EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/80558/20177
Inspections, Human Medicines Pharmacovigilance & Committees Division

Highlights from the 10th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 3 Feb 2017

The following records announcements and action points from the 10th Pharmacovigilance Industry Platform meeting held on 3 February 2016.

Welcome and matters arising

- The Regulators updated on the matters arising including the 2017 PRAC work plan[1], planned GVP in children prepared jointly with the PDCO, the EV audit milestones, MLM service, big data workshop. The process improvement and simplifications were presented. The regulators highlighted also the planned workshop[2] of the SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe) and SCOPE contribution to the EU pharmacovigilance network and the safeguarding of public health.

Good pharmacovigilance practices for the EU

- The regulators presented the overview of the GVP work for 2017, including the finalisation of the revised GVP V on RMPs, GVP XVI on RMM and GVP II on PhV System Master Files (end of March/beginning of April), as well the planned finalisation of the revised GVP VI, IX and XV expected towards Q3. The Definition Annex will undergo a major revision (no public consultation is planned, as this compiles definitions already agreed through other processes). Chapters finished in 2016 included PASS and biologicals.

- The regulators clarified questions from industry including on the white paper on off label use prepared last year which will inform the final revised GVP V, VI and other concerned modules. The new population specific chapters (i.e. pregnancy, children) were given high priority in 2017, and a new module VI addendum on duplicates' management will be published for consultation too. The

[1] PRAC workplan for 2017
[2] http://www.scopejointaction.eu/news/scope-stakeholder-event/

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
Send a question via our website www.ema.europa.eu/contact

EMA also raised the question on the priority of the GVP chapter on geriatrics medicines, and industry stakeholders gave positive views in support of such a chapter.

PSUR

- The regulators presented the updates on the PSUR developments including the PSUR Road Map and specifically the explanatory note to GVP Module VII. The discussion focused on the outcome of the consultation with Industry of this explanatory note to GVP VII.
- The industry welcomed the updates on the PSUR developments and presented their feedback on the consultation of the explanatory note. The industry's feedback was followed by a dedicated discussion on specific points highlighted in relation to information presented in the submitted PSURs, these include the strengthening of the EU regional appendix of the PSUR, the considerations between RSI versus EU PI, the changes to the summary of safety concerns, the regional annex requirement for ongoing variations to be clarified and shorter, the clarification with regards to the need for close monitoring of signals and on the QPPV oversight in the PSUR context.

EU PASS, PAES requirements for disclosure

- The Regulators presented an overview of the regulatory requirements for disclosure of Post-authorisation studies[3], incl. Post-authorisation Safety & Efficacy Studies, EU RMP Categories, as well as statistics for different study types published in the EU Clinical Trials Register and EU PAS Register.
- **Action:** EFPIA to identify points to consider for the disclosure of the voluntarily conducted studies, an area of industry's special interest. Regulators' suggestions to identify such points to consider are welcomed by the industry.

Registries

- The regulators and industry provided their updates on the registries' related aspects, including types, harmonised protocols, data structure, sustainability, validity of results, and importance of data sharing, transparency, as well as patients' privacy.
- The regulators presented the EMA Initiative on Patient Registries including the report[4] from the workshop held on 28th Oct 2016 setting out stakeholders' observations and recommendations in five theme areas: benefits of patient registries and obstacles to be overcome, benefits and challenges of collaborations, technical considerations, governance, and sustainability.

[3] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/02/news_detail_002692.jsp&mid=WC0b01ac058004d5c1

[4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000658.jsp&mid=WC0b01ac058096121 1

MAH compliance with PRAC signal recommendations for PI update of CAPs

- The regulators provided an update of the MAHs' compliance with PRAC signal recommendations requesting variations of the PI for the CAPs (reference period: May 2015 - Apr 2016) with an overall positive results with more than 90% of variations submitted within the recommended timelines. The efficiency gains from concurrent submission of variations for the innovator vs. generic companies, as well as the availability of all the EU translations of the PI text adopted by PRAC were highlighted.

Next meetings:

2 Jun 2017, 21 Sep 2017 (annual meeting)

The industry prioritized the following topics for 2017: GVPs in pregnancy, GVP Modules VI & IX; update on the EV audit; traceability on biologicals. It was agreed that MLM was also a priority but would be subject to a specific workshop.