



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:

- [XEVMPPD e-learning presentations](#);
- [Step-by-step guides](#);
- [eXtended EudraVigilance Medicinal Product Dictionary \(XEVMPPD\) Data-Entry Tool \(EVWEB\) user manual](#);
- [Chapter 3.II: Extended EudraVigilance product report message \(XEVPDM\) 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 \(XEVMPPD\)](#), providing detailed guidance on the submission of DMPs.

Learning Objectives (1/3)

Once the XEVMPD e-learning training is completed, 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](#).