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Procedure Management & Business Support

Summary of changes in the EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) production environment

Following a release of EudraVigilance version 7.7 and in the context of preparation for the maintenance process of medicinal product entries submitted in the XEVMPD in the new eXtended EudraVigilance Product Report Message (XEVPRM) format in compliance with the initial medicinal product submissions as outlined in Article 57(2), second subparagraph, point b of Regulation (EC) 726/2004, the below changes were introduced in the XEVMPD:

- **New operation type (AP..1) 'Invalidate MA'**

  This operation 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).

- **New authorisation status (AP.12.3) values**

  Four new values are now available from the 'Authorisation status' controlled vocabulary:

  Valid – Renewed Marketing Authorisation (8)

  Valid – Transferred Marketing Authorisation (9)

  Not Valid – Superseded by Marketing Authorisation Renewal (10)

  Not Valid – Superseded by Marketing Authorisation Transfer (11)

Until further guidance is issued by the European Medicines Agency (EMA), **the maintenance operation types 'Variation / 'Invalidate MA' and the new marketing authorisation status values cannot be applied to medicinal product entries submitted in the new XEVPRM format**, in compliance with the initial medicinal product submissions as outlined in Article 57(2), second subparagraph, point b of Regulation (EC) 726/2004.

In addition, these operation types should also not be applied for electronic submissions of information on medicinal products authorised in the European Union after 2nd July 2012.

- **'Withdrawn date' field (AP.12.12) re-labelled to 'Withdrawn / Invalidated Date'**

  'Withdrawn / Invalidated Date' field (AP.12.12) is linked to the authorisation status value.

- **'Previous EV Code' section (AP.PEV) amended**

  Previously, only the EV Code of a development medicinal product entry could be referenced in an authorised medicinal product entry using the 'Previous EV Code' section (AP.PEV). It is now possible to reference an EV Code corresponding to an authorised medicinal product entry using this section. The following values are available:

  New Previous Authorised EV Code

  New Previous Development EV Code

Further guidance on how these fields should be used will be provided by the EMA as part of the maintenance process of medicinal product entries submitted in the new XEVPRM format in compliance with the initial medicinal product submissions as outlined in Article 57(2), second subparagraph, point b of Regulation (EC) 726/2004.

- **Additional criteria available in advanced queries for authorised products**
  - 'Article 57 Format' field

    A new field 'Article 57 Format' was added in the 'Authorised Products' section of the 'Queries' section. This is to enable users to search for medicinal product information submitted in the XEVPRM Format (Article 57 format) or in the EVPRM format (Pre Article 57 format).

    The following values are available:

    Article 57 Format (1)

    Pre Article 57 Format (2)

    To select the requested value, go to 'Queries', 'Authorised Products', 'Conditions'. Select 'Article 57 Format' field, click 'Enter' and choose one of the available options.

  - 'MA validity' field

    Enables users to search for authorised medicinal products with the authorisation status value set as 'valid' or 'invalid.

  - 'Withdrawn / Invalidated Date' field

    Enables users to search for authorised medicinal products as per specific date or period (From – Up to).

  - 'Master File Location Code' field

Enables users to search for authorised medicinal products based on the Master File Location information.

- **Additional sections available in 'Queries' section**
  - Attachments

    This section enables users to search for attachments submitted in the XEVMPD.

  - Master File Locations

    This section enables users to search for the Master File Location information submitted in the XEVMPD.

Should you require further information or clarification please contact the Article 57 helpdesk (art57@ema.europa.eu).