5 February 2016
EMA/736031/2014, Rev. 1
Information Management

# Electronic submission of medicinal product information by marketing-authorisation holders

Article 57 (2) of Regulation (EC) No 726/2004

## *Legal Requirements*

The submission of medicinal product data by marketing-authorisation holders (MAHs) is a legal requirement introduced by Article 57(2) of Regulation (EC) No 726/2004.

This legal provision requires all holders of marketing authorisations for medicinal products for human use in the European Economic Area (EEA) to **submit** information to the European Medicines Agency (EMA) using the electronic format referred to as Article 57 format or eXtended EudraVigilance Product Report Message (XEVPRM) format.

MAHs are also obliged to **maintain** the submitted medicinal product information and notify the EMA of any newly authorised medicines or variations to the terms of the marketing authorisation using the XEVPRM format.

## *Why submit: Scope*

The aim of the data submission is to establish a complete inventory of all medicines authorised for human use in the EEA, including medicines authorised centrally via the EMA and those authorised at national level via the National Competent Authorities (NCAs).

This information will be used to support regulatory business activities, including:

- coding of substance and product information reported in Individual Case Safety Reports (ICSRs) within the Eudravigilance system to support *Pharmacovigilance signal management* activities and the performance of *data analysis* and *business intelligence* at the Agency;
- facilitating the *coordination of regulatory decisions and actions* to safeguard public health, e.g. to support referral procedures, the establishment of a repository of Periodic Safety Update Reports (PSURs) and literature monitoring;
- calculating the Pharmacovigilance Fees payable by MAHs;
- *strengthening transparency* and *communication* with the Agency's stakeholders by establishing the European medicines web portal, granting access to safety data, efficiently exchanging data within

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the EU Network and international partners, and supporting communication between the Agency's Committees and pharmaceutical industry.

## *What to submit: Information on medicinal products*

MAHs are required to submit to the EMA information on all medicinal products for which they hold a marketing authorisation in the EEA, i.e.:

- nationally authorised medicinal products;
- centrally authorised medicinal products;
- medicinal products authorised through the mutual recognition procedure;
- medicinal products authorised through the decentralised procedure.

## *How to submit: Registration & Training*

To begin data submission of authorised medicinal products, marketing-authorisation holders need to register with Eudravigilance. This is to ensure that privacy and security measures are in place and that the principles of integrity, accountability and availability of data are adhered to.

To ensure the quality of data submitted to the EudraVigilance database, at least one user from each organisation should receive training. An eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course is available as a face-to-face or e-learning training course.

## *When to submit*

Marketing-authorisation holders were initially required to submit information on medicinal products for human use by 2 July 2012.

Since July 2012, MAHs are required to submit information on new marketing authorisations granted after 2 July 2012 within **15 calendar days** from the date of notification of the granting of the marketing authorisation by the NCA.

By 31 December 2014 MAHs were also required to improve quality of information on authorised medicines submitted to the EMA, bring their medicinal product entries up-to-date and submit additional information in line with the guidance and processes described in Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance document.

Information on any amendments to the terms of marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal shall be notified to the EMA no later than **30 calendar days** from the date on which the amendments have been authorised as per guidance and processes described in Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance document.

## *Useful sources of information*

For information related to submission of authorised medicines data visit the Data submission webpage.

For documents related to submission of authorised medicines data visit the Guidance document webpage.

## *How to contact the Agency*

Enquiries related to Article 57(2) submissions can be submitted to the EMA via the EMA Service Desk portal (https://servicedesk.ema.europa.eu).

For enquiries related to the EU SME definition please contact the SME office (sme@ema.europa.eu).

For enquires on how to register contact the Eudravigilance registration office (eudravigilanceregistration@ema.europa.eu).