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Procedure Management & Business Support

Re-allocation of eXtended Medicinal Product Dictionary (XEVMPD) Organisation entities ownership to the marketing authorisation holders (MAHs)

In August 2013, in the context of quality improvement of the Controlled Vocabularies (CVs) used in medicinal product information submitted to the Agency in accordance with Article 57(2) of Regulation (EC) 726/2004, marketing authorisation holders were requested:

- To review the details of their QPPV in the EudraVigilance registration database and communicate any changes to the EudraVigilance Registration Team; and
- To review the list of the XEVMPD Organisation entities created and owned by the Agency and provide the Agency with an Organisation ID to which the ownership of such entities should be re-allocated.

Following the receipt of the requested information from the marketing authorisation holders, the Agency has re-allocated the ownership of the organisation entities previously created and owned by the Agency to the owner organisations as identified by marketing authorisation holders.

Marketing authorisation holders are therefore able to review the organisation entities assigned to their organisation ID, and if necessary, correct the organisation information, remove duplicates and amend their authorised medicinal product entities to reference the correct MAH organisation as required.

Marketing authorisation holders may do so immediately, however as per communication published on 31 January 2014, marketing authorisation holders will need to update, complete and improve the quality of the submitted information between 16 June and 31 December 2014 following the implementation of the new XEVPRM schema. This will involve the completion of the previously submitted medicinal product data information with the additional data elements, as well as checking the quality of all information in line with the updated reporting requirements.

Between **11 February and 15 June 2014** MAH may perform the following activities on their organisation entities:

- Review organisation entities assigned to their organisation ID.

  List of available MAH organisations with their assigned EV Codes can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the Agency's website - see "*eXtended Eudravigilance Product Dictionary (XEVMPD) organisations*".

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- Amend their authorised medicinal product entities to reference the correct MAH organisation as required using operation type 'Update (2)'.
- Make obsolete any duplicated organisation entities or organisation entities which are no longer valid and will not be used in any future medicinal product submission using operation type 'Nullification (4)'.

  The nullification of XEVMPD entities is not allowed in the XEVMPD if the organisation entity is referenced in any authorised medicinal product entity. Please see section *2.3.4 Nullification of duplicated/obsolete XEVMPD entities* of Chapter 3.II: eXtended EudraVigilance Product Report Message (XEVPRM) User Guidance available on the Agency's website for related information.
- Correct or amend any information within the organisation entity using operation type 'Update (2)'.

Between **16 June and 31 December 2014** MAH must perform the following activities on their organisation entities:

- Review organisation entities assigned to their organisation ID.

  List of available MAH organisations with their assigned EV Codes can be found in the XEVMPD look-up table and in the Controlled Vocabulary (CV) lists published on the Agency's website - see "*eXtended Eudravigilance Product Dictionary (XEVMPD) organisations*".
- Correct or amend any information within the organisation entity including providing additional information as per amended XEVPRM schema using operation type 'Update (2)'.
  - Address (O.6) - mandatory information to be provided
  - Postcode (O.9) - mandatory information to be provided
  - SME status (O.19) – mandatory information to be provided
  - SME number (O.20) – optional information to be provided

  Related information can be found in section *1.6 Initial Submission of a Marketing Authorisation Holder (MAH) Organisation* of Chapter 3.II: eXtended EudraVigilance Product Report Message (XEVPRM) User Guidance available on the Agency's website.
- Amend their authorised medicinal product entities to reference the correct MAH organisation as required using operation type 'Update (2)'.
- Make obsolete any duplicated organisation entities or organisation entities which are no longer valid and which will not be used in any future medicinal product submission using operation type 'Nullification (4)'.

  The nullification of XEVMPD entities is not allowed in the XEVMPD if the organisation entity is referenced in any authorised medicinal product entity. Please see section *2.3.4 Nullification of duplicated/obsolete XEVMPD entities* of Chapter 3.II: eXtended EudraVigilance Product Report Message (XEVPRM) User Guidance available on the Agency's website for related information.

In addition, the Agency has assumed the XEVMPD ownership of legacy product data (i.e. authorised medicinal products submitted in the XEVMPD using the previous EudraVigilance Product Report Message format [i.e. Pre-Article 57(2) format]) by referencing *'**Maintained by EMA'** (Organisation EV Code ORG15457)'* as the MAH in the concerned AMPs. This is to flag medicinal products which are not

compliant with Article 57(2) and that should therefore not be maintained by marketing authorisation holders under the Article 57 (2) obligations.

The Legacy product data are still visible in the XEVMPD and can be retrieved by the MAHs using the Advanced Queries section - the condition 'Pre Article 57 format (2)' must be selected.

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

European Medicines Agency