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Press Office

Press release

European Medicines Agency publishes updated set of mandatory Article 57(2) requirements for marketing authorisation holders

Mandatory data set to be submitted by 2 July 2012

The European Medicines Agency has published an updated set of mandatory requirements for marketing authorisation holders to comply with Article 57(2), one of the key measures of the new pharmacovigilance legislation. The Agency has considerably reduced the number of data fields initially required in the format published on 2 July 2011, thus significantly reducing the administrative burden and helping marketing authorisation holders to meet their legal deadline of 2 July 2012.

The Agency will continue to support marketing authorisation holders on the data submission process through online and face-to-face training and a dedicated helpdesk. An online data entry tool (EVWEB) hosted by the Agency to facilitate data submission by small and medium-sized enterprises was also released into production today.

Article 57(2) of the new pharmacovigilance legislation requires the Agency to establish lists of all human medicines authorised in the European Union (EU), based on structured data submitted by the marketing authorisation holders of these medicines. These lists will assist the Agency in the coordination of pharmacovigilance activities and the protection of public health by facilitating clear identification of medicines in reports on adverse reactions and of medicines affected by a safety review.

Since the initial publication of the requirements in July 2011, the Agency has listened carefully to all stakeholders and looked at how the mandatory data set could be reduced while ensuring that the public-health goals of the legislation and patient safety are not compromised. These goals have been successfully achieved and have resulted in a reduction in the number of data fields which are mandatory.

In January 2012, the Agency held a workshop with EU pharmaceutical industry associations for human medicines. During this workshop, stakeholders were supportive of the Agency's proposal for an updated set of mandatory data for submission by 2 July 2012. A summary of the workshop is available on the Agency's website.

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The Agency will work with stakeholders throughout 2012 on further defining requirements for data maintenance, submission of structured substance information and the implementation of ISO IDMP standards, a set of internationally harmonised specifications for the unique identification of medicines.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the revised Article 57 requirements is available in the summary note 'Article 57 requirements: information to marketing authorisation holders on the revised format for electronic submission of information on medicines' on the Agency's website.
3. The revised legal notice on the implementation of Article 57(2), second subparagraph of Regulation (EC) No 726/2004, together with the format (detailed guidance and XEVMPD messaging schemas) of the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency and a frequently asked questions document are available on the Agency's website. Working examples are included in the detailed guidance.
4. For any questions on the implementation of Article 57(2), marketing authorisation holders are advised to use the Agency's dedicated mail box: art57@ema.europa.eu and dedicated helpline +44 (0)20 7523 7010.
5. Information on training and how to register to submit data to the Agency can be found on the Agency's website.
6. The summary of the workshop held on 30 January 2012 is available on the Agency's website.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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