



What's new in Pharmacovigilance QPPV UPDATE

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QPPV Update

This second edition of 'What's new in Pharmacovigilance' aims to provide Qualified Persons responsible for Pharmacovigilance (QPPVs) with information on the latest developments in EU Pharmacovigilance.

For information on the Agency's main initiatives and activities that will be undertaken in the coming years please refer to the [multiannual work programme to 2020](#), published on the EMA's website on 30 June 2016.



Need more information?

Further information about the work of the European Medicines Agency is available on our [website](#)

For topics on implementation of the new Pharmacovigilance legislation – [see here](#)

Links to the National Competent Authorities can be found [here](#)

Pharmacovigilance in the product lifecycle

Simplified procedures for marketing authorisation holders (MAHs)

What's new?

In June 2016 the Agency published a [new Q&A](#) on the procedural management of risk management plan (RMP) submissions and a Q&A on the [classification of changes to the marketing authorisation](#) post authorisation.

How is it relevant for you?

The new RMP Q&A provides information on how RMP changes are classified and which changes can be included in an RMP update without the need for an additional variation. It also clarifies the process of how to present an RMP update and how to handle parallel submissions.

The Q&A on classification of changes to the marketing authorisation post authorisation provides advice for certain variation classification categories and includes a simplified approach for the handling of quality-related changes.

Single EMA contact point for procedure management

What's new?

Since 1 June 2016 all type II variations, extension applications, periodic safety update reports (PSURs), renewals and post-authorisation measures (PAMs) along the lifecycle of a centrally authorised product are handled by a single procedure manager at the Agency. To improve the co-ordination of regulatory activities with a product, the procedure managers and procedure assistants will be allocated per product, rather than per procedure. This new operational model is applicable to the evaluation procedures for human medicines only.

What do you need to know?

The Agency has notified all MAHs directly of the names of the procedure manager and the procedure assistant who together serve as the single EMA contact point for their medicine;

The pre-submission query service mailboxes for various types of procedures are no longer in use externally; therefore companies should submit queries relating to any of these procedures directly to the assigned manager for their medicine.

Pharmacovigilance processes

Clarification regarding the concept of Emerging Safety Issue (ESI)

MAHs are required to notify any new safety information with their authorised medicinal product which requires the urgent attention of competent authorities due to a potential major impact on the risk-benefit balance of the product and that could warrant prompt regulatory action and communication to patients, healthcare professionals. Such information should be notified forthwith in writing to the competent authorities of Member States where the product is authorised and to the Agency at P-PV-emerging-safety-issue@ema.europa.eu (with copy to the (co-)rapporteurs and the EMA Product lead when it involves a centrally authorised product). The notification should describe the safety concern including the source of information, the actions proposed or already taken and include any relevant documentation.

What do you need to know?

The EMA has performed a categorisation exercise of the notifications received via the ESI mailbox (P-PV-emerging-safety-issue@ema.europa.eu) since 2012. We have observed that 63% of the notifications correspond to ESIs, while 37% correspond to information on medicinal products which are not considered to be "new" information and which therefore should not have been sent to the EMA via the ESI mailbox.

Only new information ESI should be sent to EMA. Other notifications should instead be submitted to the competent authorities (i.e. the EMA for centrally authorised products or the national competent authorities as appropriate) via relevant channels.

The following should not be sent to the ESI mailbox:

- Quality defects (for more details on the procedure for centrally authorised products, see [Product defects and recalls](#));
- Withdrawn products notifications (for more details, see [EMA Webpage related to withdrawn product notifications](#));
- Issues already being handled through appropriate procedures (variation, PSUR, etc.);
- Issues related to non-authorised medicinal products.

Pharmacovigilance guidance

This table provides an overview of the latest adopted guidance as well as guidance planned and under development.

Recently published guidance:

- Good pharmacovigilance practices (GVP) Module VIII – [Post-authorisation safety studies](#) (Rev2) and its [addendum I](#) was published on 8 August 2016;
- The final pharmacovigilance guideline for biological medicinal products will be published later in August 2016.

Guidance under public consultation:

- GVP Module IX – [Signal management](#) (Rev 1) and revised [guidance on statistical methods](#) (addendum I) was released for 10 weeks public consultation on 8 August 2016;
- GVP Module VI – [Management and reporting of adverse reactions to medicinal products](#) (Rev 2) was released for 10 weeks public consultation on 8 August 2016.

New guidance to be released as final in 2016:

- Publication of the final scientific guideline on post-authorisation efficacy studies is expected in Q4 2016.

Updated guidance to be released as final in 2016:

- GVP Module XV – Safety communication (Rev 1) and Annex II is expected in Q4 2016.

Guidance under revision or development:

- The pharmacovigilance guideline for paediatric medicines is under revision to become a module of GVP;
- GVP Module V – Risk management systems (Rev 2), public consultation closed in May 2016;
- The pharmacovigilance guideline regarding use of medicines in pregnancy is under development;
- The pharmacovigilance guideline for medicines used by older populations is planned to be re-released for public consultation in late 2016;
- GVP Module III – Pharmacovigilance inspections (Rev 2) drafting of the updated module is ongoing;
- GVP - Annex I - Definitions (Rev 4) drafting is ongoing.

For more info please visit the GVP [webpage](#).

Pharmacovigilance dialogue

Upcoming EMA events

Meetings*

- Quarterly Industry Platform meeting - 21 September 2016;
- Pharmacovigilance Inspectors Working group meeting with Interested Parties - 22 September 2016;
- Quarterly Industry Platform meeting - 5 December 2016.

Annual Stakeholder Forum

- 21 September 2016.

Workshops

- Patient Registry Workshop—28 October 2016 (by invitation only);
- Big Data Workshop—14-15 November 2016 (by invitation only);
- EMA International [Workshop on Impact of Pharmacovigilance](#) – 5-6 December 2016.

Information Days

- Info Day on Good Practice Guidance on Medication Errors – 20 October 2016;
- PSUR Info Day – 28 October 2016;
- Info Day on RMP and PAS – 7 November 2016;
- EudraVigilance Info day –8 November 2016;
- Info Day on Signal Detection and management for MAHs– 2 December 2016.

Training

- For EudraVigilance training courses, please visit the [EudraVigilance training page](#).

*Meetings are organised for representatives of trade associations.
For more information please visit Agency's [News and Events](#).

Pharmacovigilance IT Systems

EudraVigilance

What's new?

To further strengthen the performance of the new EudraVigilance system prior to its launch, the EMA Management Board has approved an updated schedule for the implementation of the system. The key project milestones have been updated: the EudraVigilance audit is planned for the first quarter 2017, the EMA Management Board decision on the audit outcome is planned for May 2017, with the move to simplified reporting and the release of the new EudraVigilance functionalities scheduled to take place in November 2017 (see figure below);

On 5 August 2016 the Agency published an updated [EudraVigilance stakeholder change management plan](#). This iteration includes an update timetable of the upcoming changes to EudraVigilance as well as detailed guidance on preparing for the changes;

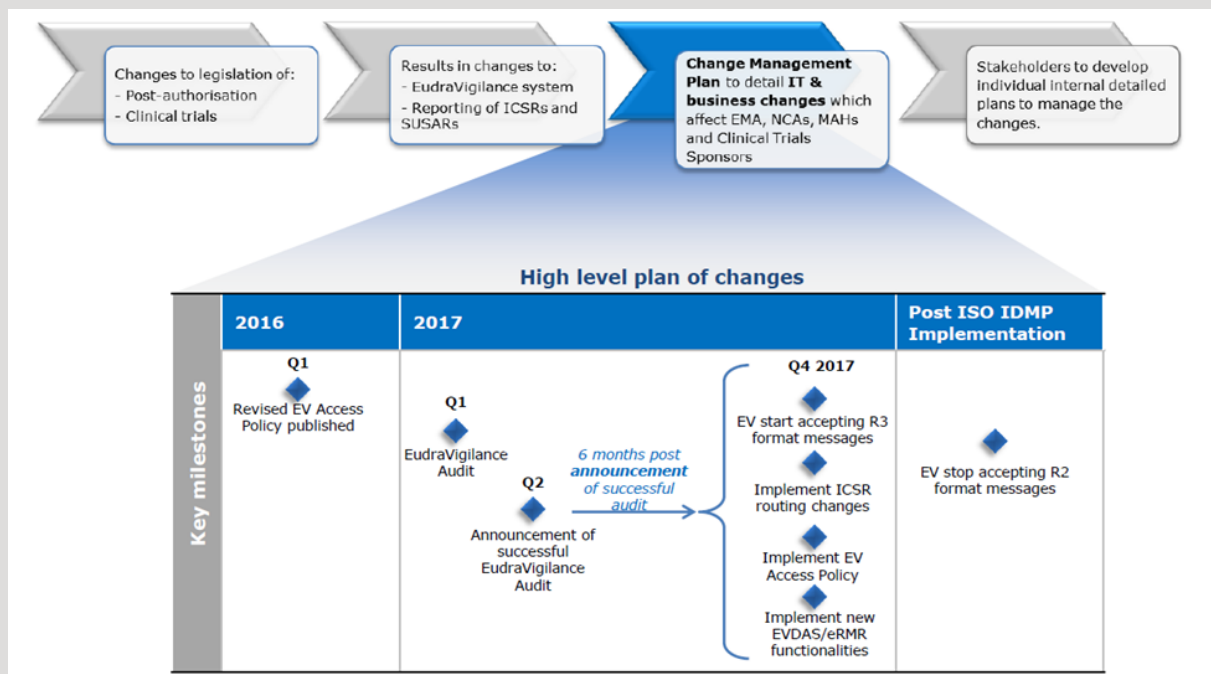
To support stakeholders when using the enhanced EudraVigilance system, the Agency is developing modular training. Training materials will be provided in three waves of publication during the course of 2016 and 2017. The first set of EudraVigilance e-learning modules are now available via the [EudraVigilance training page](#);

In June 2016 the revised EudraVigilance pages were launched on the EMA corporate website. The dedicated [EudraVigilance pages](#) contain information on: how to register, electronic reporting, access to data, change management, EudraVigilance system components and training. Registered users will also be able to access the EudraVigilance production and test environment through the corporate website;

The EudraVigilance public website has now been decommissioned and the content removed accordingly. Stakeholders should refer to the [new webpages](#) for the latest information on EudraVigilance.

What do you need to do?

- Marketing Authorisation Holders should start training on the new EudraVigilance functionalities and are invited to provide feedback on the e-learning modules. A [survey link](#) is available in all of the training materials, or can also be accessed via the [EudraVigilance training page](#). For additional information on the recommended learning paths for each stakeholder group please refer to the module 'PhV-M0 Introduction to EMA's training offerings';
- Stakeholders are advised to individually develop detailed internal plans to manage the changes.



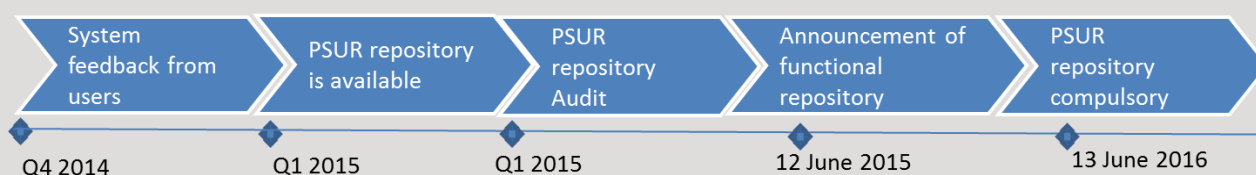
PSUR repository is now mandatory

What's new?

As of 13 June 2016, all periodic safety update reports (PSURs) for human medicines authorised in the European Economic Area (EEA) must be submitted to the [PSUR repository](#). The central platform was introduced by the EU pharmacovigilance legislation and will contain all information related to PSURs in the EEA. It will facilitate the assessment of PSURs and the exchange of information on the safety of authorised medicines between regulators and pharmaceutical companies.

What does this change for you?

MAHs must now use the repository as a single point for all submissions and should no longer submit their PSURs directly to national competent authorities. Guidance, interactive training sessions and links to all relevant documents are available on EMA's [eSubmission website](#). More information on how to submit a PSUR to the repository using the eSubmission Gateway/ Web Client can be found in a [questions-and-answers document](#).



Pharmacovigilance Fees

What's new?

EMA's [Annual Activity Report for 2015](#) has been published and includes statistics on pharmacovigilance fee-related activities for last year, which was the first full year following the introduction of the Pharmacovigilance Fee Regulation during 2014.

What you need to do?

The annual pharmacovigilance fee chargeable units for 2016 have been processed based on the product data in the Article 57 database on 1 July 2016, and all MAHs should have received their invoices by the end of July. The fees are payable to EMA within 30 calendar days from the date of the invoice. MAHs can get instant access to their accounts, view and print invoices, raise invoice queries and make payments via SEPA direct debit through [EMA's invoicing portal](#).

Further information can be found on the Pharmacovigilance fees payable to the European Medicines Agency [webpage](#).

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