EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Medical Literature Monitoring (MLM) Service

8th Stakeholder Forum - Session 3 – Process improvement for public health and product lifecycle support

Presented by Sabine Brosch, 15 September 2014
Monitoring and Incident Management Services

Overview

A. Legal background

B. Key concepts for MLM service

C. Establishment of MLM service

D. Conclusions

A. Legal Background

Article 27 of Regulation (EC) 726/2004:

1.The Agency shall **monitor selected medical literature** for **reports of suspected adverse reactions** to medicinal products containing certain active substances. It shall **publish the list of active substances being monitored** and the medical literature subject to this monitoring.

2.The Agency shall enter into the **Eudravigilance** database relevant information from the selected medical literature.

3.The Agency shall, in consultation with the Commission, Member States and interested parties, draw up a **detailed guide** regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

A. Legal background

Article 107(3) of Directive 2001/83/EC:

……

For medicinal products containing the active substances referred to in the list of publications monitored by the Agency pursuant to Article 27 of Regulation (EC) No 726/2004, **marketing authorisation holders** shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed medical literature, but they **shall monitor all other medical literature and report any suspected adverse reactions**.

B. Key concepts for MLM service

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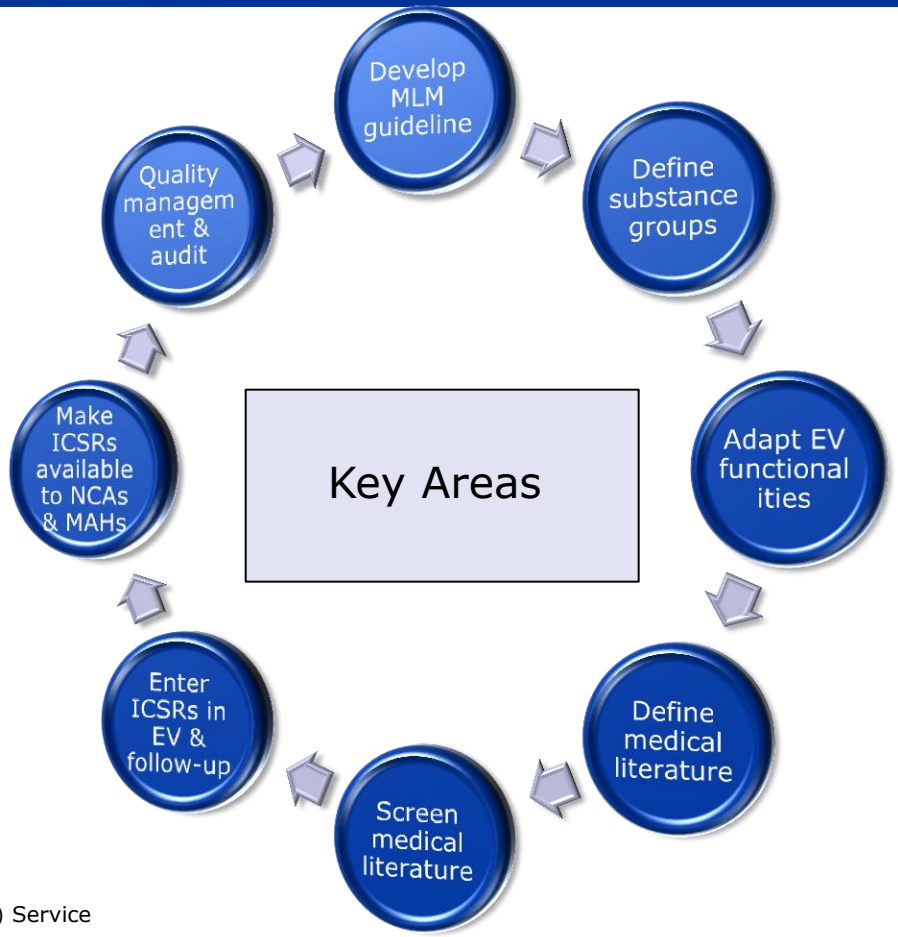
- As part of the requirements gathering EMA consulted EU pharmaceutical industry associations end of 2013
- Key concepts raised by industry are as follows:
  - Alleviate the burden on maximum number of MAHs
  - Innovative medicinal products should not be covered
  - Avoid partial service that would necessitate duplicative efforts by industry
  - Provide quality controlled literature monitoring services
  - Establish a process so that MAHs can comply with the worldwide regulatory requirements

C. Establishment of MLM service



C. Establishment of MLM service

Drafting of MLM guide (EMA/161530/2014)

- Released for public consultation on 5 June 2014
- Consultation closed on 27 July 2014
- Very good response – comments focus mainly on process and scope related aspects

Final guide expected end of 2014

C. Establishment of MLM service

Defining substance groups

- Based on highest number of MAHs in the EU and grouped as follows:
  - 300 substance groups (by active moiety including e.g. salts, esters and fixed combinations)
  - 100 herbal substance groups (by genus)
- *Actual number of substance groups included in the Agency's MLM service will depend on allocated budget and price of service by third party service provider*

Substance groups will be updated annually

C. Establishment of MLM service

Adapting EudraVigilance functionalities

- Publication of reference to medical literature database(s) and search parameters by substance group
- Publication of search and screening results with flagging of specific interest areas
- Processing of ICSRs by third party service provider
- Transmission of ICSRs to Member State where the reactions occurred
- Downloading of MLM ICSRs by MAHs in E2B format

Expected for completion end of January 2015

C. Establishment of MLM service

Putting in place the MLM service

- MLM open tender to establish suitable third party service provider
- Set up phase
- Pilot phase to prepare for implementation with involvement of concerned MAHs and NCAs
- Service desk

Start of pilot phase by mid 2015 with view towards a full service by the end of the year

C. Establishment of MLM service

Quality management and Auditing

- Well-defined and regularly audited quality management practices to be put in place by third party service provider
- Two yearly, independent audit of the contractor's internal quality management and control systems and of MLM service

1st independent audit no later than six months from operation of the service

D. Conclusions

The EMA MLM service will deliver on:

- Process improvement for MLM activities
- Resource savings for MAHs benefiting from the MLM service
- Improved guidance on MLM
- Reduction of duplicates in EudraVigilance – better data quality facilitating signal detection

Thank you for your attention

Further information

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000520.jsp&mid=WC0b01ac05804fa031

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