EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Pharmacovigilance systems and services

4th Industry Stakeholder platform, 12 June 2015

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Head of Pharmacovigilance department

An agency of the European Union

Pharmacovigilance Projects

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Projects & Outputs	Benefits Delivered	Driven By
Article 57 Database *European database of all medicinal products*	• Support PV Procedures which facilitates coordination of regulatory decisions • Supports the product index for EudraVigilance • Reduction of duplication	**Effective programme management** which ensures successful delivery of changes
EudraVigilance Auditable Requirements *Enhanced adverse reaction collection and management system*	• Simplified reporting delivered • Data in ISO format will be higher quality, improving searchability & analysis efficiency	
Medical Literature Monitoring *Delivery of literature monitoring service to MAHs*	• Improved safety monitoring of medicines • Reduction in costs for MAH literature monitoring activities	
Pharmacovigilance Fees *Collection of fees to cover costs of conduct of certain PV activities*	• NCAs paid for certain PV assessments • Annual fees support implementation & maintenance of measures from 2010 legislation	
PSUR Repository *Centralised repository for PSURs and assessment reports*	• Provides a simplification of PSUR submissions for industry • Repository will include all PSURs and assessment reports	

Provides public health benefits across Europe

EU medicinal product database (Article 57)

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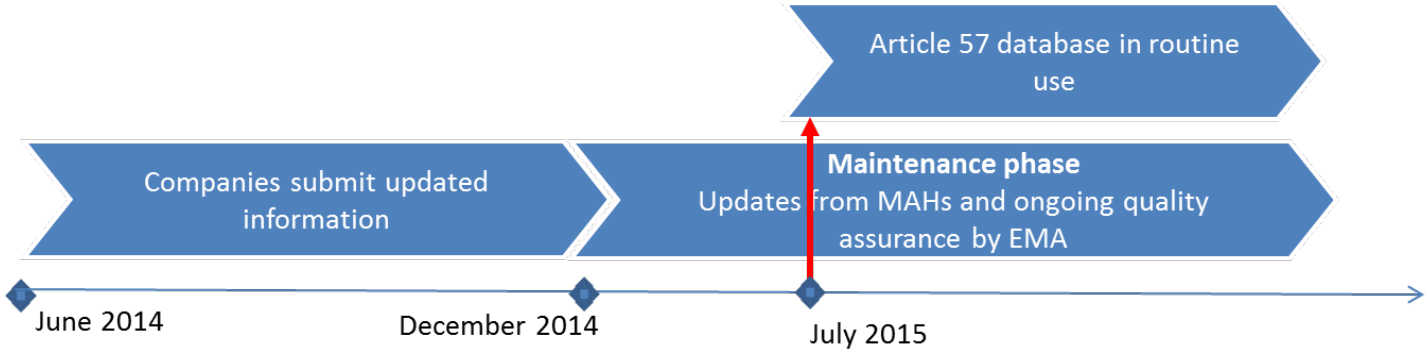
Scope

- 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.

Timelines



EU medicinal product database (Article 57)

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News

- 500,000 products submitted to the Art57 database;
- EMA continues its co-operation with industry to ensure Article 57 data correctness;
- To further support with submission of the high quality data Agency and Industry have agreed to implement an additional XEVPRM XML Acknowledgement message (the 3rd Acknowledgement) to the sender's organisation ID. The roll-out of this notification is scheduled for November 2015;
- QPPVs named in the Article 57 database should reflect the individual carrying the responsibility of QPPV laid down in EU legislation. However, QPPVs may delegate operational activities associated with maintaining the Article 57 database to their internal teams;
- In autumn 2015 the Agency is launching a service for the National Competent Authorities to make available the relevant information from the Article 57 database such as the QPPVs contact details, the contact information for pharmacovigilance enquiries and the locations in the Union where pharmacovigilance system master files are kept.

EudraVigilance

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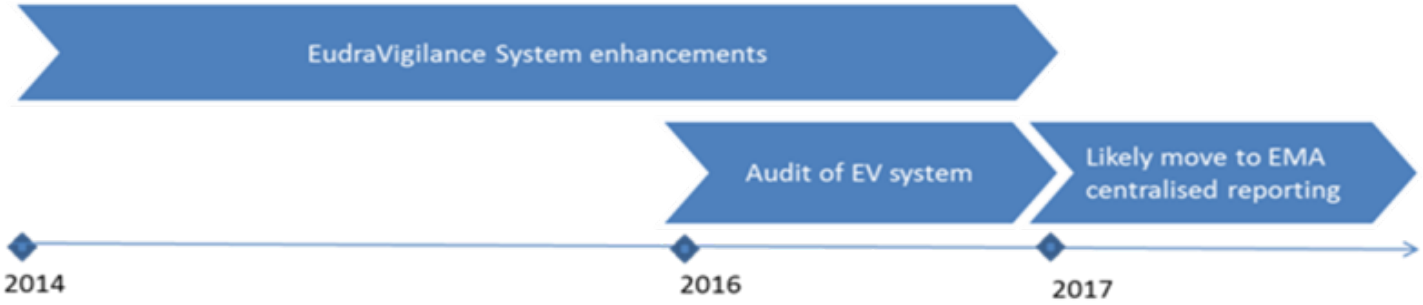
Scope

- 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.

Timelines



EudraVigilance

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- Following the closure of the public consultation in September 2014, the EudraVigilance Access Policy is being finalised and is expected to be published in Q4 2015. This foresees enhanced access to data to conduct product monitoring;
- The EudraVigilance functionalities audit is scheduled to take place in 2016, with the move to centralised reporting in 2017;
- The transition to using the new international standard will be actively managed by the Agency in collaboration with NCAs and MAHs. The Stakeholder business change management plan will be launched in Autumn 2015;
- The extensive testing of the ICSR forwards conversion rules for EU specific data fields has been completed and further testing is planned for the backwards conversion rules at the end of the 2015, once E2B(R3) generating PhV systems become available.

Medical Literature Monitoring

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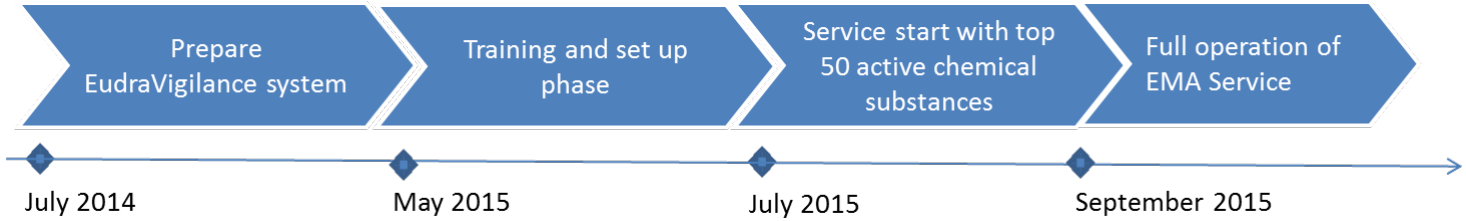
Scope

- 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).

Timelines



Medical Literature Monitoring

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News

- On 12 May 2015 the EMA published: a list of substances and a description of the literature reference database, a detailed guide regarding the monitoring of medical literature and a series of training videos;
- As of the 1st July 2015, the service will cover the top 50 active chemical substance groups and is expected to reach full operational levels by September 2015, covering 300 active substances and 100 herbals;
- Additional supporting documents, including the duplicate management process and Questions and Answers document were published on 12 June 2015;
- Dedicated questions and answers sessions with NCAs and MAHs were held on 26 May, 2 June, 8 June and 15 June. The MLM support sessions are planned on a monthly basis until the end of the year (see Medical Literature Monitoring website for schedule);
- A dedicated service desk will be available as of 1st of July to assist in dealing with specific enquiries from MAHs and NCAs in EEA Member States;
- Teleconference with Industry on the MLM change management took place on 5 June (EFPIA/EuropaBio, EGA, AESGP). Additional teleconference on the MLM change management planned for 19 June 2015, focusing on review of the Start-up Plan;
- EMA is preparing a “Start-up Plan” for the first two months of the operation of the service, which should also recognise the need for MAHs to further adapt business processes and IT systems during the start-up phase and address other points raised by EFPIA in their letter of 1 June 2015;
- Question on world-wide unique case identifier will be addressed in Q&A document (non-issue).

PSUR Repository

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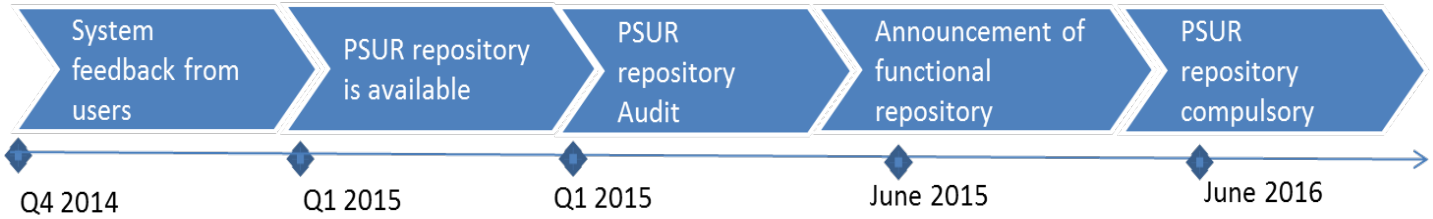
Scope

- 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.

Timelines



PSUR Repository

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- Based on a positive PRAC Recommendation and the independent audit report on 11 June 2015, the EMA Management Board decided that the PSUR repository meets the functional specifications as agreed in the 'PSUR Repository functionalities to be audited' document and therefore concluded that it has achieved its full functionality. The legislation foresees that 12 months after the EMA Management Board announcement, **the use of the repository in the European Union will become mandatory** (13 June 2016);
- Encouragement to MAHs to use the repository for all PSUR submissions, even those outside of the single assessment;
- The detailed business requirements for the 4 non-auditable requirements have been finalised and the planning for the post-audit functionalities has successfully passed the audit. The development of the post-audit functionalities will likely start in July 2015 to deliver enhancements to the system in terms of usability and support to the work of the regulatory network. The delivery of the 4 non-auditable requirements, as agreed by the EMA Management Board in December 2013, is planned for Q4 2015;
- From 1 September 2015, the use of the XML delivery file for all PSUR submissions to the EMA via the eSubmission Gateway and/or the Web Client will also become mandatory. After this date, it will no longer be possible to submit PSURs using the existing filenaming convention. The mandatory use of the PSUR XML delivery file is introduced to harmonise the submission mechanism for all PSURs submitted to EMA and it will apply to all types of PSUR and PSUR supplementary information submissions.

Pharmacovigilance Fees

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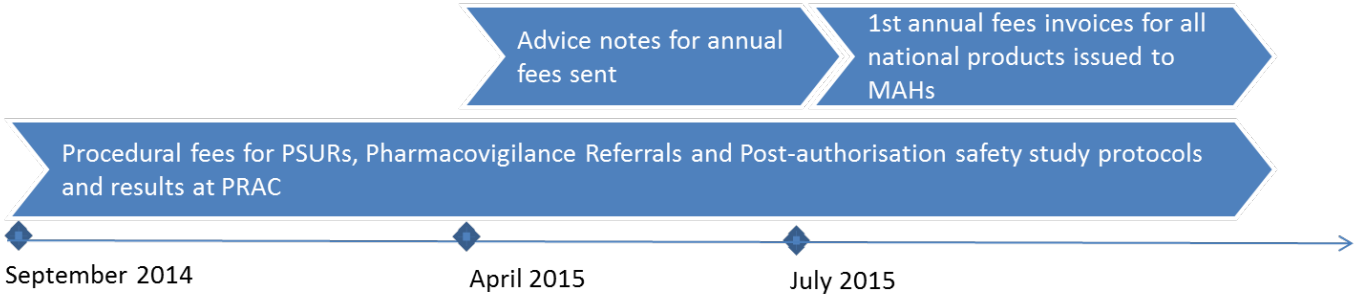
Scope

- 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;
- Delivers functionality for online payment of fees and updating of account details.

Timelines



Pharmacovigilance Fees

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News

- Pharmacovigilance annual fee advice notes were sent to QPPVs on the 20th April 2015 and the Agency will send the Pharmacovigilance annual fee invoices early July 2015;
- Following feedback received from Industry, the Agency is currently producing a document which will outline how ‘chargeable units’ for Pharmacovigilance fees are calculated;
- Pharmacovigilance fees Questions and Answers page published and dedicated pharmacovigilance fees query management system launched;
- A series of training videos to provide further information on the pharmacovigilance fees payable to the Agency was released.

- The European Medicines Agency launched the EMA invoicing portal: https://fees.ema.europa.eu/bd/public/zindex.jsp

Pharmacovigilance fees - EMA Invoicing Portal

Pharmacovigilance Fees - EMA Invoicing Portal

- Offering the **convenience** of receiving invoices, viewing account status, making payments or disputing on invoices **online** via a comprehensive Web portal;
- MAHs already been issued with an invoice at least once (since 2011) can register at any time (i.e**. existing Agency's customers**);
- MAHs never been issued with an invoice before by the Agency, will be able to register upon receipt of the first invoice (i.e. **new Agency's customers**);
- Simple **user registration process**, online form to be filled in, two validation information to be provided: customer account number and last invoice number, both available on the invoice itself (Accounts Payable department of the company should have this information)
- User registering for the portal will be receiving email **notifications** when new invoices are issued.

Pharmacovigilance Fees - EMA Invoicing Portal

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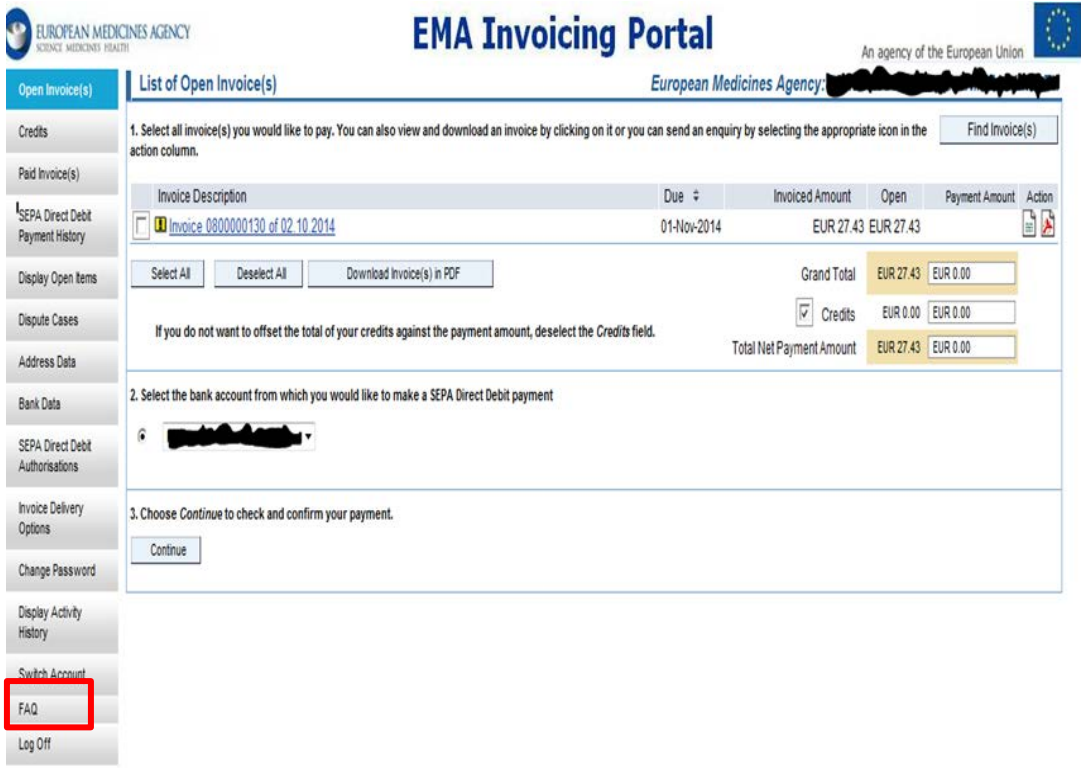
- Main portal functionalities are in landing page list of *Open Invoice(s)*
- Select invoice(s) to **pay** (by Direct Debit);
- **View** and **download** an invoice (PDF), or
- Send an **enquiry**

- ***Frequently Asked Questions (FAQ)***



Pharmacovigilance Fees - EMA Invoicing Portal

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How to pay an invoice to the Agency?

- Traditional bank transfer, customer transfers funds to Agency's bank account (outside the portal), or
- **New!** SEPA Direct debit and payment instruction to Agency (via the portal), Agency collects funds from customer's bank account.

What is **SEPA Direct Debit**?

- The payment by SEPA (*Single European Payment Area*) Direct Debit via the EMA invoicing portal allows the customer to **control which invoices to pay**
- It is not a 'blanket' or 'standing order', Agency will not be able to collect funds unless it receives:
  ✓a **signed mandate,** granted by the customer (the debtor) to the Agency (the creditor);
  ✓a **payment instruction** given by the customer to the Agency **via the EMA invoicing portal only**;
- The Agency will collect the corresponding Euro amount from the customer designated bank account **on or just after the invoice due date.**
- Customer must **hold a bank account within the *Single European Payment Area*** in order to be able to use the on-line payment method.

Pharmacovigilance Fees - EMA Invoicing Portal

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Preparing for Pharmacovigilance Annual Fees invoicing run in July 2015

- First time customers will receive invoices on **paper** to the **postal address** held on the Agency's file (i.e. Article 57 database or as otherwise communicated by you);
- Invoices will also be sent by **email** (**PDF**), provided that we have a financial contact with valid email address on file;
- **Information** on EMA invoicing portal and SEPA direct debit to be annexed to the invoice;
- Agency's invoices are **payable within 30 calendar days** from the date of the invoice;
- Any **dispute** on an invoice must be notified to the Agency **within 30 calendar days** from the date of the invoice via the portal by selecting Create Inquiry for the concerned invoice listed in *Open Invoice(s)* section;
- Each of the new accounts will be looked after by a dedicated **EMA Accounts Receivable** team member;
- The team will be available to assist you with any aspect of the registration and any other question related to general invoicing matter, such as customer account numbers, billing addresses, etc.;

Important! MAHs to be invoiced for the first time in July 2015 - if not yet done so - to provide the Agency with a **financial contact** name and valid email address **as soon as possible** to the Accounts Receivable team accountsreceivable@ema.europa.eu .


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Thank you

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