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Inspections and Human Medicines Pharmacovigilance Division

Highlights from the 7th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 4 April 2016

The following records announcements and action points from the 7th Pharmacovigilance Industry Platform meeting held on 4 April 2016.

Welcome and matters arising

- Following the publication of the PRAC strategy on measuring the impact of pharmacovigilance activities on 11 January 2016[1], a workshop is planned for the 5th and 6th of December 2016 aiming to facilitate the implementation of this strategy, with a particular focus on the development of methodologies and to foster collaboration[2].
- The revised EU pharmacovigilance network governance becomes operational as of April 2016, which follows the near completion of the implementation of the EU pharmacovigilance legislation. The governance will continue to oversee the operational aspects of the pharmacovigilance as well as the remaining implementation of IT systems. The regulators will continue dialogue with industry through the quarterly industry platform meetings, conferences and the specific implementation groups (notably the EudraVigilance Expert Working Group and the Article 57 Implementation Working Group). Slide presentation
- ***Action:*** In the context of the current ISO-IDMP developments, the industry highlighted the importance to ensure pharmacovigilance expert input into the multi-stakeholders data management project. Industry representative will coordinate an Industry mapping of the potential interlinks between some of the pharmacovilance IT systems and ISO-IDMP development and present at an upcoming Pharmacovigilance Industry platform meeting.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/01/WC500199756.pdf

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2016/04/event_detail_001275.jsp&mid=WC0b01ac058004d5c3

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PSURs roadmap

- Industry welcomed the detailed update from the regulators and the progress made for PSURs and PSUSAs, which will initially be reflected in the 'explanatory note' to the EMA PSUR Q&A, and then in the PSUR Module GVP VII and complementary templates. The planned joint assessors and industry information session will reinforce the common understanding of PSUR position in the product life-cycle. Slide presentation
- The PSUR repository becomes mandatory as of 13 June 2016, including for products authorised in one MS only. The submissions must be in an eCTD or NeeS format. No direct submissions will be allowed to the NCAs any more. To enable submission, products need to be included beforehand in Article 57 database. Webinars and Q&As will be available prior to the mandatory use.

Recording and reporting of off-label use

- The regulators presented the draft paper on the recording and reporting of off-label use which will undergo public consultation at the end of April 2016. The guidance will later to be incorporated into relevant GVP Modules (V, VI and possibly VII). Slide presentation

Update on GVPs (update, GVP V RMP and biologicals)

- Regulators summarised the EU GVP updates planned for 2016. Slide presentation
- As a follow up from the 6th stakeholder platform, the industry presented their initial comments on the GVP V (Risk Management Planning) where public consultation is on-going until the end of May 2016. Topics highlighted by industry included the practical consideration to the removal of a safety concerns from the RMP, a consideration for generic products for which the reference product does not have the RMP, the safety list published on the CMDh web-site, and work-sharing on the educational materials.
- After the discontinuation of the publication of RMP summaries in their current format, the regulators updated on the implementation of the definitive phase for RMP summaries for centrally authorised products with a further simplified template and use of clear understandable language but without avoidance of technical terms. The content of the updated RMP summary will support transparency for patients and also support RMP submission requirements for generic medicines. Slide presentation
- The CMDh agreed that once an RMP is finalised, the CMDh will ask the MAH to submit to the CMDh secretariat a list of the safety concerns (template available on the CMDh website).
- In the context of the GVP Module P.II. Biologicals, the regulators shared the overview of the comments received during the public consultation. Slide presentation
- ***Action:*** With regard to tracing biologicals, industry was invited to make recommendations for the use of ISO-IDMP and the barcoding foreseen in the safety features implementing Regulation of the Counterfeits Directive and present at next Pharmacovigilance Industry platform meeting.

PRAC interaction with SAWP

- Further to the action points raised during the 6th EMA industry stakeholder platform, the regulators introduced the Scientific Advice PASS pilot. This is in the context of the PRAC - SAWP interaction which aims to simplify and facilitate study design and conduct. The topic covered the overall procedural aspects including timelines foreseen, and mode of PRAC input. Slide presentation

Update on preparation for signal management

- Regulators presented the topics related to signal management, including the training materials, modalities of the EudraVigilance access for the industry, the revision of the GVP IX (signal management), and the planned continuous process improvement initiative. Slide presentation
- ***Action*:** The discussion on the continuous process improvement initiative (to replace the initially planned signal detection pilot) will take place at the next EudraVigilance Expert Working Group scheduled for May 2016.

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

Industry invited to provide topics for future consideration in writing in advance of the next Pharmacovigilance Industry platform on 15 July 2016.