



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance: Information systems and Services

3rd Industry stakeholder platform – operation of EU Pharmacovigilance
legislation



Presented by Peter Arlett

Head of Pharmacovigilance Department

An agency of the European Union





Preparing for business change

The new EU Pharmacovigilance legislation has been operational since July 2012. 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, involving the processes and systems of EMA, NCAs and MAHs.

We are at an important point in our projects with major deliverables scheduled throughout 2015 to support business activities of the revised pharmacovigilance legislation and to improve the relevant business functions to maximise the benefits for stakeholders.



Vision



The primary objective is to deliver the IT systems needed to support the business activities of the revised pharmacovigilance legislation, and to change the relevant business functions to maximise the benefits from these new systems.

Between 2015 and 2020...

Strengthen our foundations

Provide robust, high quality and sustainable systems and services to gather and analyse data and information for pharmacovigilance , drawing from and available to our stakeholders.

Realise benefits of regulatory change

Provide systems and services that support the implementation of pharmacovigilance by industry and regulators, to positively impact patient and consumer health.

Enhance Pharmacovigilance through effective implementation of information systems and services

Provide project oversight, accountability, aligned planning activities and integrated solutions to ensure successful delivery of changes.



Projects to deliver the vision

The vision will be delivered through 5 ongoing projects;





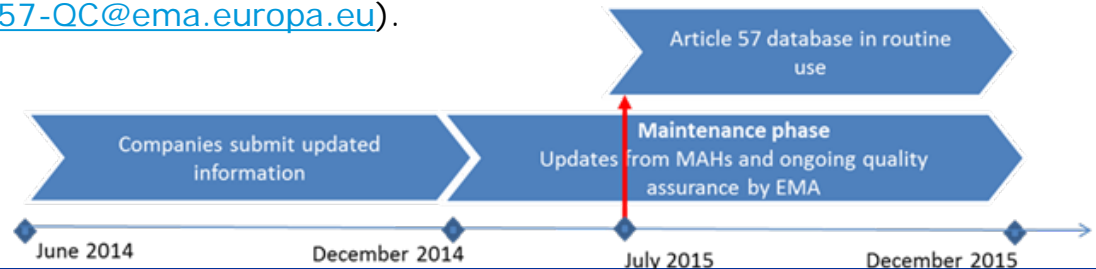
Scope

- 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.
- Facilitate the coordination of regulatory decisions and actions to safeguard public health and to fulfil regulatory actions and legal obligations including:
 - identification of products and substances in reports of suspected adverse drug reactions;
 - literature monitoring service;
 - repository of Periodic Safety Update Reports (PSURs);
 - referral procedures;
 - collection of pharmacovigilance fees.
- 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).

Benefits

News

- The current Art57 initial data re-submission produced 463000 products updated in the Art57 database. The EMA is continuing to support industry in the submission of medicinal product data under the Article 57 legal requirements.
- The EMA will follow-up on submissions from MAHs that informed of a delay in their submission plans.
- EMA continues its co-operation with MAHs to ensure Article 57 data correctness. As of the end of February approximately 97,000 Products (EVCodes) have been quality reviewed against the provided SmPCs. When errors are found, and there is information available to correct it, amendments 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 MAH wish to query any of the changes/corrections made by the EMA, or would like 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).



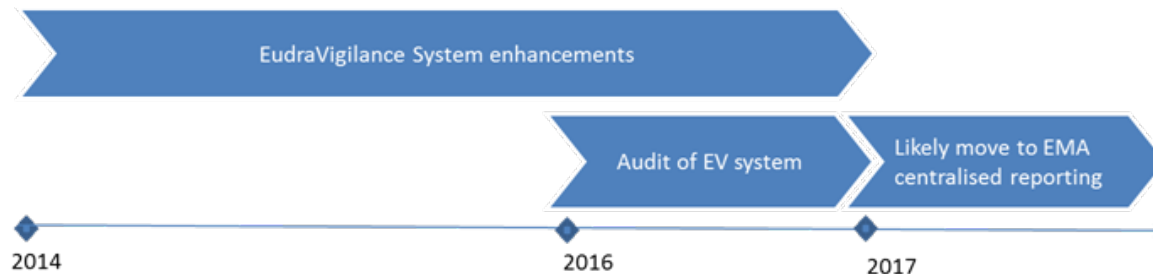


Scope

- 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 EudraVigilance data to which they have access.

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 for MAHs.





News

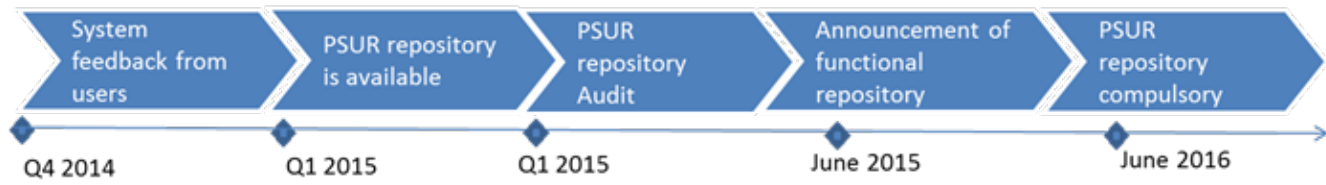
- On 21st January 2015 the EMA published a guide to support the implementation of a new international standard for the safety monitoring of medicines in the EU. The so-called ISO ICSR standard improves the reporting of suspected side effects of medicines in Individual Case Safety Reports (ICSRs).
- The transition to using the new international standard will be actively managed by the Agency in collaboration with NCAs and MAHs. This transition will be the subject of future communications;
- The testing of the ICSR backwards and forwards conversion rules for EU specific data fields is ongoing with the plan to complete the work by the end of April 2015;
- Following the closure of the public consultation in September 2014, the EudraVigilance Access Policy is being finalised and is expected to be published in Q3 2015. This foresees enhanced access to data to conduct product monitoring;
- The EudraVigilance Audit Plan will be discussed at the Pharmacovigilance Risk Assessment Committee ahead of adoption by EMA Management Board later this year;
- As a service to industry and to increase efficiency the Agency has started to translate its recommended changes to product information based on the assessment of safety signals into all official languages of the European Union (EU). The translations should be used by MAHs to update the product information of their medicines.

Scope

Benefits

- 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.

- 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.

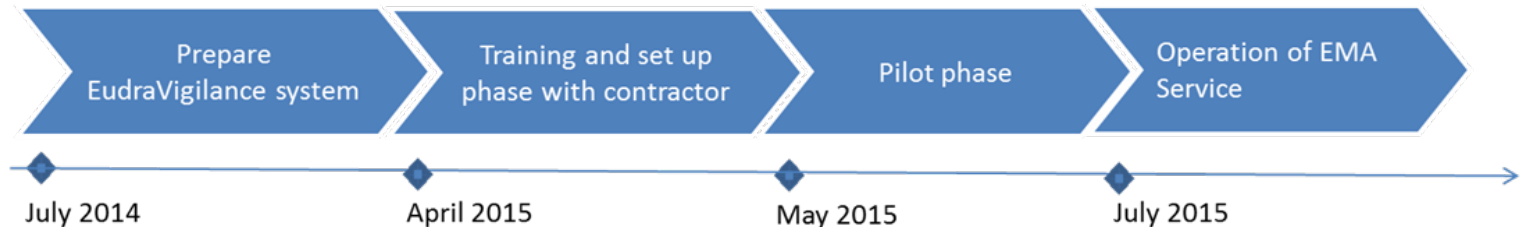


Scope

- 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).

Benefits

- This will improve safety monitoring of medicines through better quality of safety information;
- This will reduce the administrative burden on Marketing Authorisation Holders (MAHs) for the relevant substances;
- MAHs will have access to up-to-date results of MLM activities and ICSRs generated, allowing them to repost ICSRs to other regulatory bodies (outside EU) in a timely fashion;
- Supports signal detection activities by the EMA, National Competent Authorities (NCAs) in EEA and MAHs.

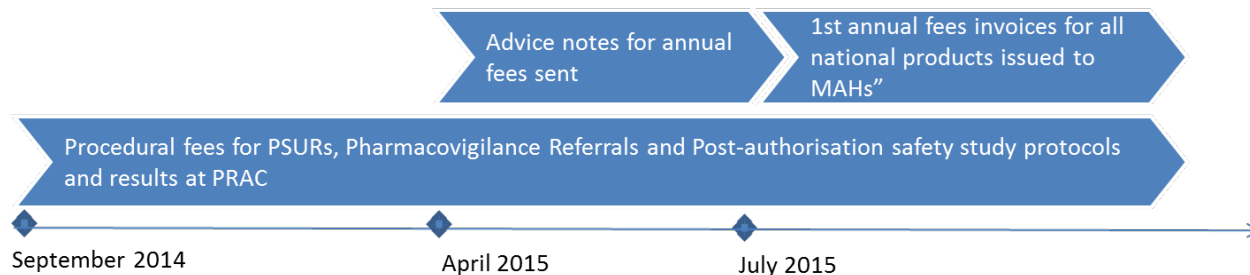


Scope

- 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 pharmacovigilance fees regulation adopted in 2014 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.





Thank you for your attention

Further information

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000491.jsp&mid=WC0b01ac058058f32d

European Medicines Agency

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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