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Pharmacovigilance and Epidemiology Department

Highlights from the 12th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 24 November 2017

The following records announcements and action points from the 12th Pharmacovigilance Industry Platform meeting held on 24 November 2017.

Welcome and matters arising

- The regulators updates included the go-live of the enhanced EudraVigilance system on 22 November 2017, as well as the scope of the pilot of signal detection for the Marketing Authorisation Holders (MAH) to be started 3 months after the Eudravigilance go-live. The pilot is planned initially for a period of one year.
- The regulators briefly discussed the European Council's announcement of the Agency's new location in Amsterdam in the Netherlands after the UK withdrawal from the EU.

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  The regulators followed up with the 2018 work plan of PRAC highlighting the role of the committee in delivering innovation by working jointly with the CAT and the CHMP. In the GVPs' development area, noting that business continuity linked to relocation may impact planning, the revisions of the GVP V, the on-going GVP VI (to include the outputs of WEB-RADAR) as well as the review of the GVP VII will be undertaken; in addition the GVPs in special populations' including pharmacovigilance in paediatric and in the elderly will be progressed. In 2018 The PRAC will be delivering guidance on assessing SCARs and hepatotoxicity adverse drug reactions; it will also be looking into the emerging area of big data, as well as into the experience with tools of risk minimisation and will continue work on the impact of pharmacovigilance. Following the positive experience with the first public hearing, the committee will continue to engage with the patients.

- **Post-meeting note:**

  The revised PRAC impact strategy has been published on 1 Dec 2017 and is included in the December PRAC Highlights[1]. The strategy was launched in January 2016, with the aim to improve

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525
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safety monitoring practices and determine which activities are most successful. The strategy has been revised to reflect, among others, how major regulatory interventions benefit patients' health.

PSUR Roadmap: Joint industry/assessors training

- The industry associations provided their overall positive feedback from the first joint industry and national competent authority assessors' training which took place on the 22 Sep 2017. Thanks to its interactive setup, it gave the opportunity for many participants to follow on-line. With the aim of a common understanding of the role of the PSUR assessment in the product lifecycle in the EU, it provided a learning platform for both the industry and regulators. All related documents, including presentations and recordings are available on the EMA web-site[2].

CMDh project on ideas for WS of assessment of RMPs and informal WS procedure for follow up requests after a PSUSA NAPs

- The regulators presented the informal work sharing procedure for follow up requests after a PSUSA for NAPs (PSUFU). The rationale being that no EU procedure existed for NAPs, as regulatory equivalent to the LEG procedure for CAPs. The regulators provided scenarios on why and when the PSUFU should be utilized as well as its key elements including lead MS, procedure number (to be published by CMDh in a press release), the submission route and requirements, AR template, timetable, the publication & implementation of the outcome. In addition, the regulators followed up with the 'generic RMP project' on ideas for work sharing of assessment of RMPs.

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EudraVigilance Auditable Requirement

- The regulators discussed the go-live of the new enhanced EudraVigilance system, including the expected benefits in terms of the improved signal-detection and data-analysis tools, a better quality and completeness of ICSR data, a simplified reporting rules of ICSRs in addition to the contribution of the EV data to the WHO's Uppsala Monitoring Centre. The excellent collaboration with NCA experts in MSs and the pharmaceutical industry was highlighted as key to the delivery of the new EudraVigilance system in production. Support to stakeholders and partners will also continue throughout 2018.

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Good pharmacovigilance practices for the EU

- The regulators presented GVPs' status update. The progress in paediatric specific module (a joint product of the collaboration between the PDCO and PRAC) was highlighted with the final version expected for Q1 of 2018.

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[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2017/08/event_detail_001502.jsp&mid=WC0b01ac058004d5c3

Post-authorisation Safety Studies results

- The regulators provided recent positive examples regarding the joint PASS studies, including the valproate, the cyproterone acetate/ethinylestradiol (i.e. Diane) and Direct Acting Anti-Virals. The following issues were highlighted: the choice of the lead MAH, the communication aspects in case of many MAHs involved, and the cooperation between the regulators and the consortium, including at the early stages of the procedures.

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United Kingdom's withdrawal from the European Union preparedness activities – "Q&A session on PhV Brexit related topic"

- The regulators gave an update on EMA preparedness activities further to the UK notification on 29 March 2017 of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union and the consequences thereof. As published on the European Commission – EMA notice published on 2 May 2017, in relation to the UK status, "*This means that unless the withdrawal agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). The United Kingdom will then become a 'third country'*".
- The regulators reminded pharmaceutical companies of their legal obligations in that context. The regulators highlighted the recent publications of several guidance documents, namely the EMA procedural guidance (published on 24 November 2017) and the updated version of the European Commission-EMA Q&A (published on 1 December 2017). These documents are aimed respectively to provide Industry with procedural guidance for submission of their "Brexit" related changes to the EMA for their centrally authorised medicinal products and provide clarification on the legal requirements and consequences of the UK withdrawal from the EU. Finally, the regulators presented the EMA planned "Brexit preparedness" meetings with industry stakeholders in 2017 and 2018 (subject to changes) as well as all the contact details in case of further questions. Industry was advised to highlight to EMA any particular challenges they would be facing as early and pro-actively as possible either at EU pharmaceutical Trade level or at company specifics.

- **Action:**

  EMA to clarify (in form of a EMA public Q&A or guidance update) the status/ location of the deputy QPPVs post Brexit.

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Next meeting/topics:

- Quarter 1 2018
- Signal management pilot, updates on the MLM experience, patient support programmes, RMMs, UK withdrawal from the EU.