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Information Management

## eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) training

### Frequently asked questions

#### 1. Mandatory participation

**Question:** Is it mandatory for every user to receive training on submission of medicinal product report messages in the XEVMPPD?

**Answer:** At least one user from each organisation should follow the training and obtain a '*Notification of successful completion of the XEVMPPD knowledge evaluation*'. This is to ensure the quality of data submitted to the database. Also, '*Notification of successful completion of the XEVMPPD knowledge evaluation*' is required from at least one user from each organisation during the organisation's registration process with EudraVigilance before the data submission can begin:

- If your organisation will be registering for the submission of **authorised** medicinal product data, at least one participant from your organisation should perform the XEVMPPD knowledge evaluation for the submission of authorised medicinal product data in the XEVMPPD.
- If your organisation will be registering for the submission of **un-authorised** (referred to in the XEVMPPD as 'development') medicinal product data, at least one participant from your organisation should perform the XEVMPPD knowledge evaluation for the submission of development medicinal product data in the XEVMPPD.

##### 1.1. Participation from 3<sup>rd</sup> party service provider organisations

**Question:** We are using a 3<sup>rd</sup> party service provider organisation to submit extended EudraVigilance product report messages (XEVPRMs). Do they need to be trained on how to use the XEVMPPD?

**Answer:** If you arranged with a 3<sup>rd</sup> party service provider to submit electronically, via an XEVPRM, information on authorised or development medicinal products on your behalf, it is sufficient that a member of staff from the 3<sup>rd</sup> party service provider organisation has successfully completed the XEVMPPD training.

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<sup>1</sup> EMA Service Desk link updated



## 2. XEVMPD knowledge evaluation

**Question 1:** After finishing the e-learning course, users can perform an XEVMPD knowledge evaluation. Can everyone register for the XEVMPD knowledge evaluation?

**Answer 1:** A maximum of five users from the same organisation can be registered for the XEVMPD knowledge evaluation. It is not necessary for each and every member of staff of the same organisation to obtain the '*Notification of successful completion of the XEVMPD knowledge evaluation*'. Users, who have received the notification of successful completion can train other users within their organisation.

**Question 2:** As a user from sponsor organisation, do I have to participate in the knowledge evaluation on the submission of authorised medicinal product data?

**Answer 2:** If your organisation will be registering as a 'sponsor' organisation, and your organisation will submit only development product data in the XEVMPD, you should review the materials relevant for the submission of development medicinal products in the XEVMPD. You can then perform the knowledge evaluation on the submission of development medicinal products only.

### 2.1. Validity of knowledge evaluation

**Question:** I followed the XEVMPD training and received the '*Notification of successful completion of the XEVMPD knowledge evaluation*'. I will be leaving my current organisation and would like to know if this notification will be valid in my new organisation, or if I'll have to repeat the knowledge evaluation?

**Answer:** The notification will be valid even if you move to a new organisation. The knowledge evaluation is assigned to the person, who performed it. You will not need to repeat the knowledge evaluation.

### 2.2. Training certificate

**Question:** Following the training and completion of the XEVMPD training course will I receive a certificate?

**Answer:** Training certificates are no longer requested/provided. Users, who successfully complete the XEVMPD knowledge evaluation, will receive a '*Notification of successful completion of the XEVMPD knowledge evaluation*' via email (in case the participant attended the face-to-face training course) or via the EMA Service Desk ticket (in case the participant attended the e-learning training and registered for this e-learning training via the EMA Service Desk).

### 2.3. Timeline for performing the XEVMPD knowledge evaluation

**Question:** When can I perform the XEVMPD e-learning knowledge evaluation?

**Answer:** Once you review the published XEVMPD e-learning materials and guidance documents, you can register for the XEVMPD knowledge evaluation by sending an [XEVMPD e-learning registration request](#) via the [EMA Service Desk portal](#). You will then receive the necessary documents and instructions on how to perform the XEVMPD knowledge evaluation, including your login details to the XEVMPD Test Environment (XCOMP). The provided login details are valid for 4 weeks since you receive them, and you are therefore strongly advised to perform the knowledge evaluation within this period. Should you need to repeat the second part of the knowledge evaluation (i.e., the product report exam case submission), this should also be done within the 4-week period.

**Question:** I am performing the XEVMPD knowledge evaluation and cannot find some of the information I need in the XEVMPD training environment (e.g., the organisation that I am supposed to reference in my product entry). What should I do?

**Answer:** Generally, if data is missing in the XEVMPD, users are requested to insert it as per the applicable business processes described in the training documents and/or the relevant user guidance document. The approach should be the same when performing the XEVMPD knowledge evaluation in the XEVMPD test environment (XCOMP). Please refer to the [XEVMPD Data-Entry Tool \(EVWEB\) User Manual](#) or the e-learning videos to see how to insert the various entities in the XEVMPD.

### 3. Knowledge update

**Question:** Years ago, I attended the EVMPD training and received a training certificate after the completion of the course. Is this certificate still valid or do I need to refresh my training?

**Answer:** If you already attended an EVMPD training course in the period of May 2004 to March 2012, your previously issued training certificate will allow you to use EVWEB and start the electronic submission of product reports to the Agency. However, users previously trained on EVMPD are strongly advised to review the updated [XEVMPD Data-Entry Tool \(EVWEB\) User Manual](#) and the relevant guidance document(s):

- [Chapter 3.II: Extended EudraVigilance product report message \(XEVPRM\) user guidance](#) and/or
- [Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary \(XEVMPD\)](#).

### 4. Access to the XEVMPD test environment (XCOMP)

**Question:** As part of my registration for the XEVMPD knowledge evaluation I received login details for the XEVMPD test environment (XCOMP). However, when I try to log in, I receive an error message that I cannot access this page. What should I do?

**Answer:** Providing that you successfully installed ActiveX on your computer, and you are accessing XCOMP using the IE Tab extension, you need to check if the login credentials you are using (i.e., username and password) are still valid. The login details are valid for 4 weeks since you received them. If your **login credentials expired**, please submit a [request for new XEVMPD credentials](#) via the [EMA Service Desk portal](#).

If your **logging credentials are still valid**, this might be a technical issue. Please contact your IT department to check for restrictions on your computer. If the issue persists, please report it using the EMA Service Desk form

[https://support.ema.europa.eu/esc?id=sc\\_cat\\_item&sys\\_id=dbcfabdac3995d10e68bf1f4e4013143](https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=dbcfabdac3995d10e68bf1f4e4013143).

### 5. Cost of XEVMDP e-learning knowledge evaluation

**Question:** What is the fee for participation in the XEVMDP e-learning knowledge evaluation?

**Answer:** The XEVMPD e-learning training materials are available cost-free, and the e-learning XEVMPD knowledge evaluation is also free of charge.