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 5.5

# XEVMPD: Available operation types (1/3)

The following operation types can be used on medicinal product data in an Extended EudraVigilance product report message (XEVPRM):

- **'Insert' (1)**: allows the sender organisation to insert medicinal product data in the XEVMPD;
  - 'Reinsert' (1) is also available in EVWEB to allow 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 data as per specific guidance and processes available in Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance and Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD);

# XEVMPD: Available operation types (2/3)

- **'Nullification' (4)**: allows the sender organisation to flag incorrectly submitted information (including duplicated information) as 'non-current';
- **'Invalidate MA' (6)**: allows the sender organisation to submit a notification about the renewal/variation/withdrawal/expiry and transfer of marketing authorisation via an XEVPRM;
  - Further details on the maintenance of authorised medicinal product data using this operation type is available in section 2. Maintenance of medicinal product data of Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance;

# XEVMPD: Available operation types (3/3)

- **'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.:
  - An authorised or development medicinal product;
  - Sponsor or MAH organisation;
  - Pharmacovigilance system master file location (PSMFL);
  - Substance reference source;
  - New terminology (administration route, ATC code or a 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 where the authorisation number changed following the renewal procedure.

# Data quality: Authorised medicinal products

- Review of the quality and integrity of the medicinal product information submitted in the Article 57 database by MAHs began in July 2014.
  - Outlines of the quality control (i.e. validation) process performed by the European Medicines Agency (EMA) are described in the 'Quality control of medicinal-product data submitted as per the legal requirement introduced by Article 57(2) of Regulation (EC) No. 726/2004' document.
- MAHs shall ensure that information on all medicinal products for human use authorised in the EU/EEA submitted electronically to the EMA 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.

# Data quality: Development medicinal products

- Currently, the validation of medicinal product data submitted in the XEVMPD by sponsors is performed automatically by the system, to allow for the DMP to be available for the recoding of Suspected unexpected serious adverse reactions reports (SUSARs).

# XEVMPD data ownership

- The XEVMPD data ownership is based on the following rules:
  - data entry is based on creation and submission of the XEVPRM,
  - data ownership is assigned to the headquarter (HQ) of the sender organisation that created and submitted the XEVPRM,
  - only the sender organisation can maintain the information provided in the XEVMPD as per the applicable business rules.
- The operation types that the owner organisation can perform, are described in section *1.7.4. Data ownership and maintenance* of the XEVMPD Data-Entry Tool (EVWEB) User Manual.

# Data visibility

- Each entity flagged as "valid" in the XEVMPD, except for development data, is visible to the end users.
  - The visibility of development substances, development products and development terms in EVWEB is restricted to the owner organisation, to the national competent authorities (NCAs) and to the EMA.
- Approved substances are visible to the end users whether they 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.
- Subset of authorised medicinal product data is published on the 'Public data from Article 57 database' webpage.

# 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.
- Guidance related to the submission of development product data in the XEVMPD is available in the Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD).
- Technical enquiries or questions related to the submission of AMPs and DMPs in the Article 57 database/XEVMPD should be submitted to the EMA via the EMA Service Desk portal (https://servicedesk.ema.europa.eu).