible/desired, then EMA will correct the impacted products accordingly
5	Could you please give more détails about the enrichment of data? What are the deadlines for ULCM products? What are the differences between pack sizes in XEVMPD and structured pack sizes in PMS?	Individual pack sizes should be submitted to XEVMPD by the end of May 2025. Manufacturers, MBOs and structured pack size data should be submitted through the product UI by the end of December 2025. A pack size is submitted through XEVMPD so it appears in the product UI. The strucutured pack size data is the structured information on the pack size that is expressed as a number and a unit of presentation (e.g 10 tablet or 2 vial)
6	Could you please provide more info reg. medicinal products in PMS with an Auth. status of Surrendered? They have no xEVMPD entries, as they were withdrawn prior to Article 57 requirement(2012). Although the status can be filtered in PUI, it doesn't appear in the dynamic report.	These are CAPs that were withdrawn before XEVMPD requirement. There is no need to do anything with these products but they are in the system as we migrated all products from XEVMPD and SIAMED.
7	Could you provide link for SMS guidance?	The SMS guidance is available in the SPOR Portal, in the tab SMS (no login required). The direct link to the guidance is here.

8	Do we need to remove and add SVG flag zero substance in article 57?	If you are the MAH, then you can do it, if you want to do so. Otherwise, EMA will do it in your behalf, if any of your products are linked to substances with SVG flag 0. The timelines of this exercise will be communicated well in advance
9	Do you recommend invalidating an organization location in OMS even if there are still products linked to it in the XEVMPD? Those affected products can be updated to the new location independently of the info in the SmPC?	Excellent question - An extension for me: if we invalidate a location in OMS, what happens to a open Variation which is under assessment with EMA
10	Does a change in the label of an investigational medicinal product (change in the manufacturer's name) require a change in the authorization to be submitted ?	We do not keep information related to manufacturers in the XEVMPD
11	Does the "My Workspace" include the CRs of specific user only in the PLM portal?	You can see all the CRs from users of your company (the ones related to your products)
12	EMA claims that data upload from xEVMPD to PMS is in real-time, but this is definitely not the case. We don't find the record even after one month after xEVMPD submissions. Can EMA please comment on this?	EMA has stated that XEVMPD to PMS updates are performed based on a queue of messages that should be processed, but the updates should be reflected in the PMS within a couple of hours. From the PMS API to the Product UI, updates might take a couple of hours more. Nevertheless, the fact that MAHs are not able to find the product doesn't mean that changes are not processed. The issue might be on a mapping issue with OMS, or with a missing authorised dose form as explained in the PMS Q&A document that prevent the product to be seen in the UI. Please, open a ticket with the EV code and additional information so we can investigate the issue.
13	For a centralised authorised product, is it possible to submit a variation using a web eaf immediately after EU approval without doing first the submission of data in XEVMPD?	Not ideally, data coming from XEVMPD is needed in the eAF.
14	For PV Fees, please can you confirm if PV fees Advance Notice will be received for a MAH that is based in the UK but has a product on the xEVMPD in (Northern Ireland).	Please submit a query to the PV Fee colleagues using the dedicated form to receive the answer to this question
15	For the XXX product, initially authorized under MAH-ABC on 16/04/2021 and transferred to MAH-XYZ on 18/05/2022, which authorization date should MAH-XYZ use for the xEVMPD entry, and should MAH-XYZ update the authorization date in section 9 of the SmPC to 18/05/2022 or keep it as 16/04/2021?	The date of the initial authorisation should be referenced in the 'Authorisation/Renewal date' providing the the initial MA was not renewed (but only transferred to a new MAH)
16	Have national authorities set a deadline for their PMS/xEVMPD cleansing ? Can their progress be communicated by the EMA in a common publication (spor quarterly webinar) ? Ex Some authorities have started to ask the addition of national numbers in xEVMPD...	EMA is helping some NCAs with the data mapping between PMS and their national databases. We will try to include additional information on the next SPOR webinar. For the moment, there is no specific deadline for this exercise, but EMA is committed to finish the support exercise by the end of the year so NCAs have most of the data mapped at the same time MAHs need to provide enrichment for ULCM products.
17	How long does it take for EMA to solve an issue in PMS? We did timely xEVMPD submissions following an initial MA approval, but the record is not visible in PMS even after a month. We need this	We try to resolve the tickets opened in PMS within the SLAs stablished. Nevertheless, some tickets are taken longer than the SLAs. Please, comment on the ticket so we can pick it up. Otherwise, you might need to use

	info. to submit an urgent type II variation - a ticket already raised, but no progress.	the PDF eAF if the issue is not solved before you need to submit the variation. Sorry for the inconvenience.
18	If a company AAA had bought a product and all the MAH transfer was done but the MA was transferred yet again to company BBB. Is the company BBB responsible for maintaining data for entire lifetime of the product in xEVMPD? Or only from the moment the MA was transferred to her?	If company AAA and BBB are two different legal entities with their separate HQ profiles in EudraVigilance, the new MAH (BBB) inserts new AMP entity in the XEVMPD and is responsible for the information in that AMP entity
19	If a MAH name changes from S.A. to S.A.U. (unipersonal), should this be reported in OMS? Does this change affect MA?	Please refer to our OMS Data Quality standards where we described the conditions we outlined with the Spanish NCA on how to handle S.A. vs S.A.U. entities. If the record is updated in OMS and is now reflecting the latest version of the data we kindly ask you to refer to the system/procedure guidance on how to correctly handle those type of changes in each regulatory procedure.
20	If a product with multiple EV codes has few of its pack sizes (EV codes) withdrawn, is it normal to see these withdrawn EV codes in the EV Code field under Medicinal Product attribute in PMS PUI (the very first page that is displayed on loading a PMS ID)?	Only if they have been transferred. Withdrawn by MAH should not show the EV Codes in this way. If you have any doubt, you can open a ticket in service now so we can investigate it.
21	If I already have a product on XEVMPD, may I update the composition following Module 3 or is this only possible for new registration?	It is also possible for products that are already in XEVMPD. Make sure you update all the EV Codes belonging to the same product so there is no impact in PMS
22	If the SmPC states Macrogol and the dossier Macrogol 6000. Which one has to be selected in xEVMPD?	If you wish to submit the entire composition as per info in Module 3, then you enter Macrogol 6000. If you wish to submit the entire composition as per info in the SmPC, then you enter Macrogol.
23	If the substance/excipients is volatile (alcohol) or like water and part of the M3, but not be available in the final product. Should these also need to be part of the excipients list and to be submitted?	If data is to be provided as in M3, then, they need to be provided. If data is to be provided as in SmPC, then, no need to submit if they don't appear in SmPC. These are the rules right now for XEVMPD. We will nevertheless discuss with the SMEs how this information will have to be submitted in PMS once XEVMPD is decomissioned.
24	If there is a small change in address but the location is still the same then whet shall be done or how to handle this change in PMS and other tools?	Please, take into account that PMS is just consuming data from other systems. Therefore, you need to follow the specific steps in OMS to update the address, you need to update XEVMPD to reflect the same address, etc. PMS will just be consuming the LOC ID from OMS that is mapped to the ORG EV Code from XEVMPD, so no specific action is needed in PMS.
25	In case of mismatching data between xEVMPD and PMS in regards to pack size updates, which is the best way to reach out to PMS team to get this mismatching corrected in PMS? xEVMPD entries are the same but multiple PMS entries have been created instead of one with all pack sizes	Please, open a ticket in Service Now with all the information so we can investigate the issue. Make sure that grouping values as explained in Ch 6 of the EU are the same in XEVMPD.
26	In case of pack size update - in the SmPC the following two pack sizes are mentioned : 30, 30x1. Is it expected to submit a product record for each pack size, even though it is technically the same pack size? Material is the same but	That depends on how the specific NCA has approved the medicinal product. If the NCA has authorised them as separate pack sizes, then, different EV Codes should be provided. If they are authorised as only one pack size, then, there is no need to split it in XEVMPD.

	one is single dose blister and the other uses blisters of 10.	Please, contact your NCA to understand how these pack sizes where approved.
27	In section 9 of the SmPC, both MAHs (ABC and XYZ) currently list the authorization date as 16/04/2021. Should MAH "XYZ" update this date to 18/05/2022 or keep it as 16/04/2021?	See the provided reply to the same/similar question
28	Instances where Section 1 of SmPC includes both Medicinal Product Full Name & active moiety is mentioned separately in bracket then in that case, active moiety should also be considered with MP full name as Invented Name is already mentioned in MP Full name?	For the full presentation name, the full information in section 1 of SmPC, i.e. both Medicinal Product Full Name & active moiety in bracket, should be provided
29	If in Section 1 of SmPC, 4 different Medicinal Product Full Name are present & active moiety is mentioned separately in bracket in the end of section 1, then in that case also we have to include active moiety with each Medicinal Product Full name?	Please submit a ticket via the Service Desk and provide a copy of the SmPC, our colleagues will advise appropriately.
30	Is adding a national code to the package description mandatory and does it need a supporting document?	It is not mandatory but highly recommended. And no, there is no need to submit additional support documentation. But, we need to be able to identify the pack size so the SmPC or other document should contain the list of pack sizes.
31	Is it possible to have a substance that is being used in a CT showing in XEVMPD when registering the product with the substance sponsor code and not a PT like if it is registered in PUBCHEM?	All substance records are owned in the XEVMPD by the EMA; there is no link between the sponsor and the substance in the XEVMPD. If the substance systematic name is already publicly available in reliable external sources, then that name will be used as the substance preferred term. For further information on this topic please note section 3 (Confidentiality) and Annex 1 (Business Rules) of the SMS Guidance.
32	Is there a way to get notifications when new products are added to ULCM or are notifications published anywhere? If so, link is appreciated.	ULCM is not managed by the XEVMPD or the PMS team. Notifications and updates are provided by monitoring value stram and ESMP.
33	Manufacturer Review CAPs: What data should we maintain in our RIM? The ones in the RMS List-eaf or those in the PMS (SIAMED)?	For the moment, the manufacturers captured in SIAMED are the ones that can be seen in the Product UI and don't follow the same granularity as the eAF. There will be discussions at EMA, if CAPs should start capturing the same information and granularity as the one request for non-CAPs. For the moment, no additional information can be shared for the moment. Nevertheless, as CAP data can't be updated by MAHs, it is MAHs decision which data to capture in their RIMS.
34	Manufacturers (MBO's) needs to be submitted by 2025 via using ema provided API or via PMS UI. If software vendors don't integrate then only other way is via write PMS UI. This will be very cumbersome. IS there any way the pharma companies can do bulk upload via an excel or XML or any other way?	EMA is developing the bulk update functionality through the Product UI but there is no plan to allow bulk update through Excel or XMLs.
35	National ID is mandatory for pack size submissions?	No, as explained in Chapter 3.II it is not mandatory but highly recommended. As it will help NCAs to identify specific pack sizes and also will help MAH to identify the pack size in the Product UI when the data has to be enriched.

36	On xEVMPD for a AMP in the UK Northern Ireland, can the EU PSMF location on the xEVMPD be the MAH address which is in the UK?	If the medicinal product was authorised by the MHRA under EU law, then the location of the PSMFL must comply with EU law requirements. Therefore, EU PSMF location would be acceptable in this case
37	Just for further clarification, this is a MAH based in the UK with a UK license. Please can is ask if the PSMFL in xEVMPD can be the MAH address which is in the UK?	It is the MHRA that authorised that product. If they authorised it under EU law, they the location of the QPPV/PSMFL must comply with EU law. If under UK law, then the location of the QPPV/PSMF must comply with UK law.
38	PLM/PMS: we don't see our data sending to XEVMPD for UK (with respect to Northern Ireland - NAPS) in PMS, it is ok? Should be XI included in PMS and shortage platform? What about XI as a part of already approved CAPS?	XI products are available in PMS. So in case you are not able to see them, please, raise a ticket in service now with the EV Codes missing so we can investigate the issue. XI is already included in the EU record from XEVMPD.
39	PMS- Can consultancy raise a request for Public PMS API access? Without tie up with any MAH or NCA.	The public PMS API is not live yet, but the idea is that everybody will be able to request access to the Public API.
40	PMS: As not all of the fields have been synced over from the Art. 57 database you mentioned that there this will be fixed. When is the release date to fix the known issues?	In the PMS Q&A document you have the expected dates when each of the known issues are expected to be solved. We will be updating this document during this month with more information.
41	PMS: can I filter in PMS my products on List of critical medicines? If not, can be this funcionality created there, plese?	You can use the dynamic report in the PLM portal and filter by specific ATC Codes. Additionally, we want to work this quarter on additional reports to support this activity.
42	PMS: For non-ULCM data enrichment, Is it mandatory to do this before the end of 2026? or is this date just a guide and it is not fully mandatory	We are still discussing that internally and will confirm in the PMS Info day
43	PMS: Is it still voluntary to send data for UK (with respect to Northern Irelnad) to XEVMPD? If we decide not to send UK registrations (with respect to XI) to XEVMPD, there is no need to enrich packaging and manufacturers in PMS and shortage platform will not covers these products, is it ok?	It is optional to submit data for products approved by the MHRA for GB under GB law. If the product is authorised by the MHRA under EU law for NI, then the product information must be submitted in the Art57 database
44	PMS: Is it still voluntary to send data for UK (with respect to Northern Irelnad) to XEVMPD? If we decide not to send UK registrations (with respect to XI) to XEVMPD, there is no need to enrich packaging and manufacturers in PMS and shortage platform will not covers these products, is it ok?	If you submit a medicinal product referencing GB as the country of authorisation and Non-EU MA procedure in the Art57 on voluntary basis, you do not need to enrich the data
45	PMS: Is it still voluntary to send data for UK (with respect to Northern Irelnad) to XEVMPD? If we decide not to send UK registrations (with respect to XI) to XEVMPD, there is no need to enrich packaging and manufacturers in PMS and shortage platform will not covers these products, is it ok?	I am talking about old UK products, which were registrated for whole UK (GB + XI = UK as NP or in MRP/DCP) before Brexit and I am talking about UK products registrated this year, when MHRA stop to use "PLGB" and "XI" reg. nubers and use "PL" numbers covers XI again as well.
46	PMS: Is there a timeline for when PMS product data will become available within the Online eAF DADI application forms in the future?	PMS data is already available in the web based eAF. Not all the data, but product details such as names, MA numbers, etc are already available. eAF team is working on the structured changes to show additional information such as manufacturers but the team is still working on the timelines for this feature.
47	PMS:When are newly approved CP products available in PMS — after the	Within 2 working days after receipt of the adoption fax from the Commission, SIAMED is updated and the product will appear in PMS.

	CHMP opinion or only after the Commission decision?	
48	Regarding the pack size updates in xEVMPD, is it expected for a product with pack size e.g. 10 tablets in either Al/Al blisters or Al/PVC blisters to add two separate product records, one for 10 tablets with material Al/Al and one record for 10 tablets with material Al/PVC? Also in regards to PMS	That depends on how the NCA has approved the medicinal product. If for the NCA, these are considered different pack sizes, then, different EV Codes should be provided. Otherwise, only one EV Code is needed. Please, lease with your NCA to know how these products were authorised.
49	RMS: What is IWG, QWP, BWP, QIG mentioned in slide 24?	These are the EU Network committees consulted - Inspectors Working Party (IWG), Biologics Working Party (BWP), Quality Implementaion Group - we will update/clarify the slide and republish
50	RMS:Could you advise which terms should be used to replace the following pharmaceutical forms in XEVMPD: Gastro-resistant powder and solvent for oral suspension, Powder and solvent for solution for injection, solution for injection in pre-filled syringe	Please raise a ticket through the EMA Service Desk (https://support.ema.europa.eu/) so that we can look into this in detail. Please add supporting documentation such as product information to facilitate the assessment. Thank you.
51	RMS:Could you clarify what the impact would be if the pharmaceutical form terms marked as 'no current' are not updated in XEVMPD? We haven't taken any action yet, as it's still unclear which replacement term should be used in XEVMPD, even after raising several ServiceDesk tickets	If there is not a current replacement for the pharmaceutical form, the non-current term can still be used in XEVMPD.
52	RMS:Should we expect additional cleansing of the dosage form terms and is the clean-up process still ongoing? We have noticed some duplicates current terms in the D1 XEVMPD - RMS- EDQM pharmaceutical dose form terms mapping V2	In principle the review and cleansing of the pharmaceutical dose form list was already completed. Having said this, if you have any questions or if you spot any issues such as the duplicates that you are mentioning, please raise a ticket through the EMA Service Desk (https://support.ema.europa.eu/) so that we can look into it.
53	Separate entities are expected to be inserted into XEVMPD for all marketed pack sizes. Often the MA is granted years before the product will be launched when pack sizes to be marketed are not yet known. Is it sufficient to insert only one entity until the pack sizes to be marketed are decided?	It depends on the country of authorisation. Please, refer to the diagram at the end of Chapter 3.II where it is explained how pack sizes should be submitted depending on the authorisation country.
54	Should we expect additional flag 0 substances, and is the clean-up process still ongoing?	SMS has around 69.000 current substances and 46% are cleansed. Since there are over 30.000 substances to be cleansed, it is expected for several additional substances to get SVG flag 0.
55	SMS: Could you confirm if we don't update the products in XEVMPD regarding substance flag 0, will the EMA update them?	That is correct. Once the timelines are defined for that exercise, we will communicate them in advance. The impacted product and substance EV codes will also be shared in advance.
56	SMS: What about the according documents? Would we need to update them afterwards?	The product documentation is not required to be updated. The substance names of the future nullified substances (SVG flag 0) will be added as aliases of the respective replacement substances
57	So if we receive a 3 Ack for SVG=0 we can ignore it?	No you should process the 3rd ACK and correct the data in your system so that it doe snot overwrite XEVMPD at the next submission.
58	SPOR: would you mind explaining when / how/ if Article 57 public Database will be Adapted to SPOR?	XEVMPD will not be consuming data from SOR. The plan is to decommission XEVMPD submissions in the future and replace it by PMS submission. Therefore, XEVMPD will not be consuming data from SOR.

59	The frequency for the data updating in XEVMPD is 15 days for new data and 30 days for variations; can you clarify the planned frequency for updating new data and variations in PMS?	EMA explained that same timelines should apply to PMS as these timelines are stated in Art. 57 legislation. Therefore, as for the moment only manufacturers and structured pack size data has to be submitted to PMS, MAHs are allowed to submit new data or updates on a monthly basis.
60	The substitution of substances with SVG=0 is not mandatory, but we are receiving 3 Acks, so it is mandatory?	It is not mandatory, we are making this type of "correction" as part of our data validation, hence why the 3rd ACK
61	The XXX product, initially authorized under MAH-ABC on 16/04/2021, was transferred to MAH "XYZ" on 18/05/2022. Which authorization date should MAH "XYZ" use for the xEVMPD entry?	The initial authorisation date
62	There are several sync issues in PMS with EV: Unit of measure for numerator/denominator, incorrect generation of Presentation and concentration API strength info. And PMS export have issues too: quantity operator missing, significant 0 not available in strength info (instead 50 is 5 in the export).	All these issues are explained in the PMS Q&A document and when the expected resolution date is planned. Please, have a look at the document to know all the known issues.
63	We (MAH) are still not able to see our products in PMS, although we have all the right users. When do you expect to have this issue solved? Thank you very much!	Have you opened a ticket and have you received a reply? Depending on the issue the resolution can be done shortly or might require more time. Please, raise a ticket with the EV codes that you are missing or the Org EV Code so we can investigate the issue.
64	We have been informed xEVMPD data in PMS not synchronized as is and we could some differences, is there any update on this part and any plans how ema over come this problems?	We have seen some delays on the synchronisation of data between XEVMPD and PMS due to the amount of data we are receiving. We are investigating the issue. Additionally, we will put in place additional reports to make sure we are able to identify any issue related to this topic.
65	We have noticed errors on the PMS, where not all of the fields have been synced over from the Art. 56 database. Please can I ask if this is an ongoing task or when the EMA expect for the PMS will be fully synced up?	Please, review the PMS Q&A document to understand the known issues. Some of these fields will be fixed during this quarter like the authorised dose form.
66	Is there already an exact release date to fix the known issues. In a ticket this is promised for this quarter.	We have just started the quarter. But yes, additional information can be found in the Q&A document of PMS.
67	We have noticed some discrepancies in the units of measurement mapping to UCUM and have reported critical mapping issues through the Update Change Request (CR). We would like to understand how bulk changes can be managed in this context.	In principle users should raise one change request for each term that needs to be updated, i.e. it is not technically possible to submit one change request to update several terms as a bulk update. Having said this, please raise a ticket through the EMA Service Desk service if you haven´t done it yet, please include all the relevant details and we will look into it.
68	We received several 3°ack XEVMPD with removal of substances with SVG =0 and added the replaced one. During the previous webinar the change of SMS activity was identify as no mandatory for the time being. But the 3°ack force to perform this activity..	We update the substance information as part of our standard AMP validation. By making this change and notifying this to you via the 3rd ACK, we understand that you need to make an update in your RIM however, however, we consider this to be of beneficial for your future submissions.
69	What is the PMS ID? an automatic code generated by EMA?	Yes, the PMS ID is the ID that identifies a medicinal product. It is generated by the system as soon as the product is created.
70	What we can do with SVG flag zero substance? Do we need to update those substance in article 57 database	This is up to the Applicant. If you want to update these substances, you can do it. But for the moment there is no mandatory requirement to do so.

71	What will be the approach for SVG flag zero substance in Article 57.Do the MAH need to perform a check and update	It depends on the MAHs strategy. It is not mandatory for the moment to perform this activity. Nevertheless, if MAHs want to replace them, they can already do this in XEVMPD. Additional information can be found in Chapter 3.II of XEVMPD.
72	When will all manufacturers be obligated to have LOC-/ORG-ID?	repeated question
73	When will the known issue of changes done in OMS not reflecting in PMS will be solved?	We don't have timelines for the moment. We are working internally in the analysis of the solution to be implemented. That involves multiple teams at EMA. Once additional information is available, we will share it.
74	When will the substances and excipients with blank SVG codes be updated?	Like mentioned before, for this year we will focus on organisms (herbals,fungi,animals), human vaccines and homeopathics. The remaining substance types/groups will be addressed in the coming years
75	Where can I find a detailed list of fields that determine which fields in XEVMPD create a second PMS-ID instead of summarizing all pack sizes into one PMS-ID	Please, have a look at chapters 6 and 9 of the EU IG: 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
76	Where can the knowledge articles be found in serviceNow portal?	These are currently being developed. You will be able to perform a search on a keyword in the 'Search' panel (under How can we help?), as it is currently possible for many other articles
77	Which authorisation number should be used with the status "valid-national phase pending", if the number is still not available	You can include 'Not assigned' and then update the record with the correct number once assigned. The text "Not assigned" can be provided in this field, unless the authorisation number is already known. If this is the case, then the authorisation number can be provided. This will be reflected in the next version of the FAQ document/Chapter 3.II
78	Will EMA also align with NCA to make sure Substances classified 0 / duplicate shall not be influenced to be used during application approval	Substances with SVG flag 0 are not available in the eAFs, so they cant be selected for new markething authorisation applications.
79	Will there be a fixed list of the type's of manufacturers needed for the enrichment to PMS? i.e. API manu., Release, Finished Prod, QC, Packager?	This list can be found in Chapter 3 of the EU IG.
80	Will we get the slides?	They are already published: https://www.ema.europa.eu/en/events/spor-status-update-1
81	XEVMPD: It is understood for composition the API/Excipients etc info is now according to Module 3 and not SmPC, is this correct?	It can be provided either as it is referenced in the SmPC OR as it is in Module 3
82	XEVMPD: What must be done if data in Module 3 is different from SmPC, which one takes the precedence?	We understand that the data is different. You can chose if you wish to submit it as it is in the SmPC OR in Module 3
83	XEVMPD : Is it mandatory to add the national number in the package description and what is the deadline?	No, it is not mandatory but it is highly recommended. That will help NCAs and MAHs to identify specific pack sizes in PMS.
84	XEVMPD user interface related guidance: when we can expect?	We need management approval first, then this UI must be developed. As part of the change management process, the UI manual and training presentations will be updated. We cannot however provide you with a concrete date at this point when this can be expected
85	XEVMPD: when Will the Meddra indication version 28 be effective in XEVMPD?	MedDRA versions are updated in XEVMPD in May and in November