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Highlights from the EMA Industry Platform meeting on the Operation of EU pharmacovigilance legislation – 12 June 2015

The following records announcements and action points from the 4th Pharmacovigilance Industry Platform meeting held on 12 June 2015. Topics presented/discussed included: pharmacovigilance information systems and services (incl. Article 57 database, EudraVigilance, Medical Literature Monitoring, the periodic safety update report (PSUR) repository, and pharmacovigilance fees), impact of the pharmacovigilance system, Risk Management Plan (RMP) activities, patient support programme (industry observations), and Good pharmacoVigilance Practices (GVP) – Module P-II Biological medicinal products.

Pharmacovigilance information systems and services

slide presentation

Article 57 database

- ***Note***: EMA continues its dialogue with industry within the specific EMA implementation Working Group to ensure "Article 57" data correctness.

- **Action**: Noting that EMA has stated that Article 57 details for the QPPV will not be released, EMA to clarify its release policy for the QPPV details following Access to Documents (AtD) requests.

PSUR repository

- ***Note:*** On 11 June 2015, the EMA Management Board, based on a positive PRAC recommendation and an independent audit report, announced that the PSUR repository meets the functional specifications as agreed in the 'PSUR Repository functionalities to be audited' document and concluded that it has achieved its full functionality. The legislation foresees that 12 months after the Management Board announcement, the use of the repository for the submission, storage and

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

retrieval of all PSURs and related documents (assessment reports) in the European Union will become mandatory (**June 2016**).

Further details can be found on EMA website under the related news item:

Central repository for safety reports - one year to go before mandatory use

EudraVigilance system

- ***Note:*** The finalised EudraVigilance Access Policy is expected to be published in Q4 2015. The EudraVigilance functionalities audit is scheduled to take place in 2016. The transition to using the new international standard will be actively managed by the Agency in collaboration with NCAs and MAHs. The Stakeholder business change management plan will be launched in autumn 2015.

Medical Literature Monitoring service (MLM)

- ***Note***: It was noted that from 1st July 2015, the service will cover the top 50 active chemical substance groups and is expected to reach full operational levels by September 2015, covering 300 active substances and 100 herbals. Dedicated question and answer sessions with NCAs and MAHs were held on 26 May, 2 June, 8 June and 15 June 2015. The MLM support sessions are planned on a monthly basis until the end of the year. Training sessions for the inspectors are taking place at the same time.

- **Action**: EMA to clarify the position of the EMA case identifier for cases with already existing world-wide unique case identifier.

Pharmacovigilance fees

- ***Note***: Details of the new method of payment of fees were provided (EMA invoicing Portal (with SEPA Direct Debit – see enclosed link: https://fees.ema.europa.eu/bd/public/zindex.jsp).
- ***Action****:* Industry (MAHs) will be invoiced for the first time in July 2015. Those Marketing Authorisation Holders, who have not yet done so, should provide the Agency with a financial contact name and valid email address as soon as possible to the Accounts Receivable team: accountsreceivable@ema.europa.eu. At least one financial contact *per* company needs to be provided.

Impact of pharmacovigilance system

- ***Note:*** Regulators presented a proposed approach for collecting data and information relevant to the impact of the EU pharmacovigilance system slide presentation.

- ***Action:*** An ad-hoc group involving Industry Stakeholders will be set up in Q3 2015 to discuss existing initiatives/activities that could be used to analyse certain impacts of the Pharmacovigilance Systems and to brainstorm on a possible survey. EMA to send a written call to Industry to nominate two members from interested EU industry stakeholder organisations.

Risk management planning (RMP)

- **Note**: Industry welcomed the Regulators feedback on the draft GVP V RMP updates - slide presentation; on draft changes to "RMP Templates"- slide presentation and the CMDh subgroup on RMP - slide presentation. Proposals for significant simplification in the process & templates were presented subject to further internal EU network and EMA Committee review. The CMDh Working Party on Pharmacovigilance Procedures Work Sharing (PPWS) published the safety concerns list for the active substances which should facilitate submission of high quality generic RMPs. External EMA public consultation on both the RMP template and GVP Module V is scheduled in parallel in autumn 2015.

Patient Support Programmes: Industry observations

Note: Industry presented their experience with patient support programmes.

Good pharmacoVigilance Practices (GVP) – Module P-II Biological medicinal products

- ***Note:*** Regulators presented the table of contents of the new GVP Module P-II for biological medicinal products as well as the timelines of its development including consultation with EMA Committees - slide presentation. Vaccines are out of scope, being covered by GVP P-I. Challenges include signal detection related to the immunogenicity of the products and their batch-to-batch variability following changes in the manufacturing process.

- ***Action:*** Industry to provide the Agency with its position on what the threshold for significant manufacturing changes is with adequate details/examples and any background information on signal detection related to batch record reporting.

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

- RMP summaries external consultation update;
- GVP Module II – Biological medicinal products;
- PSURs;
- Off label use – without ADRs.