Centrality

The Facts: Mandatory EVMPD submissions

Getting ready for the July 2012 deadline

EU pharmacovigilance legislation now requires all Marketing Authorisation Holders in Europe to electronically submit detailed, XML-based product records to the European Medicine Agency's EudraVigilance Medicinal Product Dictionary (EVMPD) by 2nd July 2012 at the latest. For MAHs that fail to comply, the consequences are punitive a potential fine of up to 5% of gross profit in the European market. Beyond the 2012 deadline, all MAH submissions will soon need to comply with a coming ISO IDMP (Identification of Medicinal Products) standard, expected to be in force by 2015. So regulatory affairs professionals in Europe will need to implement an effective e-reporting solution now, to reduce the MAH submissions management overhead and ensure seamless ongoing regulatory compliance.

What is the EVMPD?

The EVMPD has been developed by the EMA in collaboration with the EudraVigilance implementation fora to help the pharmacovigilance activities in the European Economic Area. The EVMPD was designed to support the collection, reporting, coding and evaluation of authorised and investigational medicinal product information in a standarised and structured way.

What do MAHs need to do to comply?

By 2nd July 2012 at the latest, Marketing Authorisation Holders will need to submit XML Schema Definition (XSD)-compliant product information on all medicines authorised or registered in the European Union. Data will need to be entered and maintained in a compliant format on an ongoing basis by the Qualified Person for Pharmacovigilance, as defined in the EU Directive 2001/83/EC. MAHs need to register with EudraVigilance (if not previously registered), collate all the required data and enter it by the deadline date. Electronic submission will require new or updated software from a vendor that offers full XEVMPD support and understands the highly detailed data and technical specifications of the new - and coming - mandates.

Key facts at a glance

Mandate issued by EMA

Data must be submitted electronically to EVMPD

Applies to all MAHs in Europe

Compliance by Jul 2 2012

Punitive fines in place

What is XEVMPD?

Extended Medicinal Product Dictionary (XEVMPD) is a re-branding of the EVMPD to reflect the new format for the Electronic Submission of Information on Medicines published by the EMA in July 2011. XEVMPD has been developed to allow the EMA to create a list of all medicines authorised and registered in the EU, to identify medicines accurately (especially those included in reports of suspected adverse reactions), and to co-ordinate the regulation and safety monitoring of medicines across the EU.

What is XEVPRM?

The Extended EudraVigilance Medicinal Product Report Message (XEVPRM), as defined by the XSD documents published by the EMA on 1 September 2011, is the format to electronically submit and update information to the EVMPD. More information on EVMPD, XEVMPD and XEVPRM can be found on the EudraVigilance website.