EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) e-learning

Session 1.0: Introduction

Version 5.5

Overview

The European Medicines Agency (EMA) offers a self-paced e-learning training on the submission of authorised and un-authorised (referred to in the XEVMPD as 'development') medicinal product data in the XEVMPD:

- Authorised medicinal product (AMP) data is submitted in the XEVMPD (also referred to as 'Article 57 database') by marketing authorisation holders;
- Development medicinal product (DMP) data is submitted in the XEVMPD by sponsors of clinical trials.

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 training:

- XEVMPD e-learning presentations;
- Step-by-step guides;
- eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Data-Entry Tool (EVWEB) user manual;
- 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 (1/3)

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, i.e.:
  - Describe the eXtended EudraVigilance product report message (XEVPRM) format and the data elements required each product type,
  - Become familiar with practical examples of different types of medicinal products,
  - Get hands-on experience in working with the XEVMPD data entry tool (EVWEB);

Learning Objectives (2/3)

- Understand the legal requirements for marketing authorisation holders (MAHs) to comply with the provisions set out in Article 57(2) of Regulation (EC) 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012;
- Understand the requirements for sponsors of clinical trials as outlined in the Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use' ('CT-3') (OJ 2011/C 172/01);

Learning Objectives (3/3)

- Understand the controlled vocabularies and terminologies to be used during the submission process;
- Use the XEVMPD data entry tool (EVWEB) for the electronic submission and maintenance of different types of medicinal products;
- Explain the data structure of the XEVMPD for data entry and data retrieval;
- Understand the importance of the XEVMPD to support the pharmacovigilance activities in the EU/EEA.

XEVMPD knowledge evaluation

Once the e-learning course is completed, users can perform an XEVMPD **knowledge evaluation** to obtain a *'Notification of successful completion of the XEVMPD knowledge evaluation'* if a passing score is received

'Notification of successful completion of the XEVMPD knowledge evaluation' is required from at least one user during the organisation's registration process with EudraVigilance:

- 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 a User ID and password, allowing them to access the **XEVMPD test environment (XCOMP)** to practise and to complete the XEVMPD e-learning knowledge evaluation:

- The credentials are valid for four weeks since they were provided to the user;
- Any possible subsequent attempts must be performed during this time frame.

XEVMPD knowledge evaluation details (1/2)

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 EVWEB;
  - Points are assigned for each correctly populated field;
  - Points are deducted for major mistakes.

XEVMPD knowledge evaluation details (2/2)

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

Registration with EudraVigilance

- Detailed steps and definitions are described on the “Registration with EudraVigilance” webpages, section 'EudraVigilance: How to register' webpage.
- **EudraVigilance related questions** should be submitted via the ‘Ask a question’ form in the EMA Service Desk Portal.
- **EudraVigilance Registration queries** should be submitted via the ‘EudraVigilance Registration queries’ form in the EMA Service Desk Portal.

Contact details

- **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
- **Technical issues** should be reported using the via the 'Report an Issue' form in the EMA Service Desk Portal
- **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.