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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance Programme UPDATE

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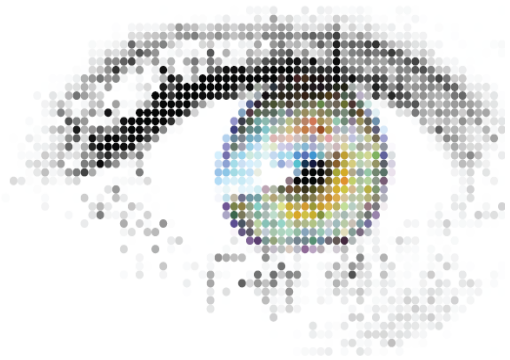
IN THIS ISSUE

This Update

This Update is the first in a series of documents primarily aimed at providing marketing-authorisation holders (MAHs) with information on the development of the enhanced systems, helping MAHs prepare for the business change to come. Update documents will be issued quarterly.



Preparing for business change

New European Union (EU) Pharmacovigilance legislation became operational in 2012 with new responsibilities for industry and regulators and new business processes, channelled through the Pharmacovigilance Risk Assessment Committee (PRAC). A recent report demonstrates success with the operation of the new systems and processes

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/05/news_detail_002092.jsp&mid=WC0b01ac058004d5c1)

In addition, 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 the promotion and protection of public health through optimisation of the safe and effective use of medicines. They should also facilitate pharmacovigilance, delivering rationalisation and efficiency gains.

Need more information?

For topics on implementation of the new Pharmacovigilance legislation – follow the link below:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000491.jsp&mid=WC0b01ac058058f32d

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

http://www.ema.europa.eu

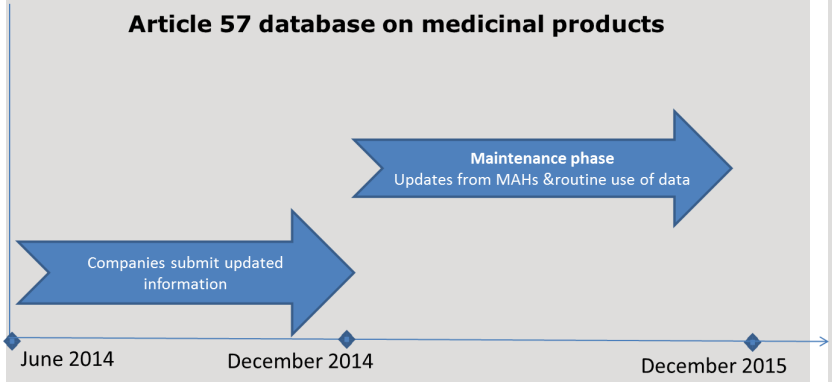
Links to the National Competent Authorities can be found at:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63

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

MAHs for all authorised products should submit updated medicinal product information by the end of 2014, in line with plan agreed with the industry associations.

(http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002126.jsp&mid=WC0b01ac058004d5c1)

Need more information?

Further information to be found at :

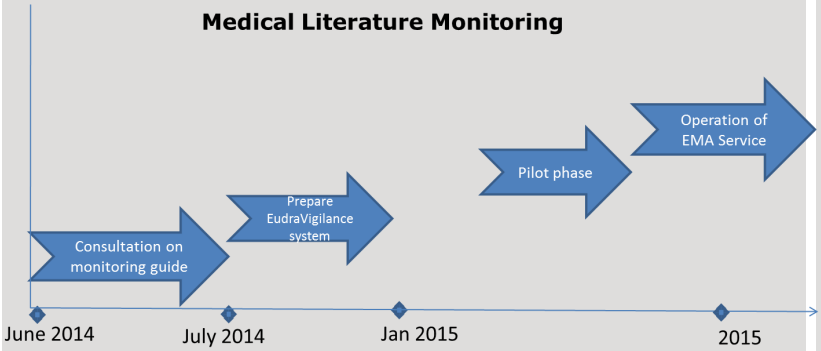
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0

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.



What MAHs need to do

Comment on the draft Medical Literature Monitoring guide (see link below).

Consider whether EMA literature service operational from 2015 will impact your business processes.

Need more information?

Further information to be found at :

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002118.jsp&mid=WC0b01ac058004d5c1

Adverse drug reaction reporting and Signal management

Scope

There is a legal requirement for 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.

In addition

Compliance with international data standards including backwards and forwards conversion tools for E2B(R2)/(R3) messages.

Conversion of legacy data (>7 million ICSRs currently held).

System performance and scalability based on more users and more data.

Reinforced security (authentication, authorisation and data transaction).

For those involved in pharmacovigilance, delivers

Marketing Authorisation Holders: simplified reporting to EudraVigilance and enhanced access to data to conduct product monitoring.

Member State authorities: reporting to EudraVigilance, company data forwarded from EudraVigilance and enhanced data analysis, signal detection and tracking tools available.

Healthcare professionals and public: data and search availability via the web for medicines and substances authorised in EU.

World Health Organisation: prompt electronic availability of all suspected ADR reports reported in the EU.

What MAHs need to do

Comment on the revision of the EudraVigilance Access Policy (Public consultation to be launched in July 2014).

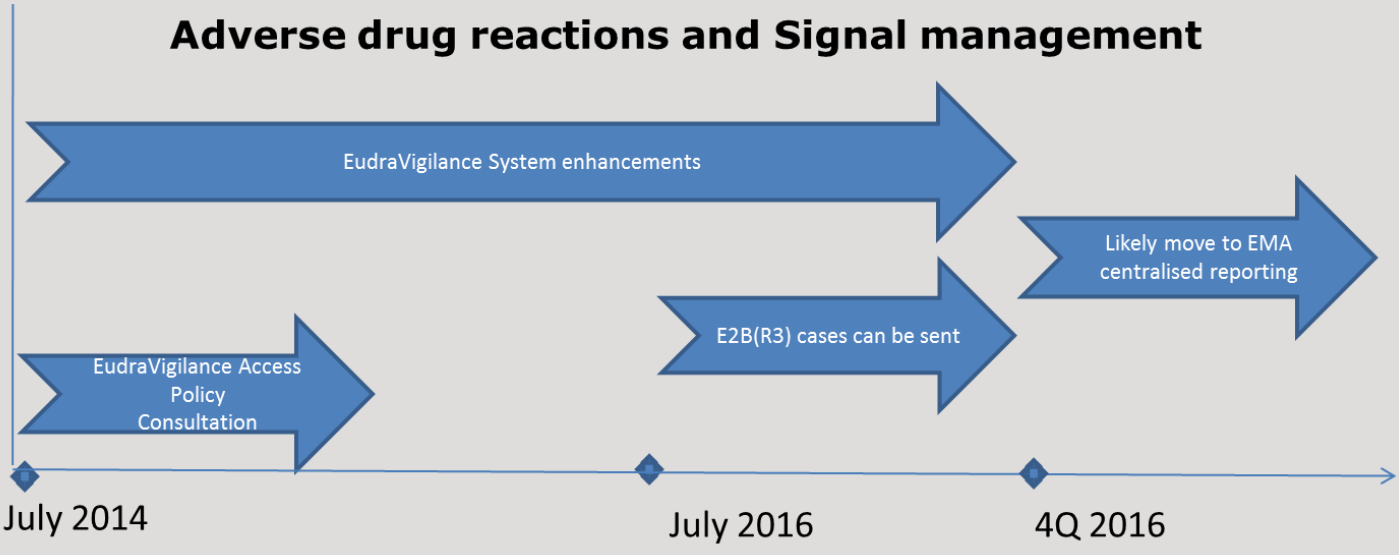
Engage with information and training events.

Prepare for new data format - E2B(R3) – and simplified reporting to EudraVigilance.

Need more information?

Further information to be found at :

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



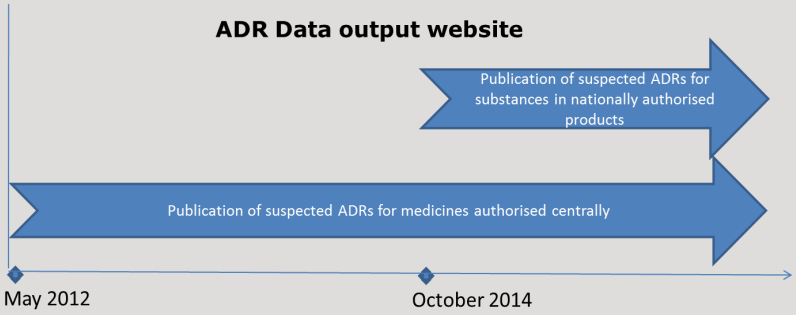
Public website of suspected adverse reactions

Scope

To make aggregated information on reported suspected adverse drug reactions (ADRs) available to the general public and healthcare professionals.

The www.adrreports.eu website already covers reported suspected ADRs for substances included in centrally authorised products from the EudraVigilance database.

Expand the scope of publication of suspected ADRs for substances in most Nationally Authorised Products from October 2014.



What MAHs need to do

No action required – for information only.

Need more information?

Further information to be found at :

www.adrreports.eu

PSUR repository

Scope

Legal requirement for EMA to set up a repository for periodic safety update reports (PSURs) and their assessment reports.

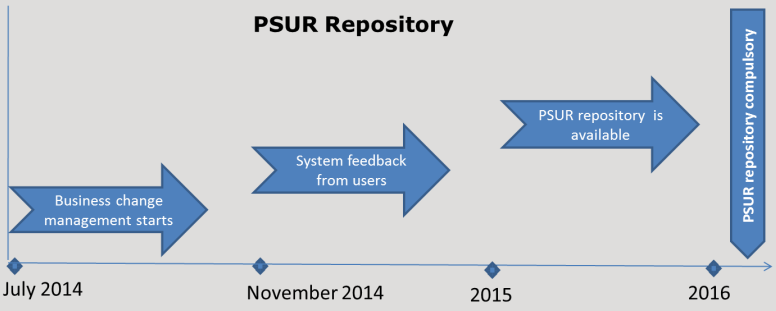
To allow centralised PSUR reporting and to enhance access to data and information, thereby supporting benefit risk assessments of medicines.

System will provide

One secure electronic submission point for marketing authorisation holders (streamlining PSUR submissions for the pharmaceutical industry).

A common storage place for PSUR, PSUR assessment reports and PRAC recommendations (access for Member States and assessors).

Support the PSUR single assessment procedure.



What MAHs need to do

Follow announcements on the EMA website in anticipation of the PSUR repository being available in 2015 and compulsory in 2016.

Need more information?

Further information to be found at :

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

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 of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) and to contribute to the pharmacovigilance-related costs of the Agency.

Two types of fees will be charged

Procedure-based fees will be charged for the single assessment of periodic safety update reports (PSURs) and the assessment of imposed, non-interventional post-authorisation-safety-study (PASS) protocols and study results, and for pharmacovigilance-related referrals. This fee is split among the marketing-authorisation holders concerned by the procedure and will be charged for procedures starting from 26 August 2014.

An annual fee that applies to nationally authorised products. This fee will be applicable from January 2015 and will be charged as of 1 July 2015. Annual fees related to centrally authorised products are covered by the existing fee Regulation.

What MAHs need to do

All Marketing Authorisation Holders of both centrally authorised as well as nationally authorised medicinal products to familiarise themselves with the new rules (those being charged procedural fees will receive specific instructions).

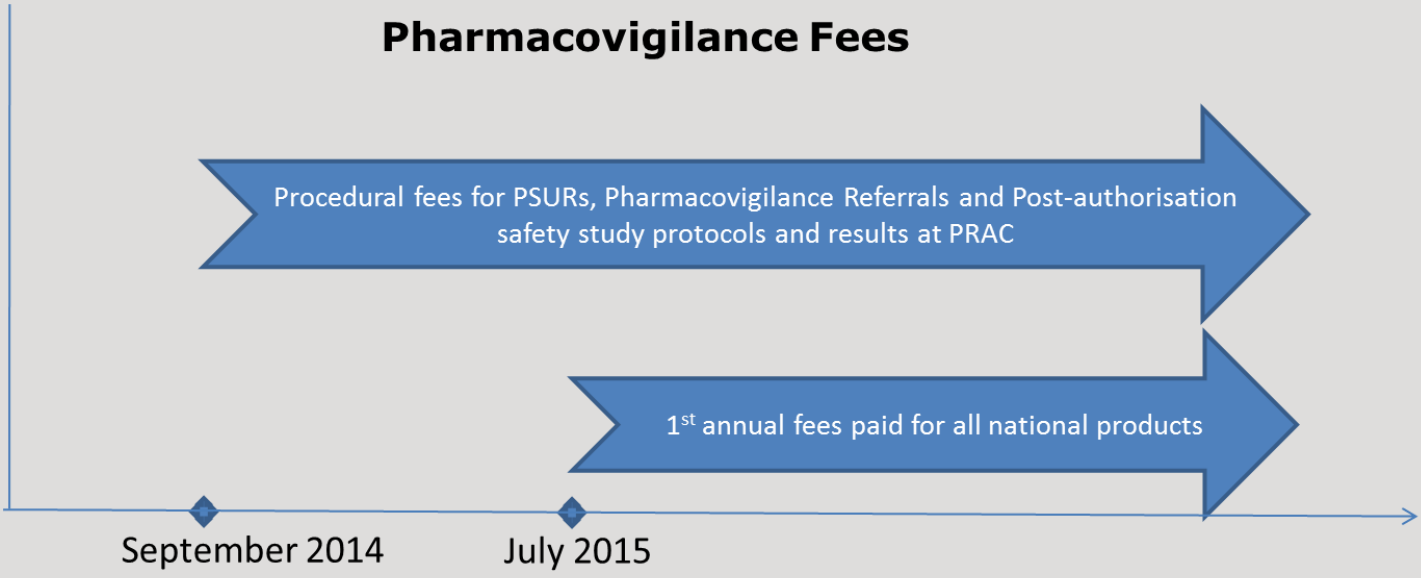
First procedural fees (PSURs, PASS and referrals) invoiced for procedures starting from 26 August 2014.

First annual fee in July 2015 for all nationally authorised products in the EU.

Need more information?

Further information to be found at :

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000327.jsp&mid=WC0b01ac0580024596



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