

What's new in Pharmacovigilance QPPV UPDATE

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QPPV Update

This is the first issue of QPPV Update. It provides Qualified Persons responsible for Pharmacovigilance (QPPVs) and all other people working in pharmacovigilance with an update on EU Pharmacovigilance. This Update replaces the 'Pharmacovigilance Programme Update' which focussed on information systems and services.

We would welcome your feedback on this issue as well as any suggestions on topics you think would be of interest to colleagues. Your feedback should be sent to

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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

Risk Management Planning critical for patient safety and product innovation

What's new?

In March 2016, EMA published revised guidelines on the implementation of [accelerated assessment](#) and [conditional marketing authorisation](#), two key mechanisms to facilitate access by patients to medicines that fulfil unmet medical needs.

How is it relevant for you?

The revised guidelines emphasise the importance for medicine developers to engage in early dialogue with EMA and other stakeholders, to achieve a mutual understanding of the data package to be included in the application, including on the proposed risk management plan. Prospective risk management planning is critically important in particular in the context of conditional marketing authorisations. During the annual renewal of such authorisations an evaluation of the data accrued during the post-authorisation period takes place. The assessment considers whether an update of the product information or risk management plan is necessary.

Companies encouraged to seek scientific advice for PASS

What's new?

In 2015 EMA launched a pilot to encourage companies to seek scientific advice for post-authorisation safety studies (PASS). This voluntary procedure will help to improve the planning for and design of studies meant to collect further information on a medicine's safety once it is on the market. The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) is involved in every step of the procedure and adopts the final advice.

What do you need to know?

Any question relating to the collection of data and information on a medicinal product, or on risk minimisation can be submitted via the scientific advice procedure. EMA particularly encourages companies to seek scientific advice in particular on non-imposed PASS. Further information can be found under question 10 in a [Q&A on PASS](#).

Initiative on Patient Registries

What's new?

In September 2015, EMA launched the [Patient Registries Initiative](#) to make better use of existing registries and facilitate the establishment of high-quality new registries. The collection of data from a patient registry is often required of a marketing authorisation holder (MAH) as part of a package of benefit-risk management measures on the safety or efficacy of individual products in routine clinical practice. Despite the pre-existence of a disease registry, MAHs sometimes seek to establish their own independent product registry, potentially resulting in duplication of efforts and a slower resolution of the initial concern. The initiative proposes a strategy to identify and evaluate existing data sources and develop a methodological toolkit for establishing new registries if needed. The initiative starts with a pilot phase to test different components of the patient registry strategy and if it meets regulators' and other stakeholders' data and information requirements.

How can you be involved?

EMA will include medicines in the pilot based on expressions of interest by applicants or marketing-authorisation holders and a selection by EMA's cross-committee task force on registries. Expressions of interest are welcomed and should be sent to EMAregistries@ema.europa.eu. As of September 2015 the initiative has received 10 expressions of interest from both registry owners and MAHs.

Pharmacovigilance Processes

Quicker product information updates

What's new?

Every month the Agency publishes PRAC recommendations on safety signals and for those that require labelling changes these are translated into all official EU languages. Since September 2015, MAHs for generic products have been asked to submit applications for variations following a PRAC recommendation on safety signals at the same time as the MAH of the originator product to deliver warnings to patients more quickly.

What do you need to know?

MAHs should monitor [EMA website](#) to remain informed about the PRAC recommendations concerning their products.

Medical literature monitoring: Audit and survey results to be shared with users

What's new?

On 1 September 2015 the EMA medical literature monitoring (MLM) service became fully operational. The service now covers 300 chemical active substance groups and 100 herbal active substance groups. An independent audit of the EMA MLM service provider's internal quality management and control systems and of the output of the service was conducted in early 2016. The audit report will be made available on the [Medical literature monitoring](#) webpage and included in the next QPPV update. Also to be made public are the results from the customer satisfaction survey, which was launched in February 2016.

What do you need to know?

Webinars for stakeholders are organised on a monthly basis throughout 2016. Companies are encouraged to register ([link](#)).

Reliance on Article 57 data for referral procedures

What's new?

In 2015, the Agency started using the QPPV email address included in the Article 57 database as the main contact point for companies during a pharmacovigilance [referral procedure](#). All QPPVs of the medicinal products concerned by new pharmacovigilance referrals are now notified electronically (via Eudralink) by the Agency of the start of the procedure. In addition, on the Wednesday before the relevant PRAC meeting, all QPPVs identified in the Article 57 database are now informed by the Agency of expected starts of referral procedures considered by the PRAC the following week.

What do you need to do?

MAHs should ensure that the QPPV contact information in Article 57 database is up to date in order to receive all relevant information during the procedure.

Joint PRAC/CHMP assessment reports for renewals

What's new?

Since September 2015, CHMP and PRAC rapporteurs prepare a single joint assessment report for the five-year renewal process for centrally authorised products (CAPs).

Following successful implementation of the new process, this approach was also rolled out to the renewal of a conditional marketing authorisation (annual renewal) and annual re-assessment for authorisations granted under exceptional circumstances in December 2015. The joint CHMP/PRAC assessment reports will be used to support the adoption of final opinions at the CHMP. The new process reinforces collaboration between the two committees.

Relevant guidance documents, i.e. the [EMA Q&A on renewals](#) and the Guideline on the processing of renewals in the centralised procedure (Doc. Ref.: [EMEA/CHMP/2990/00 Rev.4](#)) have been updated to reflect the changes in processes.

Measuring the impact of pharmacovigilance activities

What's new?

In January 2016, the PRAC adopted a [strategy](#) for measuring the impact of pharmacovigilance activities. Measuring the impact of pharmacovigilance activities will allow regulators to determine which activities are most successful, to identify enablers and barriers for generating positive impacts which will contribute to the development of proactive pharmacovigilance systems and to promote best practice across the EU. The strategy includes a three year work plan underpinned by collaboration with industry through the quarterly platform meetings with EU associations.

What do you need to know?

A workshop on pharmacovigilance impact, with a particular focus on methodologies for measuring impact will be held on 5-6 December 2016 at EMA. Register your interest to participate [here](#).

Workshop: measuring the impact of pharmacovigilance activities

Call for expressions of interest

5 - 6 December 2016

European Medicines Agency, London, United Kingdom



Pharmacovigilance guidance

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

Recently published guidance:

- [Good practice guide](#) on medication errors to improve the reporting, evaluation and prevention of medication errors by pharmaceutical industry and regulatory authorities throughout the EU.

Guidance under public consultation:

- [Good pharmacovigilance practice \(GVP\) Module V](#) – Risk management systems (Rev 2), was released for 3-months public consultation on 29 February 2016.

New guidance to be released as final in 2016:

- Publication of final GVP Module PII: Biological medicinal products is expected in Q2 2016;
- Publication of final scientific guidance on post-authorisation efficacy studies is expected Q3-Q4 2016.

Updated guidance to be released as final in 2016:

- Publication of GVP Module VIII – Post-authorisation safety studies (Rev2) and GVP Module XV – Safety communication (Rev 1) is expected in Q2.

Guidance under revision or development:

- GVP Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2), GVP Module IX – Signal management (Rev 1) and revised guidance on statistical methods (addendum I) will be released for public consultation in Q2 2016;
- The Pharmacovigilance guideline for paediatric medicines is planned to be released for public consultation in 2016;
- GVP Module P III: Pregnancy and GVP Module P IV: Medicines used by the older population are planned to be released for public consultation in late 2016.

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

Pharmacovigilance IT Systems

Article 57 database

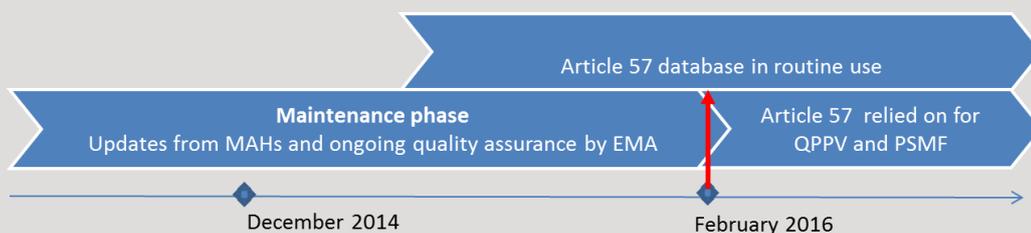
What's new?

On 17 December 2015 the EMA Management Board considered that the Article 57 database is functional for the purpose of notifications of changes in QPPV information and pharmacovigilance system master file (PSMF) location.

What does this mean for you?

From 1 February 2016 MAHs no-longer need to notify EMA (for centrally authorised products) and National Competent Authorities (for nationally authorised products) of changes to the QPPV or PSMF data by submitting a type IA_{IN} variation. MAHs should continue to ensure entries in the Article 57 database for medicinal products for human use are up to date, including with QPPV and PSMF location data.

Further information can be found on the [Data submission for authorised medicines](#) webpage.



EudraVigilance Auditable Requirements

What's new?

An enhanced EudraVigilance system with new functionalities will be available in 2017. The EudraVigilance training curriculum for the new EudraVigilance functionalities is now available on the Agency's website ([link](#)). Targeted trainings on the business processes and new IT systems will be made available over the course of 2016-2017. An updated EV communication plan has also been [published](#), detailing communications to prepare stakeholders for the business and IT changes.

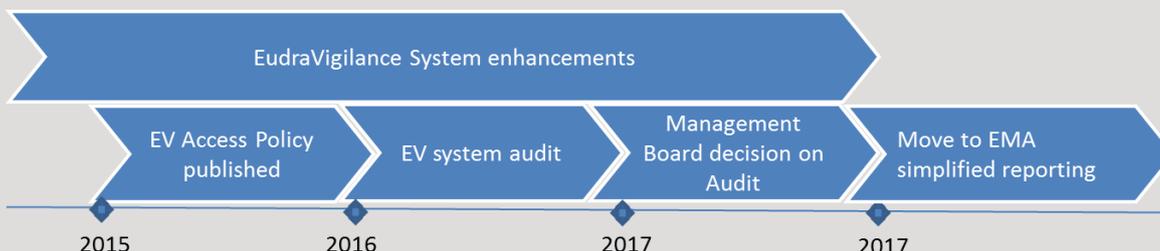
The current [EudraVigilance website](#) will be decommissioned by mid-2016. Existing information will be revised and moved to a dedicated EudraVigilance section of the Agency's corporate [website](#).

In December 2015 the EMA [Management Board adopted](#) the [revised EudraVigilance Access Policy](#) which will apply from Q3 2017 when the new EudraVigilance system becomes operational. The revised policy enhances access to data to various groups of stakeholders and simplifies the reporting of adverse reaction reports for pharmaceutical companies. EMA publishes data from EudraVigilance in the [European database of suspected adverse drug reaction reports](#) website. The public website is translated into all official EU languages. Recently the website has been made available in Croatian and Icelandic.

Many of the IT development activities of the new EV system, including EVDAS, have been completed to prepare the EV system audit in 2016. The successful completion of the audit is the starting point to the launch of centralised reporting in 2017.

What do you need to do?

Training on the new EudraVigilance functionalities should be planned for MAH staff as soon as possible and prior to implementation of the new EudraVigilance functionalities in 2017.



PSUR Repository

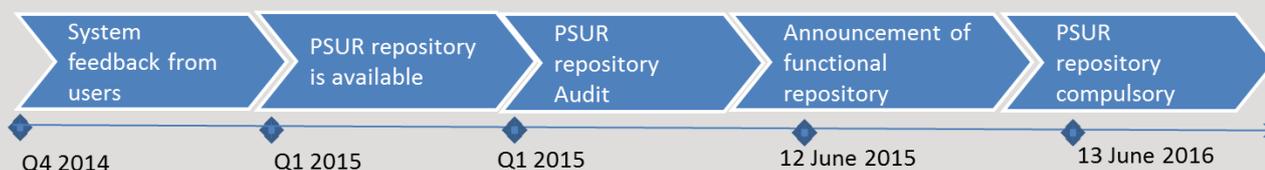
What's new?

In January 2016 the new PSUR Repository version (v.1.05.00) was released, delivering the post-audit functionalities in line with the plan approved by the EMA Management Board in June 2015. This version consists of an Application Programming Interface (API) allowing an automated two-way exchange between the National Competent Authorities' (NCAs) IT systems and the PSUR Repository, and also automated tracking and alerting functionalities and workflow support for NCA assessors. The use of the PSUR repository in the EU will become mandatory on 13 June 2016.

What does this change for you?

From 13 June 2016 all PSURs have to be submitted to the PSUR Repository. From that date PSURs can no longer be submitted to National Competent Authorities. In February 2016 the Coordination Group for Mutual Recognition and Decentralised Procedures – human (CMDh) issued a [press release](#) inviting MAHs for medicines that are authorised purely through national procedures to submit via the PSUR Repository with the aim of ensuring that business processes for the *non-EU single assessment* procedure are also ready for the upcoming mandatory use.

Further information can be found on the [eSubmission PSUR Repository](#) webpage.



Pharmacovigilance Fees

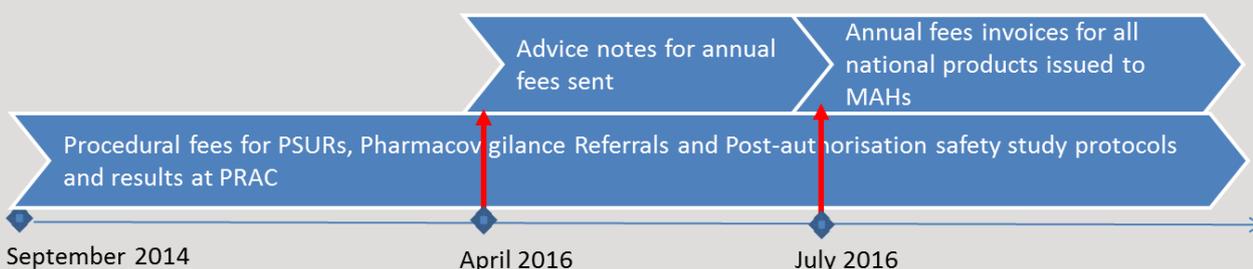
What's new?

The advice notes for 2016 annual fee invoices were sent to QPPVs in April. This is the second year that annual pharmacovigilance fees (annual and procedure based) will be collected. The received income covers the costs for the conduct of pharmacovigilance procedures and is used to support the maintenance of measures from the 2010 pharmacovigilance legislation including: literature monitoring, EudraVigilance and the PSUR repository which ultimately provide public health benefits across Europe. 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](#).

What do you need to do?

QPPVs should review the advice notes they receive from the Agency, to ensure that the product data as recorded in the Article 57 database is correct, as this data is used to calculate subsequent invoices. Any changes to the medicinal product data should be entered in the Article 57 database by the MAHs in line with their legal obligation (for more information please visit the [data submission on medicines](#) webpage). The next Pharmacovigilance Annual fee invoices for the concerned MAHs will be issued in July 2016.

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



Pharmacovigilance dialogue

Upcoming EMA events

Quarterly Industry Platform meetings*

- July 2016 (date to be confirmed)
- 21 September 2016
- 5 December 2016

Annual Stakeholders Forum

- 21 September 2016

Workshops

- EMA International Workshop on Impact of Pharmacovigilance – 5-6 December 2016

Information Days

- EudraVigilance Info day – 21 June 2016
- 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 key principles, processes and responsibilities of MAHs in Signal Detection and management – 2 December 2016

Training

- For EudraVigilance training courses, please visit [EV training](#) website

*Quarterly Industry platform meetings are organised for representatives of trade associations.

For more information please visit Agency's [News and Events](#).

For more info on Good pharmacovigilance practices please refer to section on Pharmacovigilance guidelines.

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