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Highlights from the EMA Industry Platform meeting on the Operation of EU pharmacovigilance legislation – 13 March 2015

The following records announcements and action points from the 3rd Pharmacovigilance Industry Platform meeting held on 13 March 2015. Topics presented/discussed included: pharmacovigilance information systems and services (including Article 57 product database, Eudravigilance, medical literature monitoring and the periodic safety report (PSUR) repository), the introduction of pharmacovigilance fees, as well as a review of experience with PSUR and referrals procedures. Regulatory Authorities presentations are also available on the EMA website.

Update on pharmacovigilance programme

Article 57 database of medicinal products

- ***Note***: Industry noted the good progress on submission of medicinal product information and that data are being validated by EMA and used for core business processes.
- **Action**: Concerns expressed by industry regarding version control following data validation by EMA will be explored at the Article 57 Implementation Working Group at the end of March.
- **Action**: EMA to clarify whether the QPPV can designate an alternative contact point for Article 57 issues.

Medical Literature Monitoring

- ***Note***: Industry noted that the detailed guide on literature monitoring will soon be published, together with the list of substances to be monitored.
- **Action**: Industry emphasised the important global change management aspects of the launch of the service. EMA called for industry volunteers for testing.
- **Action**: EMA to consider how best to evaluate the impact of the service, particularly on industry.

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Pharmacovigilance fees

- ***Note***: EMA provided a detailed presentation on the new fees and their collection and informed the specific PhV fees webpage and specific webmail to use to request any further clarifications.

PSUR repository & EURD list update

- **Action**: EMA agreed to clarify:
  - the version of Article 57 data used for the repository;
  - whether regulatory submission covers PRAC members;
  - the provisional road-map for transition to mandatory use of the repository, by end of Q2 2015.

Post-authorisation efficacy studies (PAES)

- ***Note***: There has been good progress in developing the scientific guidance on PAES, which will remain a relatively high level document. Public consultation is foreseen for Q3 2015.

Risk management planning (RMP)

- **Action**: EMA agreed to have a substantive item on RMPs at the next Industry Platform in June 2015 to feedback on the "RMP Templates" and RMP summaries consultations, status update of the GVP Module V and aspects presented by Industry stakeholders related to process management. If possible this will include discussion of what is an important risk and of handling parallel procedures.

- **Action**: EMA to make public lessons from the pilot of RMP summaries (when available).

- **Action**: EMA to launch pilot testing exercises of revised template for RMPs with nominated Industry association representatives in March 2015.

- ***Note***: Industry group to work with CMDh subgroup on RMPs for substances in many products, is soon to be established and nominations have started to be received.

Referrals

- ***Note***: Industry provided feedback on experience with referral procedures.

- ***Note***: EMA presented process improvements that are being launched based on a process review exercise. Many of the issues suggested by industry stakeholders have or will be dealt with through these process improvements (see slides presentation).

- ***Note***: Submissions by industry during referrals to note need to be in eCTD format.

Scientific Advice for PASS

- ***Note***: EMA presented a proposal for a pilot to encourage companies to seek scientific advice for post-authorisation safety studies (PASS), with a particular focus on those that are not imposed. This would support a proactive life-cycle approach to product development and support integration of pharmacovigilance planning in overall planning of safety, quality and efficacy (see slides presentation).

- **Action**: EMA agreed to a Q&A to support the pilot which will likely be launched in Q3 2015.

- **Action**: EMA to organise a dedicated teleconference with the industry associations to support the launch of the pilot.