



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

MLM service quarterly report

August – October 2015

It is a legal requirement for EMA to **monitor selected medical literature for reports of suspected adverse drug reactions** containing certain active substances and to **enter individual case safety reports (ICSRs)** into the EU adverse reaction database (EudraVigilance). Therefore the Agency implemented the medical literature monitoring (MLM) service to Marketing Authorisation Holders (MAHs). Between 1 July and 31 August 2015, the Agency and its contractor executed the in-scope MLM service for the top 50 chemical substance groups as listed on the Agency website. The MLM service entered full production, screening for 300 active chemical substances and 100 herbal substances on 1 September 2015. The full production phase commenced using further refined search strategies which support increased precision. Regular support webinars have been held with industry since 26 May 2015, and will continue fortnightly through to December.

Quarterly service update of the KPIs for the monitoring of the MLM service and review of accuracy of search strategies (month ending 30/08-30/10)

The critical success factor for the MLM service is to ensure timely and adequate daily screening and tracking of the medical literature with publication in EudraVigilance. Once identified, the ICSRs are processed in a timely manner, with appropriate follow-up performed as described in the detailed guide. The contractor ensures responses to all queries received through the MLM service desk to facilitate openness and transparency.

Below are the KPI targets, as set out in the [Launch Phase Closure Report](#) and the results of the August, September and October tracking:



KPI	Target	August 2015	September 2015	October 2015
Daily screening of all 50 active substances during the launch phase and 400 active substances during full production	100%	100%	100%	100%
Publication of screening results by 9am CET the following day	100%	100%	100%	100%
Response to all emails in MLM Service Desk within two business days	100%	100%	100%	98%
Consistent and accurate assessment of literature references	>99%	100%*	100%*	100%*
Timely entry of serious ICSR in EudraVigilance within seven calendar days	100%	72%	91%	96%
Timely entry of non-serious ICSR in EudraVigilance within 21 calendar days	100%	100%	100%	100%
Daily provision of listing of ICSRs generated following literature screening and publication on EudraVigilance website	100%	100%	100%	100%
Correct and timely follow-up of all suspected adverse reactions	>99%	100%	100%	100%

*Percentage of articles retrieved. This KPI takes into account feedback from stakeholders regarding the assessment of whether or not articles contained reportable cases.

Enhancements to the tracking sheets based on user feedback – planned for Q1 2016

1. Cases contained within the tracking sheets will not be removed without explanation, for example, when follow up is not successful, or when identified potential cases are rejected. These will remain in the spreadsheet for an extra day with the relevant column(s) populated which will explain their forthcoming removal;
2. The tracking sheet will include the case version numbers for further clarity;
3. The date columns within the tracking sheet are to change format from text to date
4. The published inclusion/exclusion criteria document will be updated to ensure that the terminology used in tracking sheet is exactly the same;
5. The tracking sheet will be updated to included additional exclusion criteria.

Upcoming milestones

1. Independent Audit of the MLM service to start in December 2015;
2. Stakeholder satisfaction survey to be distributed in Q1 2016.