



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Information Updates

6th Industry Stakeholder platform, 18 December 2015



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An agency of the European Union





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Pharmacovigilance Programme update

Scientific advice for PASS

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Projects & Outputs

Article 57 Database

European database of all medicinal products

EudraVigilance Auditable Requirements

Enhanced adverse reaction collection and management system

Medical Literature Monitoring

Delivery of literature monitoring service to MAHs

Pharmacovigilance Fees

Collection of fees to cover costs of conduct of certain PV activities

PSUR Repository

Centralised repository for PSURs and assessment reports

Benefits Delivered

- Support PV Procedures which facilitates coordination of regulatory decisions
- Supports the product index for EudraVigilance
- Reduction of duplication

- Simplified reporting delivered
- Data in ISO ICH ICSR R3 format will be higher quality, improving searchability & analysis efficiency

- Improved safety monitoring of medicines
- Reduction in costs for MAH literature monitoring activities

- NCAs paid for certain PV assessments
- Annual fees support implementation & maintenance of measures from 2010 legislation

- Provides a simplification of PSUR submissions for industry
- Repository will include all PSURs and assessment reports

Driven By

Effective programme management

which ensures successful delivery of changes

Provides public health benefits across Europe



Highlights of 2015

- ✓ The Article 57 database of medicinal products authorised in the EU was set up in 2012 and is now established and operational. The database contains approximately 500,000 medicinal products and is the most comprehensive database of medicinal products authorised in the European Union;
- ✓ On 19 October 2015 the Agency launched the Article 57 Publication Dashboard Report for the National Competent Authorities (NCAs). The dashboard is designed to make available key data as recorded in the Article 57 database including information on Pharmacovigilance System Master File (PSMF) location and Qualified Person for Pharmacovigilance (QPPV);
- ✓ EMA and the EU regulatory network continue co-operation with Industry to ensure completeness and correctness of Article 57 data. To further support data quality, from 4th November 2015 the EMA started to communicate the outcome of the quality assurance process via an additional XEVPRM XML Acknowledgement message (the so called "3rd Acknowledgement") to the MAH sender's organisation ID;
- ✓ **On 17 December 2015 the EMA Management Board decided that the Article 57 database is functional for the purpose of notifying changes in QPPV and location of the PSMF. Therefore, from 1 February 2016, Type 1A variations should no longer be submitted for changes to QPPV details and PSMF location.**



What's coming in 2016

- ✓ **The reliance on the Article 57 database of medicinal products for QPPV and PSMF location notifications delivers an important simplification for the pharmaceutical industry whereby Type 1A variations no longer need to be submitted for QPPV details and PSMF location.**



Highlights of 2015

- ✓ On 21st January 2015 the EMA published a guide to support the implementation of a new international standard, ICH E2B R3 for the electronic exchange of ICSRs within the EU Network to support the safety monitoring of medicines in the EU. The so-called ISO ICSR standard will improve the reporting of suspected side effects of medicines in Individual Case Safety Reports (ICSRs);
- ✓ On 27 October 2015, a dedicated EudraVigilance webpage was launched on the Agency's corporate website and included key documents for the future of EudraVigilance, including the EudraVigilance Stakeholder Change Management Plan, which outlines the IT & business changes to be made by users;
- ✓ **The revised EudraVigilance Access Policy was adopted by the EMA Management Board on 17 December 2015.**
- ✓ **Most of the IT development activities for the new EV system have now been completed.**





What's coming in 2016

- ✓ In addition to the internal testing performed at the level of the EMA, **external testing is planned for quarter two 2016 with some NCAs and MAHs**. This pilot will be performed in advance of the Audit of the system;
- ✓ Before the move to centralised reporting, the new EudraVigilance system has to undergo an independent audit. The EudraVigilance functionalities audit is scheduled to take place in 3rd quarter 2016;
- ✓ Once the Audit has been completed, all organisations with a registered Test EudraVigilance account will be able to start sending E2B(R3) Test files and will also be able to download E2B(R3) files based on test data. **The go-live of the new external testing system (XCOMP) in mid-2016** will allow approximately one year for organisations to become familiar with the new system before it is implemented into production;
- ✓ **The EudraVigilance project training and communication plans will be published in March 2016;**
- ✓ To support the stakeholders in preparation for the new ISO standards and centralised reporting, by the end of 2016 the Agency will release the final version of several key technical documents. These will include the EU Backwards Forwards Conversion Element Mapping spreadsheet, final EU Backwards Forwards Conversion Tool, EU Reference Instance, EU E2B(R3) Code Lists, EU Example Instances;
- ✓ **EMA Management Board will review the EudraVigilance system Audit outcome at its December meeting**. If the functionalities agreed at the December 2014 audit have been delivered then the Management Board will announce the **launch the new EV system and start of centralised reporting in 6 months: mid 2017**.

Highlights of 2015

- ✓ On 12 May 2015 the dedicated Medical Literature Monitoring website was launched with the key documents regarding the monitoring of medical literature;
- ✓ On 1st July 2015 the MLM service was launched, covering the 50 most common chemical active substance groups. The launch phase was completed on 31st August 2015;
- ✓ **On 1st September 2015 the full operation of the medical literature monitoring service was launched. The service now covers 300 chemical active substance groups and 100 herbal active substance groups.**



What's coming in 2016

- ✓ Since the service launch in July 2015 the support webinars for stakeholders have been organised and will continue throughout 2016 on a monthly basis;
- ✓ An **independent audit of the service provider's internal quality management and control systems and of the output of the service will be conducted in early 2016** (and 2-yearly thereafter);
- ✓ Customer satisfaction surveys will be launched in 2016 and will be distributed to all NCAs and MAHs impacted by the service;
- ✓ A quarterly service update report will be made available on the dedicated Medical Literature Monitoring website, and other key documents will be updated as needed including: search strategies, the list of active substances, list of journals, and the user manual.



Highlights of 2015

- ✓ The Repository for PSURs and their assessment reports was launched by the European Medicines Agency on 26th January 2015;
- ✓ The initial pilot phase for centrally authorised products (CAPs) started in February and the extended pilot phase started in May to include nationally authorised products (NAP) in addition to CAPs;
- ✓ The independent audit of the repository was conducted from January to March 2015;
- ✓ **Based on the positive recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC), on 12 June 2015 the EMA Management Board announced that PSUR Repository has achieved its full functionality and the use of the repository in the European Union will become mandatory on 13 June 2016;**
- ✓ 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 has been mandatory;
- ✓ The new PSUR Repository version (v.1.04.00) was released in October 2015. This new release provides new functionalities including linking of the PSUSA procedure number with products which are in scope of the procedure allowing more direct searches and improved validation functionality.





What's coming in 2016

- ✓ The release of the new PSUR Repository version (v.1.05.00) is scheduled for January 2016. The most important feature of this release will be the delivery of the post-audit functionalities in line with the plan approved by the EMA MB in June 2015. This consists of an Application Programming Interface (API) allowing an automated 2-way exchange between the NCAs' IT systems and the PSUR Repository;
- ✓ The release of the new PSUR Repository version (v.1.06.00) is scheduled in Q2 2016. This is an important release as it will be the last scheduled release prior to the mandatory use of the repository. The scope of this release is currently under finalisation;
- ✓ **The use of the PSUR repository in the European Union will become mandatory on 13 June 2016.** From then onwards, industry stakeholders no longer need to submit PSURs to National Competent Authorities, the only requirement being the submission to the PSUR Repository.

Highlights of 2015

- ✓ **Procedural fees for pharmacovigilance were first invoiced in 2014;**
- ✓ In March 2015, the EMA published an [Explanatory Note on pharmacovigilance fees](#) payable to the Agency and launched a dedicated Pharmacovigilance Fees [webpage](#);
- ✓ **Pharmacovigilance annual fee advice notes were sent to QPPVs on the 20th April 2015.** This gave MAHs the opportunity to review their product information as recorded in the Article 57 database. The advice note contained the chargeable units line listing and provided further information on pharmacovigilance fees;
- ✓ The EMA invoicing portal was launched in April 2015 (enabling MAHs to get instant access to their account, view and print invoices, raise invoice queries and make payments via SEPA direct debit)
<https://fees.ema.europa.eu/bd/public/zindex.jsp>;
- ✓ **The 1st pharmacovigilance annual fee invoices were issued in July 2015;**
- ✓ On 21 July 2015 the Agency published a [guidance document](#) which outlines how 'chargeable units' for Pharmacovigilance fees are calculated.





What's coming in 2016

- ✓ **Prior to issuing an invoice for procedure-based fees or the pharmacovigilance annual fee, the Agency will provide MAHs with an opportunity to review their product information as recorded in the Article 57 database by supplying the qualified person for pharmacovigilance with an advice not;**
- ✓ **The next pharmacovigilance annual fee invoices for the concerned MAHs will be issued in July 2016;**
- ✓ In order to simplify the creation/change of Customer Accounts process for invoicing purposes, a new digital 'customer form' will soon be released.



Content

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Pharmacovigilance Programme update

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Update on GVP

I PhV and QS	Published	XI Participation	Replaced by web info and public hearings
II PSMF	Rev 1 published	XII Regulatory action	Replaced by other guidance
III Inspections	Rev 1 published	XIV International	Replaced by web info
IV Audits	Rev 1 published	XV Communication	Rev 1 public consultation until 29 Feb 2016
V RMP	Rev 2 in preparation	XVI RMM	Rev 1 published (on educational materials)
VI ICSR	Rev 2 in preparation	P.I Vaccines	Published
VII PSUR	Rev 1 published	P.II Biologicals	Public consultation until 29 Feb 2016
VIII PASS	Rev 2 in preparation	P.III Pregnancy	Drafting
IX Signals	Rev 1 in preparation	P.IV Geriatrics	Drafting
X Add Monitoring	Published	Annex I Definitions	Rev published



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