16 December 2016
EMA/628777/2016
Inspections, Human Medicines Pharmacovigilance & Committees Division

Highlights from the 9th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 21 Sep 2016

The following records announcements and action points from the 9th Pharmacovigilance Industry Platform meeting held on 21 September 2016.

Welcome and matters arising

- The Regulators provided an update on the matters arising including the European Commission's 3-yearly report on pharmacovigilance, the feedback from the 10th stakeholder forum on the pharmacovigilance legislation, the preparation for the pharmacovigilance guidance for special populations, including a dedicated workshop planned for 2017 on pregnancy pharmacovigilance, the importance of the SCOPE project supporting pharmacovigilance at NCAs, the new EV system and how it can support fulfilling unmet medical needs including through PRIME products, the study published in Nature concerning a strong position of the scientific advice in supporting the authorisation of medicinal products, as well as the real world evidence activities with a workshop on Big Data planned for 14-15 November 16.

- Feedback was provided regarding the MLM service workshop held on 13th of September to develop proposals to optimise the service, including its benefits to industry. All the proposals will be analysed in terms of feasibility. It was highlighted that the service has led already to a significant reduction of duplicates seen in EV and therefore optimised signal detection through better data.

- Feedback was also provided from the dedicated workshop on ISO IDMP standards.

GVP VI ADR Reporting

- Industry representatives presented their preliminary feedback from the public consultation, welcoming the clarifications regarding the emerging safety issues (ESI), medication errors, off label use, as well as the note on 'nullflavors'. At present, the document provides very detailed technical guidance with the R3 requirements, and the balance in keeping it informative and the consistency in terminology was emphasised. Detailed comments will be provided until 14 Oct.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

GVP IX on signal management

- Industry representatives presented their preliminary feedback from the public consultation of the Module, including the definitions, the consistency in terminology among GVPs, the ESI deadlines, the frequency of EV monitoring, and the training. Detailed comments will be provided until 14 Oct.

GVP PII Biologics

- The Industry presented their overall positive feedback after the publication of the Module. They welcomed changes included the immunogenicity as well as the update on signal management. The good collaboration during public consultation was highlighted, with constructive comments contributing to the quality of the document. Areas where the industry suggests continued focus included: the importance of traceability, sharing of good practice among the concerned parties, the interlinkage of different systems, updates to the biological RMP, and dissemination of educational information directed to prescribers.
- **Actions**: EMA to explore feasibility and priority of a future workshop dedicated to pharmacovigilance of biologicals and good-practice sharing between the MSs

Public hearings

- The regulators provided an update on the preparedness and criteria for the public hearings. The process was developed to complement the other existing channels for the regulators to engage with the patients, such as the EMA Patient and Consumers Working Party, patient participation into the PRAC, and written consultations. It increases the transparency and gives a voice to the citizens. A positive feedback from the PRAC 'dry run' in the summer was provided. The process is ready for operation and the benefits of holding a public hearing will be considered for new referrals.

Pharmacovigilance Impact

- The Regulators presented the PRAC impact strategy and deliverables with focus on the measures following safety referrals as well as on the data on regulatory outputs and actions available, modelling outcomes based on all available information and additional risk minimisation measures.
- There are opportunities for collaboration between organisations on methods, and information sharing. Good examples of collaboration include the joint studies between MAHs (e.g. cyproterone, valproate, and domperidone).
- Dedicates tools to support collaboration between stakeholders on measuring impact include templates and principles on when to share data, and surveys with industry, patients and.
- The pharmacovigilance impact workshop (5-6th of Dec) will focus on methods provide an opportunity to discuss the effectiveness of risk minimisation.

Actions:

- To reactivate the focus group with industry (first discussed in 2015) to share information. EMA to share & monitor the contact e-mail address.

  Post-meeting note: the functional mailbox pharmacovigilance.impact@ema.europa.eu which was used to organise the workshop on pharmacovigilance impact to serve that purpose
- EMA to draft a mandate for the group.

Next meeting:

Industry was invited to provide topics for future consideration in writing in advance of the next EMA Industry Platform meeting.