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Highlights from the 5th EMA Industry Platform meeting on the Operation of EU pharmacovigilance legislation – 15 September 2015

The following records announcements and action points from the 5th Pharmacovigilance Industry Platform meeting held on 15 September 2015.

- ***Note***: Following on the action point from last meeting the release policy of the QPPV details was clarified. The EMA reactively releases the QPPV details contained in documents that are subject to requests for access to documents submitted in accordance with Regulation (EC) No 1049/2001. This is based on the "HMA/EMA guidance document on the identification of commercially confidential information and personal details within the structure of the marketing-authorisation application: Release of information after the granting of a marketing authorisation" (available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000526.jsp&mid=WC0b01ac0580789730). As has been stated previously, there is no plan to proactively publish details of the QPPVs from the Article 57 database of medicinal products.

Pharmacovigilance systems and services

Article 57 database of authorised medicinal products

- ***Note***: Industry stakeholders were informed that Article 57 data on authorised medicinal products (both centrally and nationally authorised) will be made permanently available to National Competent Authorities. These data will include the Qualified Person for PharmacoVigilance contact details and the location of the Pharmacovigilance System Master File. This access, combined with the robust data quality assurance approach in place provides foundations for further use and simplifications based on the data. The submission of Type IA variations for QPPV and PSMF location should continue until public announcements from the EU regulators regarding reliance on the Article 57 medicinal product database.

EudraVigilance Auditable Requirements

- ***Note:*** A stakeholder change management plan is under development to support industry and national authorities to prepare for the new data format and new reporting requirements. It is anticipated that his will be made public in quarter 4 2015.

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PSUR repository

- ***Note:*** The PSUR Repository is now available and it offers a secure electronic submission point for MAHs, streamlining PSUR submissions for the pharmaceutical industry. Since 1st September 2015, the use of the XML delivery file for all PSUR submissions to the EMA *via* the eSubmission Gateway and/or the Web Client is mandatory. It is no longer possible to submit PSURs to EMA using the former file naming convention.
- ***Note:*** Based on a positive PRAC Recommendation and the independent audit report on 11 June 2015 the EMA Management Board announced that the PSUR repository meets the functional specifications as agreed in the 'PSUR Repository functionalities to be audited' document and therefore concluded that it has achieved its full functionality. The legislation foresees that 12 months after the EMA Management Board announcement, the use of the repository in the European Union will become mandatory (13 June 2016);

Medical Literature Monitoring service (MLM)

Note: Industry presented their experience with the MLM service with a list of possible discussion points and EMA update on the service provision and recent enhancements (see slide presentation for details), ***Action:*** EMA to clarify (either in the GVP or another dedicated guideline) the difference in MAH and EMA literature service assessment of seriousness.

PSUR assessments

Note: Industry provided their position on various issues on the requirements for, the submission, the content and assessment of PSURs (see slides).

- ***Note:*** In case of residual MAH issues during PSUR assessment, organisation of teleconferences between the EMA, the assessment team and the MAH is possible. Contact points are the EMA procedure managers (Evaluation Procedures E, Procedure Management & Business Support).
- ***Action:*** Joint industry & regulators trainings to be organised.
- ***Action:*** Next quarterly stakeholder forum to revisit the issues raised and discuss the way forward***.***

Risk Management summary publication

- ***Note:*** Further discussion is required on how to optimise the RMP summaries noting that the audience may include industry (e.g., generics companies) as well as interested patient groups.

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

- Off label use recording and reporting within pharmacovigilance
- Patient support programmes
- GVP Module P-II Biological medicinal products to be discussed again prior to finalisation of the module (either before consultation or informed by the consultation results)
- RMP summaries update;