EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) e-learning

Introduction

Version 5.6

Overview of available training formats

XEVMPD training is available as:

- **Virtual** training course run by the Drug Information association (DIA)
  - Separate courses for MAHs and sponsors; training dates are available on the XEVMPD training webpage
  - **Paid** training course; **trainer led**, knowledge evaluation is performed by the trainers
  - No limit on the number of participants from one organisation

- **E-learning** training
  - Separate courses for MAHs and sponsors
  - **Free** training based on **self-study** of available materials; users register for knowledge evaluation via EMA Service Desk
  - Max 5 people from the same organisation can be register
    - '*Notification of successful completion of the XEVMPD knowledge evaluation'* is requested from **one person** during the **organisation's initial registration in EV**
    - Trained users can train others within their organisation

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How to participate in the e-learning training course

Users from MAH organisations, sponsor organisations, third-party service providers and/or national competent authorities should review the following documentation as part of their e-learning training:

- XEVMPD e-learning presentations;
- User manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb);
- Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance, providing detailed guidance on the submission of AMPs, **and/or**
- Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD), providing detailed guidance on the submission of DMPs.

Learning Objectives

Once the XEVMPD e-learning training is competed, users should be able to:

- Understand the concepts related to the electronic submission of information on authorised and un-authorised medicines in the EU/EEA;
- Understand the legal requirements for marketing authorisation holders and/or sponsors to submit medicinal product information in the XEVMPD;
- Use the XEVMPD user interface (XEVMPDweb) for the electronic submission and maintenance of different types of medicinal products.

XEVMPD knowledge evaluation

- To receive the notification of successful completion of the XEVMPD knowledge evaluation for the **submission of authorised medicinal product data** in the XEVMPD, participants will be required to demonstrate their knowledge on the submission of AMPs.
- To receive the notification of successful completion of the XEVMPD knowledge evaluation for the **submission of un-authorized (i.e., development) medicinal product data** in the XEVMPD, participants will be required to demonstrate their knowledge on the submission of DMPs.

XEVMPD knowledge evaluation registration

To register for the XEVMPD e-learning knowledge evaluation, an **XEVMPD e-learning registration request** must be submitted via the EMA Service Desk Portal:

- Users should clarify in their request if they wish to register for the knowledge evaluation of the submission of AMP and/or DMP data.

Following their registration, users will be provided with instructions on how to request access the **XEVMPD test environment (XCOMP)** to practise, and to complete the XEVMPD e-learning knowledge evaluation via the user interface (XEVMPDweb):

- The **access will be valid for eight weeks** since it was granted to the user;
- Any possible subsequent attempts must be performed during this time frame.

XEVMPD knowledge evaluation details

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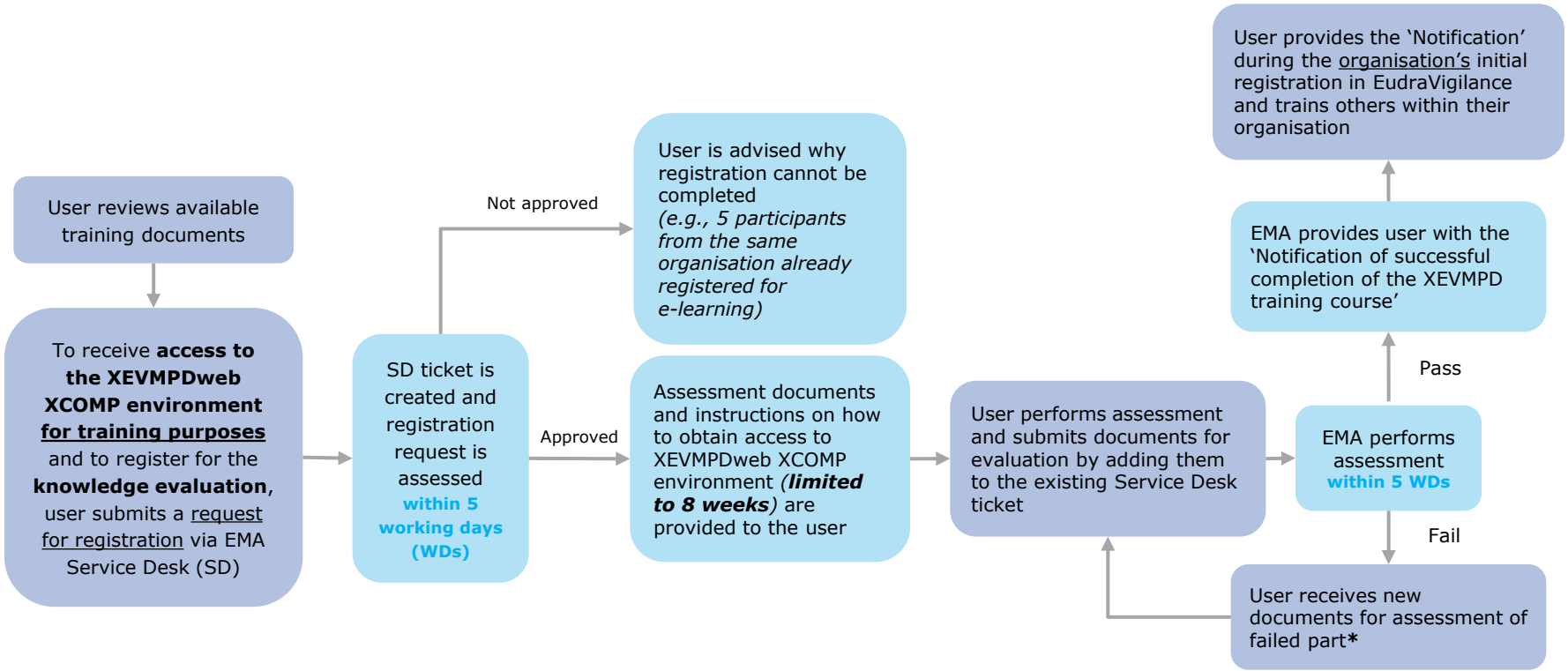
The knowledge evaluation consist of two parts:

- **Part I: Multiple choice questionnaire:**
  - Questions summarising the understanding of the XEVPRM and/or XEVMPD definitions and concepts,
  - Each correct answer is assigned one point,
  - If an incorrect answer is provided, no point is assigned.
- **Part II: Product report exam case(s):**
  - Based on the provided information, users are required to enter authorised and/or un-authorised medicinal product data in the XEVMPD using XEVMPDweb;
  - Points are assigned for each correctly populated field;
  - Points are deducted for major mistakes.

- The pass rate for each part of the knowledge evaluation is 80%.
- Participants have three attempts to pass each section of the knowledge evaluation.

E-learning training course process overview



**3 attempts for each failed part*
If user fails all 3 attempts, user is advised to follow the virtual training course

Contact points

- **Questions** related to the submission of authorised and un-authorised medicinal product data in the Article 57 database/XEVMPD should be submitted using the 'Ask a question' form in the EMA Service Desk Portal:
  - *'Service' should be selected as 'SPOR'*
  - *'Service Offering' should be selected as 'XEVMPD/Art.57'*
- **Technical issues** in the **XEVMPDweb** user interface should be reported using the 'Report an Issue' form in the EMA Service Desk Portal.
  - *Detailed description of the issue with supporting screenshots should be provided*
- **Requests** (for) **XEVMPD/Art57 services** should be submitted via the 'Request XEVMPD/Art.57 Services' form in the EMA Service Desk Portal.

Reference documents

- Further information related to product data submissions in the Article 57 database/XEVMPD can be found on the:
  - Data submission on authorised medicines (Article 57) webpage;
  - Guidance documents webpage;
  - Data submission on investigational medicines: guidance for clinical trial sponsors webpage.