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What's new in Pharmacovigilance

QPPV UPDATE

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QPPV Update

The last issue in 2016 provides you with information on recent developments in EU Pharmacovigilance, relating to medicines for human use, and includes updates on the EU network activities and relevant projects.

Three-year report on pharmacovigilance tasks by the EU regulatory network

On 8 August 2016, the European Commission published a three-year report on pharmacovigilance tasks by Member States and EMA. The report contains a high-level description of the EU pharmacovigilance system, the key achievements of recent years, the roles of various parties within the system, key activities undertaken during the reporting period (July 2012 to July 2015), a discussion on the cooperation between various stakeholders and interested parties, and considerations of the ways in which the system is being developed and adapted for future improvement.

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

Renewals, annual renewals and annual re-assessments: updated Q&A and guideline published

What's new?

In August and October 2016, EMA published the revised guideline on the processing of renewals in the centralised procedure and updated Q&A for renewals, annual renewal of conditional marketing authorisations and annual re-assessments. Additionally, to improve the quality of submissions and to reduce the number of requests for supplementary information during validation, pre-submission checklists for renewals, annual renewal of conditional marketing authorisations and annual re-assessments have been made available on the EMA website.

How is it relevant for you?

The revised guideline provides information on the process, e.g. timelines and milestones and clarifies data requirements – how to prepare the dossier. It has been clarified that the addendum to clinical overview should clearly reflect the data included and assessed in the previous PSURs and the new data that have been collected since the data lock point (DLP) of the last PSUR up to the DLP of the renewal that should not exceed 90 days prior to the renewal submission.

The Q&As for renewals, annual renewals and annual re-assessments have been updated accordingly.

Pre-submission checklists are expected to enable applicants to prepare high quality applications that avoid frequent mistakes and comply with the legal and regulatory requirements, ensuring submissions can be validated speedily.

The Agency strongly recommends applicants to use these checklists when preparing their dossiers.

Scientific advice (SA) procedures with Pharmacovigilance Risk Assessment Committee (PRAC) involvement

What's new?

The Scientific Advice Working Party (SAWP) offers SA in close collaboration with PRAC in the following cases:

- SA on post-authorisation safety study (PASS) protocols to further develop an integrated lifecycle approach pre- and post-authorisation, and to support proactive pharmacovigilance (PhV) planning. The pilot phase of requesting SA on PASS protocols ended in August 2016 and Applicants/MAHs can continue to ask for such SA.
- SA procedures with questions which are in the mandate of the PRAC concerning PhV planning and risk mitigation [i.e. Risk management plans (RMP), Risk minimisation measures (RMM)].

Scientific advice on PASS protocols and other pharmacovigilance questions in the mandate of PRAC is a voluntary option for applicants/Marketing Authorisation Holders (MAHs), and complementary to existing regulatory procedures.

How is it relevant for you?

Regarding SA on PASS protocols, Applicants/MAHs are encouraged to request scientific advice on specific aspects of the PASS protocol, especially for complex or controversial issues, or for innovative approaches or methodologies. Applicants/MAHs can consult the Q&A and, in case of need for further guidance, contact the SAWP Secretariat (scientificadvice@ema.europa.eu).

The SAWP procedure with PRAC consultation can help with the early preparation phase of RMPs; give a steer about further need of Risk minimisation measures in the post-authorisation period, e.g. educational materials or PASS. SA can be requested in all stages of development of the product (pre- and post-authorisation).

For more info please visit the dedicated webpage.

EU Network projects on Pharmacovigilance

Strengthening Collaboration to Operate Pharmacovigilance in Europe (SCOPE) Joint Action

What's new?

The Strengthening Collaboration to Operate Pharmacovigilance in Europe (SCOPE) Joint Action has now been running for three years and the core activities are nearing completion. Funded by the Health Programme of the EU (CHAFEA) and with contribution from involved Member States, SCOPE has gathered information and expertise on how regulators run their national pharmacovigilance systems. Using this information, SCOPE developed guidance, and learning materials to support best practice. These materials will be soon available on the SCOPE website, and for the National Competent Authorities (NCAs) and EMA via the EU-Network Training Centre (EU-NTC) learning platform. In addition, there are a series of animated or interactive posters that have been used in an EU wide social media campaign to raise awareness of the national adverse drug reaction (ADR) reporting systems.

The SCOPE project recently held a number of training events and workshops focusing on ADR lifecycle, signal management, risk communication, quality management systems, and strengthening capabilities for benefit risk assessment. Further information on SCOPE events can be found here.

What do you need to know?

A wider stakeholder engagement workshop for the industry, health professional and patient groups, will be organised in early spring 2017, aiming to disseminate deliverables and raise awareness of SCOPE's aims and work undertaken to strengthen national pharmacovigilance systems.

For more information on the SCOPE joint action initiative, please visit http://www.scopejointaction.eu/

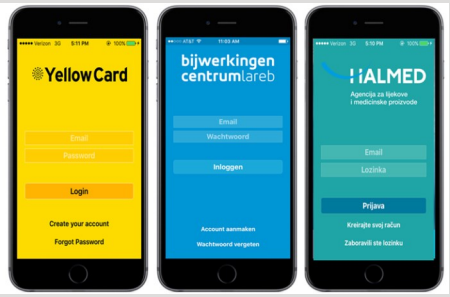
WEB-RADR: Recognising Adverse Drug Reactions

The WEB-RADR project was launched in September 2014. This ground-breaking three year project investigates how to utilise social media and new technologies for pharmacovigilance purposes. The project is funded by the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative supporting collaborative research projects.

WEB-RADR has two areas of focus: mobile applications (apps) to facilitate reporting of suspected adverse drug reaction (ADRs) by patients and healthcare professionals to medicines regulators, and the mining of social media data as a means of identifying potential issues related to the safe use of medicines. The project is also working on the development of recommendations for a future framework of regulatory guidance to support these activities.

As part of the technical outputs, the WEB-RADR project has delivered, over the past two years, text mining and analysis tools for publicly available data on social media sites to complement existing methods of safety signal detection for medicines and three smartphone apps available for iOS and Android devices. The NCAs utilising these apps are the Medicines and Healthcare products Regulatory Agency (MHRA), the Netherlands Pharmacovigilance Centre Lareb, and the Agency for Medicinal Products and Medical Devices of Croatia (HALMED).

For more information on the WEB-RADR project, please visit https://web-radr.eu/ and Twitter https://twitter.com/WEBRADR.



The mobile smartphone applications are available in Apple and Google Play stores

The Yellow Card app is available for worldwide download: App store and Google play

The LAREB app is available for worldwide download: App store and Google Play

The HALMED app is available for worldwide download: App store and Google Play

Pharmacovigilance IT Systems

EudraVigilance

Major achievements in 2016

- To support EudraVigilance stakeholders and partners during this period of change, the EudraVigilance website has been redesigned and enhanced to publish important information on the new and existing EudraVigilance system. This includes:
  - A Stakeholder Change Management Plan
  - A Communication Plan
  - A Training Plan and e-learning materials
  - Technical documentation, such as the EU ICSR Implementation Guide
  - The EudraVigilance Access Policy
- The main IT development activities for the new functionalities of EudraVigilance are now completed with the project team focusing on the testing of these functionalities. In addition to the internal testing performed by EMA, testing has also been completed with dedicated EV stakeholders including NCAs, MAHs and the WHO-UMC.
- Before the move to centralised reporting, the new EudraVigilance system has to undergo an independent audit, scheduled to take place in February 2017. The auditing company has now been selected and preparation of the audit fieldwork has started.

What's coming in 2017

- The outcome of the audit is scheduled for presentation to PRAC and the EMA Management Board in May 2017. Subject to a positive audit outcome, the new functionalities of the EudraVigilance system will be released to all stakeholders/partners in November 2017.
- The go-live of the new external testing system, namely XCOMP, is scheduled for June 2017. All registered organisations with a valid EudraVigilance Test account will be able to start sending E2B(R3) test files and to download E2B (R3) test data. This will provide organisations with a 6 months period to become familiar with the new system before it is launched in production.
- Before and after the go-live of the new system in November 2017, webinars will be organised to support NCAs and MAHs. This will allow the EMA expert team to answer implementation questions from NCAs and MAHs.
- A minor revision of the EudraVigilance Access Policy (revision 3) will be published to further strengthen the protection of personal data for reports of suspected adverse reactions related to medicines published on the adrreports.eu web portal.

What MAHs need to know and do:

- Develop plans for implementation of the new EudraVigilance system and the resulting changes that will occur to reporting, downloading and analysis of data.
- Prepare for the use of the new ICSR data format – ISO/ICH E2B(R3) – and simplified reporting to EudraVigilance.
- MAHs should plan to complete any testing of their existing systems 3 to 6 months prior to the new system going live to give time for any issues to be addressed.
- Engage with information and training events.
- Plan for training of MAH staff on the new business processes and new IT systems 6 months prior to implementation to be ready once the new EudraVigilance system is launched.
- Develop a communication plan to ensure that the necessary information is circulated within their own organisation and with other organisations that they work with.

Pharmacovigilance dialogue

Recording of recent meetings and events

- Patient registries workshop — 28 October 2016. A video recording is available. To view use the 'Multimedia' tab.
- Tenth stakeholder forum on the pharmacovigilance legislation. A video recording is available. To view use the 'Multimedia' tab.

Upcoming EMA meetings

- Industry platform meeting* - 3 February 2017.
- Industry platform meeting* - 2 June 2017.
- 11th Stakeholders forum on the pharmacovigilance legislation – 21 September 2017.
- Industry platform meeting* - Q4 2017 (date to be confirmed).

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 guidance

Recently published guidance

- The European Medicines Agency has developed a new **guidance document** on routine signal detection methods in EudraVigilance for use by the Agency, NCAs and MAHs. The guidance, named 'Screening for adverse reactions in EudraVigilance', is published on the Agency's website.
  The purpose of this guidance is to provide a **scientific** discussion on the methods recommended and implemented in EudraVigilance for screening for adverse reactions. It also describes the rationale of the methods based on evidence from research activities. It does not provide regulatory requirements, which are laid down in the Good Pharmacovigilance Practice (GVP) Module IX. The guidance also updates and supersedes the previous guideline on the use of statistical signal detection methods in EudraVigilance.
  QPPVs are welcome to pass on the information to signal detection specialists and, in particular, programmers and statisticians involved in implementing and maintaining signal detection systems.

- The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology (Revision 5) was published in July 2016.

Updated guidance to be released as final in 2017

- The final scientific guideline on post-authorisation efficacy studies will be published in Q1 2017;
- GVP Module V – Risk management systems (Rev 2), following the public consultation in 2016, will be released as final in Q1 2017;
- GVP - Annex I - Definitions (Rev 4) is anticipated to be released in Q1 2017;
- GVP Module II - Pharmacovigilance System Master File (Rev.2) is anticipated to be released, after an administrative update, in Q1 2017;
- GVP Module XVI – Risk minimisation measures (Rev.2) publication is anticipated in Q1 2017, including amendments in line with the public consultation for GVP Module V – Risk management systems;
- GVP Module XV – Safety communication (Rev 1) and related templates in Annex II is expected in Q1-Q2 2017;
- GVP Module IX – Signal management (Rev 1) and revised guidance on statistical methods (addendum I), following the public consultation in 2016, will be released as final in Q1-Q2 2017;
- GVP Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2), following the public consultation in 2016, will be released as final in Q1-Q2 2017.

Guidance under revision or development:

- The pharmacovigilance guideline for paediatric medicines is under revision to become a module of GVP;
- 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 released for public consultation in Q2 2017;
- GVP Module VI Addendum I on ICSR Duplicate Management is under development;
- GVP Module VII – Periodic Safety Update Reports (Rev 2) drafting is ongoing.

For more info please visit the GVP webpage.

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