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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance Programme UPDATE

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IN THIS ISSUE

This Update

This second Pharmacovigilance Programme Update is primarily aimed at providing marketing authorisation holders (MAHs) with information to help prepare for the business change to come.

Preparing for business change

New EU Pharmacovigilance legislation has been operational since July 2012. A recent report demonstrates success with the operation of the new systems and processes. The legislation foresees various information systems to enhance pharmacovigilance, particularly to support the collection, management and analysis of data, information and knowledge. These systems will contribute to public health through optimisation of the safe and effective use of medicines. They should also facilitate pharmacovigilance, delivering rationalisation and efficiency gains. The first pharmacovigilance Programme Update, distributed in August 2014, gave a brief overview of the key system and service developments.

Need more information?

For topics on implementation of the new Pharmacovigilance legislation – see here.

Further information about the work of the European Medicines Agency is available on our website.

Links to the National Competent Authorities can be found here.

Database of Medicinal Products (Article 57)

Scope:

- To deliver structured and quality assured information on medicinal products authorised in the EU that can support EU terminologies of products, substances, and organisations used to power pharmacovigilance and regulatory systems in the EU.

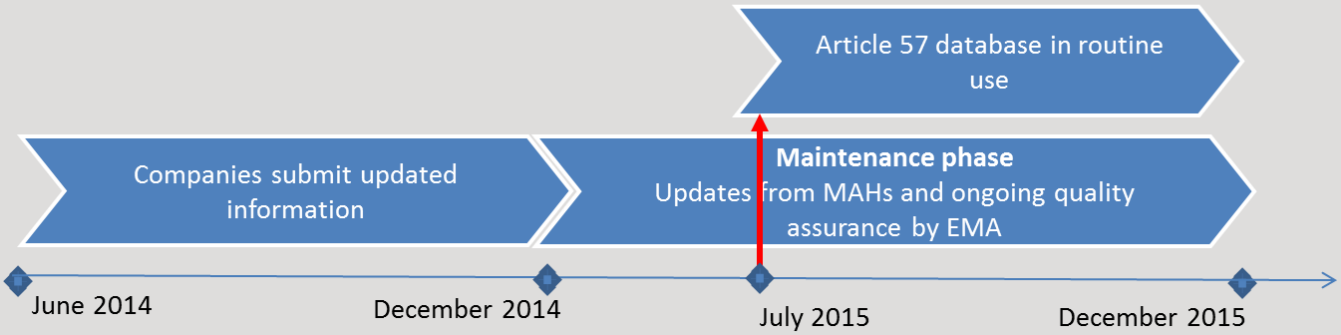
What MAHs need to do:

- By 31 December 2014, MAHs are required to complete previously submitted product data with additional information, bring this information up–to-date and improve the data quality, in line with plan agreed with the industry associations;
- From January 2015 onwards, industry is required to keep the structured information on medicines up- to-date and notify the EMA of any variation to the terms of marketing authorisation within 30 calendar days of the date of approval of the changes;
- MAHs are also required to submit information on new marketing authorisations granted in the European Economic Area (EEA) within 15 calendar days from the date of notification of the granting of the marketing authorisation by the national competent authority (NCA).

Benefits:

- Facilitate the coordination of regulatory decisions and actions to safeguard public health and to fulfil regulatory actions and legal obligations including:
  - literature monitoring service;
  - repository of Periodic Safety Update Reports (PSURs);
  - support referral procedures;
  - support collection of pharmacovigilance fees;
  - support identification of products and substances in reports of suspected adverse drug reactions.
- Strengthen transparency and communication with stakeholders by granting access to safety data, efficiently exchanging data within the EU Network and international partners, and supporting communication between the Agency's Committees and the pharmaceutical industry;
- Support the reduction of duplication of encoding and maintenance of the same information on medicines, thus reducing costs (e.g. implement a single database and set of terminologies for multiple business cases).

Article 57 database on medicinal products



Database of Medicinal Products (Article 57) news:

- At the end of July 2014, the Agency commenced the review of the quality of the structured information on medicines, which had been submitted according to the format and guidance/maintenance processes released on 16 June 2014. MAHs started to receive feedback on the outcome of the data quality review. Further information is available here;
- New functionality to allow bulk updates of structured information on medicines (i.e. changing values of individual fields in more than one product entity at the same time) has been released;
- Building on industry compliance with the 31 December timeline, the Article 57 database is expected to support various Pharmacovigilance activities as of the end of Q2 2015;
- The EMA performs data integrity revision. When errors are found and information is available to correct it, corrections are made by the Agency in the Article 57 database. A quality control report is provided to the sender organisation's Qualified Person for Pharmacovigilance (QPPV), outlining the quality findings and the required actions to be taken by the concerned MAH. Should the marketing-authorisation holder object to any of the changes/corrections made by the EMA, or to receive further clarification on the performed amendments, an email should be submitted to the Article 57 Quality Control Inbox (Art57-QC@ema.europa.eu).

Need more information?

Data submission for authorised medicines

List of guidance documents related to the data submission for authorised medicines

Public website of suspected adverse reactions

Scope:

- To allow public access to aggregated information on reported suspected adverse drug reactions (ADRs).

News:

- On 6 October www.adrreports.eu was extended to give citizens access to information on suspected side effects of an additional 1,700 active substances contained in medicines approved in the EU. Since its launch in 2012, the database already contained information on all centrally authorised products.

Need more information?

Further information to be found at :

www.adrreports.eu

Pharmacovigilance Fees

Scope:

- The pharmacovigilance legislation foresees that pharmacovigilance activities conducted at EU level for medicinal products for human use should be financed by fees paid by MAHs. The newly adopted pharmacovigilance fees regulation allows the EMA to collect these fees;
- The income will be used to remunerate national competent authorities (NCAs) of the EU for the scientific assessment carried out by the rapporteurs and to contribute to the pharmacovigilance-related costs of the Agency.

Benefits:

- In addition to remunerating procedures, supports the implementation and maintenance of measures from the 2010 pharmacovigilance legislation including: literature monitoring, enhanced functionalities for EudraVigilance and the PSUR repository which ultimately provides public health benefits across Europe;
- Delivers functionality for online payment of fees and updating of account details.

What MAHs need to do:

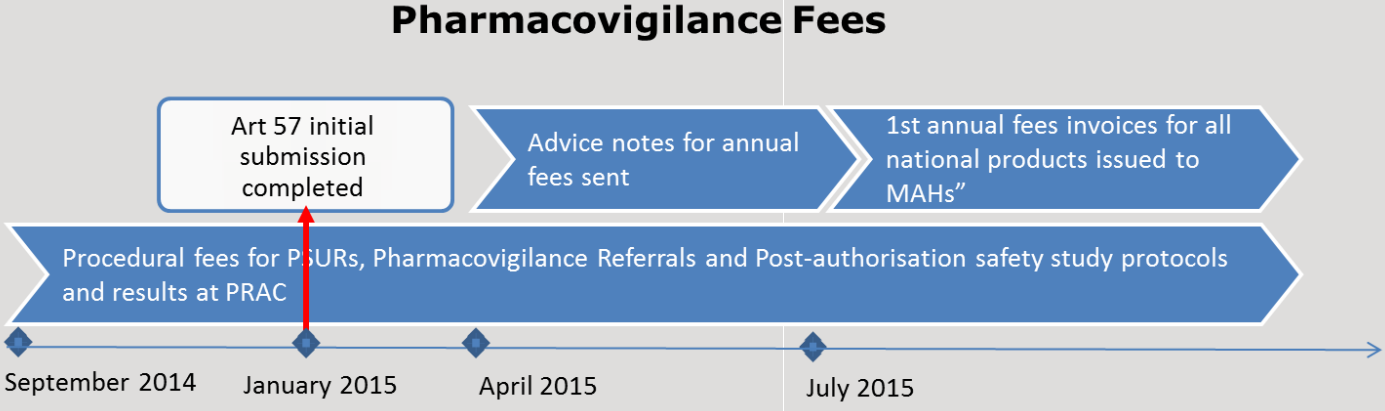
- Get familiar with the regulation and guidance (those being charged for procedure-based fees will receive specific instructions);
- Continue verifying structured information on medicines received in the advice notes. Please note that if the data in the 'Article 57 database' is not correct, you may be billed incorrectly.

News:

- Advice notes (for specific procedure-based fees) have been sent out to allow companies to preview the list of 'Chargeable Units' subject to a Pharmacovigilance Fee. This provides companies with an opportunity to update their data in the 'Article 57 database' prior to billing (chargeable units are derived from data in the Article 57 database);
- The first procedure-based fees have been charged to relevant MAHs and the first payments have been received;
- EMA co-operation with MAHs to ensure Article 57 data correctness is ongoing;
- The latest project status was presented at the Article 57 Implementation Working Group Forum;
- Work is ongoing to develop an automated, long-term solution to deliver additional functionalities.

Need more information?

Fees payable to the European Medicines Agency



Adverse drug reaction reporting and Signal management

Need more information?

https://eudravigilance.ema.europa.eu/human/index.asp

Scope:

- There is a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, better quality data and better searching, analysis and tracking functionalities. Enhanced detection of new or changing safety issues allows more rapid action to protect public health;
- Legal requirement for MAHs to monitor data they have access to in EudraVigilance.

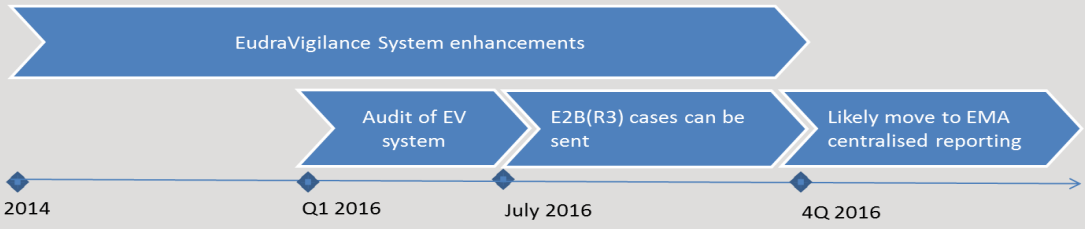
Benefits:

- Compliance with international data standards (and future compatibility with ISO IDMP standards based on Article 57 data) including backwards and forwards conversion tools for E2B(R2)/(R3) messages;
- Improved performance and scalability of new system to cope with foreseen increase in users and volume of data;
- Simplified reporting delivered.

What MAHs need to do:

- Prepare for use of the new data format – ISO/ICH ICSR E2B(R3) – and simplified reporting to EudraVigilance;
- Plan for the implementation of the revised EudraVigilance Access Policy, which will lead to increased access to adverse reactions reports and responsibilities for signal detection (see Art.18 of Commission Implementing Regulation (EU) No 520/2012);
- Engage with information and training events.

Adverse drug reactions and Signal management



News:

- Following extensive consultation the new ISO standard and ICH implementation guide for ICSRs has been published. This guidance specifies the technical requirements and the process of transmission of ICSRs. http://estri.ich.org/;
- Development of ICSR backwards and forwards conversion rules for EU specific data fields is ongoing;
- The Implementation Working Group (IWG) on E2B(R3) has adopted an updated Q&A document;
- Following the closure of the public consultation in September 2014, the EudraVigilance Access Policy is being finalised. This foresees enhanced access to data to conduct product monitoring and defines future access to EudraVigilance by MAHs;
- EudraVigilance Audit Plan will be discussed at the PRAC meeting in Q1 2015 and is anticipated for adoption by EMA Management Board in March 2015;
- Following the public consultation which ended on 30 June 2014, the EU ICSR Implementation Guide has been finalised and is expected to be published in December 2014.

PSUR repository

Scope:

- Legal requirement for EMA to set up a repository for periodic safety update reports (PSURs) and their assessment reports;
- To allow centralised PSUR reporting and to enhance access to data and information, thereby supporting benefit risk assessments of medicines.

Benefits:

- Provides a simplification of PSUR submissions benefiting pharmaceutical industry (PSURs submitted electronically to the Repository, submissions accessible to regulators);
- Once the use of the Repository is mandatory, it will include all PSURs, including those that follow the PSUR Single Assessment (PSUSA) and those PSURs which are not part of a Single Assessment;
- Delivers a user interface to regulators to query and retrieve documents by use of metadata based on fields present in the list of EU reference dates (EURD list) for each active substance/combination of active substances;
- Delivers a user interface to upload assessment reports and comments by the National Competent Authorities to the repository.

Need more information?

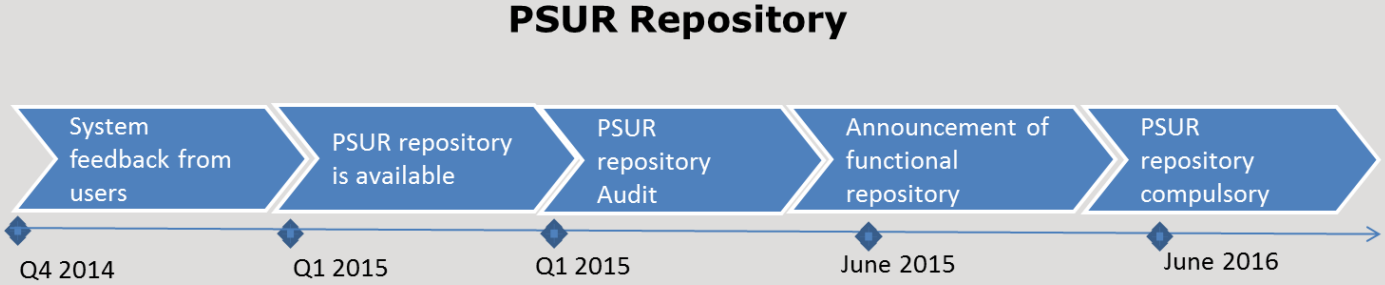
http://esubmission.ema.europa.eu/index.htm

News:

- Requirements gathering for the auditable release of the PSUR Repository have concluded and the system has been developed according to the detailed business requirements defined together with the National Competent Authorities and industry. Finalisation of detailed business requirements elaboration for post-audit deliverables is planned for the end of this year;
- User Acceptance Testing with National Competent Authorities and Industry was completed in November;
- The PSUR Repository system release is scheduled for early 2015.

What MAHs need to do:

- Follow announcements on the EMA website in anticipation of the PSUR repository being available in 2015 and mandatory in 2016;
- Enrol for webinar training sessions on how to submit to the PSUR Repository (see website for details).



Medical Literature Monitoring

Scope:

- 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 into the EU adverse reaction database (EudraVigilance);
- This will improve safety monitoring of medicines through better quality of safety information. This will reduce the administrative burden on MAHs for the relevant substances.

News:

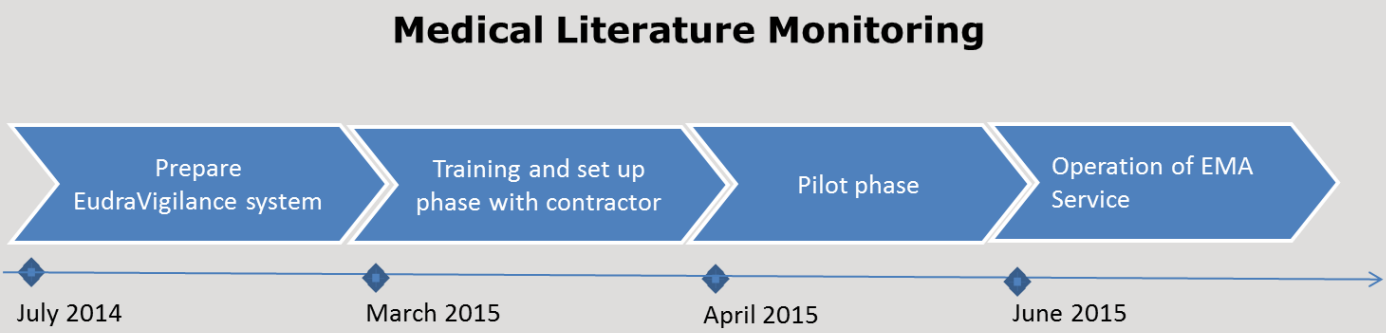
- The Medical Literature Monitoring guideline is being updated following the public consultation and the finalised guidance will be published in Q2 2015;
- On 4 November 2014 the tender for establishing the literature monitoring service by the Agency was launched;
- Operation of the Medical Literature Monitoring service starts with a pre-production pilot scheduled in Q2 2015.

Need more information?

Lists the European Medicines Agency's (EMA's) current calls for tender

What MAHs need to do:

- Consider the impact of the EMA literature service (which will be operational from Q2 2015) on your business processes;
- Q1 2015 EMA will work with stakeholders on business change preparation.



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