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Highlights from the 6th EMA Industry Platform meeting on the Operation of EU pharmacovigilance legislation – 18 December 2015

The following records announcements and action points from the 6th Pharmacovigilance Industry Platform meeting held on 18 December 2015.

Pharmacovigilance systems and services

Article 57 database of authorised medicinal products

- ***Note***: On 17 December 2015 the EMA Management Board decided that the Article 57 database is functional for the purpose of notifying changes in QPPV and location of the PSMF. Therefore, from 1 February 2016, type 1A variations should no longer be submitted for changes to QPPV details and PSMF location. The main news item is available here [add link].
- ***Action:*** The request from industry for pre-notification by EMA of the planned XEVPMD changes overriding the MAH entries - to be discussed at the Art. 57 Implementation Working Group.

Update from the CMD(h)

- ***Note*:** The regulators highlighted the importance of introducing contraindications into nationally authorised products via work-sharing variations.

Roadmap to PSURs

- ***Note:*** Industry welcomed the actions taken by the regulators, such as the establishment and work for the PRAC's granularity & periodicity advisory group, and the establishment of a PSUR action group by PRAC and CMD(h), as well as EMA's procedure management department to address Industry's concerns with the current performance of the EU PSUR assessment.
- **Action:** Regulators to consider whether lessons learnt from the PSUR single assessment could be informative in the preparation of handling of the yearly reports on clinical trials foreseen in the Clinical Trials Regulation.
- **Action:** Consideration should be given to whether GVP VII should be revised in the part equating to the regional requirements section of the ICH E2C guideline. Changes might relate

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to enhancing the dialogue between industry and regulators in the EU, especially in the context of the PSUR single assessment.

Medication errors

- ***Note:*** EMA provided an overview of the key items (e.g. the publication of the *Good practice guide on recording, coding, reporting and assessment of medication errors*) delivered after the 2013 stakeholder workshop. This was followed by an open discussion on the implementation issues and remaining gaps.
- **Action:** EMA to clarify whether a dosing error originating from a medical device not rightly delivering should be reportable as a medication error or rather as a quality defect.
- **Action:** To initiate a dialogue with inspectors, to clarify that the presentation of the cumulative tables of medication errors in PSURs is a suggestion and not mandatory.

GVP Module VIII – PASS

Note: Industry provided their feedback on PASS studies which was followed by an open discussion. Considering different aspects of the issue, it was agreed that collaboration between regulators and industry will be essential to simplify and to best facilitate study conduct.

- **Actions:**

1. Industry to expand on the problem statement with the PASS definition.
2. EMA to give greater support to the committees with regards to the categorisation of studies and in ensuring clarity regarding the research question.
3. Industry to review and comment on the categorisation of studies during the GVP V consultation in January 2016.
4. Regulators to consider improving the wording in protocols, noting that the definition of PASS refers to 'prescribed' medicines (and not to the OTC).
5. Regulators to review how to optimise support for joint PASS studies through providing contact points and teleconferences to explain the research question and support establishing a consortium. Input from scientific advice may be helpful in this regard.
6. EMA to review the wording on MedDRA use in the GVP module on PASSS. This is because for some protocols MedDRA may not always be appropriate. However MedDRA is required for ADR reporting.

EudraVigilance: preparing for business change

Industry presented their understanding of the enhanced EV and the 2017 MAH EV access. This was followed by EMA presentations on the adopted EV Access policy and some aspects of the EV, as well as the planning for the business change with trainings, and the upcoming revision of the GVP IX to ensure risk-proportionate monitoring of EV and signal detection without duplication.

- ***Note*:** The revised EudraVigilance Access Policy was adopted by the EMA Management Board on 17 December 2015 and is available here [add link].
- **Action:** MAH access to EV and consequences for signal detection to be discussed at the first stakeholder platform in 2016.
- **Action:** To make the most of the dialogue between industry and regulators via the EudraVigilance Expert Working Group (EWG), noting that the first meeting is planned for January 2016, out of total three scheduled in 2016.
- **Action:** To explore the utility and timing of a pilot between industry and regulators of signal detection using EudraVigilance.

- **Action:** Industry to share the publication on signals developed in collaboration with the MHRA.

Topics for future EMA Industry Platform meetings on the Operation of EU pharmacovigilance legislation:

The following topics were put forward for consideration

- Signal detection and management in the context of MAH access to EudraVigilance
- EMA Committees' work plans
- PASS examples
- GVP V
- GVP VI
- GVP biologicals
- Off label use
- Patient support programmes
- MLM (incl. audit)
- RMP update and CMD(h)work sharing
- Medication errors - FU on implementation