EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2013
EMA/656849/2013
Procedure Management & Business Support

Legacy product data in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)

Authorised Medicinal Products (AMPs) submitted to the XEVMPD using the previous EudraVigilance Product Report Message (EVPRM) format [Pre-Article 57(2) format] are considered legacy data. As previously communicated, **the marketing authorisation holders (MAHs) do not need to maintain these legacy data.**

As per point 6. Information previously submitted to the EudraVigilance Medicinal Product Dictionary (EVMPD) of the published Legal notice on the Implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004: *"Marketing authorisation holders, which have electronically submitted information on medicinal products for human use authorised in the Union in accordance with the provisions set out in Volume 9A of The Rules Governing Medicinal Products in the European Union, part III, chapter 11.6, may update such information in accordance with the format, content and requirements as referred to in point 1, 3, 4 and 5 and shall comply with the provisions set out in paragraph 2(a) and 2(b). The operation type 'Insert' should be used for these updates."*

Not using operation type 1 = 'Insert' or 'Reinsert' (available for EVWEB users) to convert the previously submitted legacy data to the eXtended EudraVigilance Medicinal Product Report Message (XEVPRM) format for the initial electronic submission of information on medicinal products for human use authorised in the Union as per Article 57(2) results in the marketing authorisation holder **being non-compliant** with the provisions set out in Article 57(2), second subparagraph of Regulation (EC) 726/2004 - electronic submission of information on medicines authorised in the European Union.

In the context of preparation for the maintenance process of medicinal product entries submitted in the XEVMPD in the 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 Agency has assumed the XEVMPD ownership of the legacy product data by referencing *'**Maintained by EMA'** (Organisation EV Code ORG15457)'* as the MAH in the concerned AMP entries.

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).