EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Addendum 1

Brexit-related audit update

As specified in the Detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency (Doc Ref. EMA/161530/2014), the Medical Literature Monitoring (MLM) service should be subject to an independent audit every two years.

The first independent audit started in December 2015 and the final report was delivered in December 2016. Therefore, a second audit was planned to take place starting in December 2018, two years after the first audit was completed.

Following the decision of the European Council to relocate the European Medicines Agency to Amsterdam in March 2019, the Agency has to ensure the continuation of its main activities throughout the move and has implemented phase 4 of its business continuity plan (BCP) accordingly. The focus will be on the authorisation, maintenance and supervision of medicines, ongoing Brexit preparedness/implementation activities and preparing for the implementation of the new veterinary legislation (highest priority – category 1 activities). As regards the performance of audits, the main focus since July 2017 is on those audits, which are legally required.

On 23 January 2019, the Agency announced additional activities other than the category 1 activities referred to above that will continue in 2019. Since the independent audit of the MLM service is not a legal requirement, the planning of the second audit is currently scheduled for 2020.

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