EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) e-learning

Session 2.4: Operation types, data quality and data ownership

Version 5.4

XEVMPD: Available operation types (1)

The following operation types can be used on medicinal product data in an XEVPRM:

- **'Insert' (1)**: allows the sender organisation to insert medicinal product information in the XEVMPD;
  - For EVWEB users, a command button 'Reinsert' (1) is also available. This operation type allows EVWEB users to re-insert an existing medicinal product whilst retaining the previous information and create a new medicinal product with the operation type 'Insert'.
- **'Update' (2)**: allows the sender organisation to correct erroneous information previously submitted and maintain some of the medicinal product information as per guidance in section 2. Maintenance of medicinal product data of Chapter 3.II: XEVPRM User guidance.

XEVMPD: Available operation types (2)

- **'Nullification' (4)**: allows users to flag incorrectly submitted information (including duplicated information) as 'non-current‘ in line with guidance provided in section 2. Maintenance of medicinal product data of Chapter 3.II: XEVPRM User guidance.
- **'Invalidate MA' (6)**: allows the sender organisation to submit a notification about the withdrawal of an authorised medicinal product from the market via an XEVPRM. The 'Invalidate MA' operation covers a number of scenarios including the transfer of an authorised medicinal product to a third party and a renewal of the marketing authorisation (MA) by the marketing-authorisation holder (MAH) if the marketing authorisation number changes as described in section 2. Maintenance of medicinal product data of Chapter 3.II: XEVPRM User guidance.

XEVMPD: Available operation types (3)

- **'Variation' (3)**:
  - this operation type is not available in EVWEB;
  - gateway user organisations should not assign this operation type to an XEVPRM to notify the Agency of a variation procedure of an AMP in the context of maintenance of medicinal product data during the transition maintenance phase - an XEVPRM containing an AMP entity with assigned operation type 'Variation' (3) will receive a negative XEVPRM acknowledgement as the entire XEVPRM will be rejected.

Operation Type ‘Insert’ (1)

- **'Insert' (1)** allows organisations (EMA, MAH, sponsor) to add a new entity in the XEVMPD, e.g.:
  - new sponsor or MAH organisation;
  - new pharmacovigilance system master file location (PSMFL);
  - new substance reference source;
  - new authorised or development medicinal product;
  - new terminology (administration route, ATC code or pharmaceutical form).

Maintenance operation types

- 'Update' (2) allows the owner organisation to modify the content of an entity previously submitted via an XEVPRM (as per the applicable business rules);
- 'Nullification' (4) allows the owner organisation to flag as “non-current” a duplicated/obsolete entity previously submitted via an XEVPRM (as per the applicable business rules);
- Invalidate MA’ (6)’ allows the owner organisation to flag an AMP entity previously submitted via an XEVPRM to notify:
  - revocation/withdrawal of marketing authorisation,
  - transfer or marketing authorisation,
  - renewal of marketing authorisation.
- All relevant processes are described in section 2. Maintenance of medicinal product data of Chapter 3.II: XEVPRM User guidance.

Data quality

- MAHs shall ensure that information on all medicinal products for human use authorised in the Union submitted electronically to the Agency using the format and content as referred to in the Legal notice on the implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004 is accurate and up to date.
- The Agency began a systematic review of the quality and integrity of the medicinal product information submitted by MAHs in July 2014. Outlines of the quality control (i.e. validation) process are described in Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No. 726/2004.

Data visibility

- Each entity (with the exception of development data) flagged as “valid” in the XEVMPD is visible to the end users.
  - The visibility of development substances, development products and development terms is restricted to the owner organisation, to the national competent authorities (NCAs) and to the European Medicines Agency.
- Approved substances are visible to the end users whether they’re flagged as “valid” by the EMA or not.
- Data access policy is described in section 1.7.7. Data Access Policy of the XEVMPD Data-Entry Tool (EVWEB) User Manual.

XEVMPD data ownership

- The XEVMPD data ownership is based on the following rules:
  - data entry is based on creation and submission of the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) ;
  - data ownership is assigned to the sender organization that created and submitted the XEVPRM;
  - only the sender organization can maintain the information provided in the XEVMPD.
- The operation types that a sender organisation can perform are described in section 1.7.4. Data Ownership and Maintenance of the XEVMPD Data-Entry Tool (EVWEB) User Manual.

Further information and contacts

- All documents related to electronic submission of information on medicines as per Article 57(2) requirements are available at the "Guidance documents" webpage.
- Technical questions or questions related to the submission of investigational medicinal products (IMPs)/authorised medicinal products (AMPs) should be submitted via the EMA Service Desk portal (https://servicedesk.ema.europa.eu).