



## SPOR & XEVMPD status update webinar – Questions and Answers

Date: 08/10/2025

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      | Is there a list which national referencies are used?                                                                                                                                                                                                                                         | Yes, this is available in our OMS portal under the OMS data quality standards document.                                                                                                                                                                                                                                                                                           |
| 2 | OMS      | OMS: the HA in Luxemburg (Ministry Of Health And Social Security) LOC-100000043 is inactive in OMS the LOC, but is mentioned in the HMA web as a current national contact. kindly clarify                                                                                                    | I kindly ask you to please open an OMS question in EMA Service Desk, the team will be able to review previous changes and provide you further clarification.                                                                                                                                                                                                                      |
| 3 | OMS      | The source documents for New/Update Organization and New/Update Location for Industry - Is only NBR documented is accepted or GMP certificates or Letter Header will also be considered. Recently we noticed especially for New Organisation and New Location only NBR document is accepted. | To create a new organisation we need a document from the national business registry, after this a headed letter or a GMP certificate can be used to add any other locations used by a certain entity. For further information we recommend the review of the guidance E - OMS Change requests published in our OMS portal.                                                        |
| 4 | OMS      | What is the duration of OMS request (EP111) search locations searchtoken? Has it been reduced to 4 hours recently?                                                                                                                                                                           | With the refactored the OMS API to Azure, deployed in November 2023, the time has been reduced from 8 hours to 4 hours.                                                                                                                                                                                                                                                           |
| 5 | OMS      | Who is responsible for organization creation in OMS? The organization itself or the MAH?                                                                                                                                                                                                     | Ultimately the MAH should be the responsible, as the responsible to ensure all regulatory requirements are meet. The MAH can also delegate the registration to each manufacture and this is why we open our dictionary to allow any user to propose any type of change, as long as the required supporting documentation is provided and we are able to validate the information. |

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| 6  | OMS          | Why is the Company Attribute (fed from OMS) mandatory for Contacts in the eAF? Freelance Consultants cannot be created in OMS anymore. But the OMS Company is a mandatory field.                                                                                                                | Please note OMS team can help with any question related with the management of the data, how the data is used or its mandate of usage, this is a question that each system will be able to provide you more information. I kindly ask you to please open a question in EMA Service Desk directed to eAF colleagues, they will be able to better address your question. |
| 7  | PMS          | Where we can find valid version of Critical list of medicines, on dedicated page is outdated list and ATC dynamic report in PMS is not correct                                                                                                                                                  | Please consult <a href="#">this page</a> .                                                                                                                                                                                                                                                                                                                             |
| 8  | RMS          | RMS: can we get all terms in single excel workbook?                                                                                                                                                                                                                                             | Users can get all terms from one list in a single export, but it's not possible to get all terms from all RMS lists in one single excel.                                                                                                                                                                                                                               |
| 9  | SMS          | If a substance has a flag 0 but there's no comment like duplicate of... Can that substance with flag 0 be maintained for the moment?                                                                                                                                                            | Please refer to the SMS guidance document and data cleansing section                                                                                                                                                                                                                                                                                                   |
| 10 | SMS          | Why Human normal immunoglobulin (IV) was flagged 0 in SMS? Now human normal immunoglobulin is the preferred term, while the Ph Eur monograph 0918 already states that it is for intravenous administration.                                                                                     | Please raise a SMS query in SN                                                                                                                                                                                                                                                                                                                                         |
| 11 | SPOR general | As you publish these Events (clinics and Q&As) on the EMA YouTube channel, could you please limit the amount of advertisements? You can choose the ad option during the upload. Currently the ads are coming VERY frequently which makes it very hard to follow what is being presented by EMA. | Thank you for raising this, we will check this with our audiovisual team                                                                                                                                                                                                                                                                                               |
| 12 | SPOR general | Could you explain why the option to download an organization's change history has been discontinued? It was very useful                                                                                                                                                                         | I have the same remark. This was very useful.                                                                                                                                                                                                                                                                                                                          |
| 13 | SPOR general | Please upload the demo video and presentation promptly after the demo.                                                                                                                                                                                                                          | Unfortunately, this is not something we can influence, the uploads of videos are done by our audio visual team. The presentation is already published on the <a href="#">event page</a> .                                                                                                                                                                              |
| 14 | SPOR general | Where do we can find the video of the webinars and materials shared during this webinar?                                                                                                                                                                                                        | The presentation will be available in the SPOR Portal Documents section and EMA Event Web Page. The recording will be made available on the EMA YouTube Channel (also in SPOR webinars playlist), as well as on the EMA Event Web Page. SPOR webinars playlist is available <a href="#">here</a> .                                                                     |

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| 15 |                    |                                                                                                                                                                                                                                                                                               |                                                                  |
| 16 | XEVMPD/<br>Art. 57 | If substances having SVG=0 is submitted will these still accepted, or we receive negative or 3rd level acknowledgement saying this has been corrected or EMA follow up saying we need to, correct?Please note the deadline for correction of flag 0 to 1 is put on hold until further notice. | These will still be accepted and you will receive a positive ACK |