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Inspections and Human Medicines Pharmacovigilance Division

Highlights from the 8th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation – 1 July 2016

The following records announcements and action points from the 8th Pharmacovigilance Industry Platform meeting held on 1 July 2016.

Welcome and matters arising

- The Regulators provided an update on the planning for new and revised pharmacovigilance guidance. Slide presentation

Risk Management Plan guidance and templates

- The Regulators provided detailed feedback from the public consultation of the GVP V Module and the respective RMP template.
- **Post-meeting note:** all the comments received during this consultation will be published together with the final Module on EMA web-site by Q1 2017. Slide presentation
- The Regulators presented the published RMP questions and answers[1], to clarify certain operational and procedural management aspects of RMP submissions during post-authorisation lifecycle of centrally authorised products. Slide presentation
- Updates from CMDh on the possibility of RMP work-sharing were sought by Industry Stakeholders and will be followed up as part of the next meeting of the "CMDh and Industry Ad Hoc Group to discuss RMP Initiatives" which hopefully will be arranged in September 2016.
- The need for adequate training and workshop/communication with stakeholders was highlighted. **Action**: The "CMDh & Industry Ad Hoc Group to discuss RMP Initiatives" to address in their next

1 http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000171.jsp&mid=WC0b01ac0580a53f5f

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

meeting several topics identified such as the frequency of the updates and the harmonisation issues around the list of safety concerns included in approved RMP.

- **Action**: Industry to send CMDh (Kora Doorduyn-van der Stoep and Anne Ambrose) and copy to EMA its reflections for a WS procedure for RMP assessment on RMP AR work-sharing in advance of the next "CMDh & Industry Ad Hoc Group to discuss RMP Initiatives".

EudraVigilance system

- The Regulators informed Industry Stakeholders of the rescheduling of the roll-out of the new EudraVigilance (EV) system (with go live now planning for Q4 2017). They also updated stakeholders of the Eudravigilance updated communication tools, including the new EV corporate web-site launched in June 2016. The topics also covered the e-learning platform together with the training strategy. The Regulators highlighted the importance of industry preparedness for the on-going changes in EV. Slide presentation

  Action: EMA agreed to investigate whether detail of the audit scope and vendor could also be published.

- **Post-meeting note**: the MAHs are required to test the enhanced EudraVigilance system once they are ready to implement the new system supporting the submission of E2B (R3) ICSRs. Testing of existing E2B (R2) system with the new EudraVigilance system is not required; however the MAH are encouraged to do so in advance of the new system going live in Q4 2017, in order to identify any potential issues. The MAHs should plan to complete any testing of their existing systems three to six months prior to the new system going live in order to give time for any issues to be addressed. This information can also be found in the EudraVigilance stakeholder change management plan published on the EMA website[2]

Medical Literature Monitoring (MLM) update

- The Industry presented the results of their MLM survey on the utilization of the EMA MLM service. Improvements in the case quality, the search strategy and the inclusion of the non-serious non EEA cases into the service were noted. The survey highlighted areas for improvements and suggested that consideration should be given to expanding the service to cover aspects of literature monitoring beyond than just ADR reports (off-label use, medication errors not relating in harm etc).
- The Regulators updated Industry stakeholders on the EMA survey and on MLM service latest improvement and future directions. The EMA intends to share its survey results and audit results. Slide presentation
- **Action**: The Regulators will hold a workshop on the 13th of September 2016 with Industry Stakeholders to discuss the scope, performance and optimisation of the MLM service. Registrations, through the EU level industry associations should be emailed to Malgorzata.Durka-Grabowska@ema.europa.eu with the subject line "EMA-industry MLM workshop"

2 http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/10/WC500196029.pdf

Pharmacovigilance System Master File (PSMF)

- The Regulators explored the need for an update of the GVP Module II (PSMF) with Industry Stakeholders whom overall, confirmed the current adequacy of its content as it stand as recognised to be one of the clear and easy to follow. Industry suggested the GVP Module only required a few clarifications which could be achieved through a dedicated Q&A document. For the drafting of the Q&A, the feedback received from the inspectors, including common pharmacovigilance inspection findings as well as the queries received by the regulators will be taken into account.

Clinical trials Reference safety information (FSI)

- Industry stated that they were receiving an increased number of questions and objections to RSI as submitted in trial applications or IB updates and this was delaying trial start and product development. The Industry highlighted the need for an aligned EU guidance document on the RSI for clinical trials of sufficient granularity to avoid rejections going forward. In addition, there may a need for an implementation transition period to avoid further impacting clinical trial start-ups. In principle such a document should be issued by the Clinical Trial Facilitation Group (CTFG).
- **Action**: Industry to highlight the concern to CFTG together with specific consideration within the CT EU Portal discussions and the need for an EU updated guidance to be developed.

ISO IDMP – pharmacovigilance interface

- Further to the action point raised during the 7th platform meeting, the Industry presented their initial feedback on the ISO-IDMP developments from a pharmacovigilance perspective. Industry considered the implementation of ISO-IDMP to be a multi-stakeholder data management project representing a transformative approach supporting business processes, and considered as a strategic asset for the regulators. The project requires data uniformity, accuracy and consistency and represents a major change in data management for the regulators and industry. A pragmatic, efficient and collaborative approach is needed to identify business use cases that justify any new data element requirements.

- The Regulators presented the high level stakeholder engagement approach regarding the IDMP and SPOR (substance, product, organisation, referentials) implementation. The plan involves specific industry and NCA liaisons contacts/groups who will play a key role in communication of the ISO-IDMP key steps and communication guidance documents. A specific 'kick-off' webinar for Industry Stakeholders is planned on 21 July 2016, where representatives of each EU Pharmaceutical Industry Associations (human and veterinary) will be invited as observers). The telematics task force with the industry representatives will monitor the implementation of the agreed actions. Slide presentation

  It was stressed that best use of these workshop/webinars was important to identify further business use cases such as product falsification, simplifying of regulatory procedures, e-prescription, and manufacturing.

- **Action:** industry and regulators to both consider how ensure that pharmacovigilance business requirements are taken into account during the implementation phase of ISO-IDMP.

Falsification of medicines

- Further to the action point raised during the 7th platform meeting regarding the tracing of biologicals, the Industry presented their initial feedback on how the ISO-IDMP project can be used in barcoding of the safety features foreseen in the Commission Delegated Regulation (EU) 2016/161 which will apply from 9 February 2019. In principle the GTIN number (Global Trade Item Number) will link with the IDMP from the start in the supply chain until the product reaches the patient. The utilisation data would be at the country level. Discussions are currently on-going on how these data can be enabled, including the possibility of a direct link between the GMP and GVP stages in product life cycle.
- **Action:** The Regulators will follow up with the European Commission, which is currently discussing the creation of Member State working groups on specific technical topics to ensure a harmonised application of the safety features rules.

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

Industry was invited to provide topics for future consideration in writing in advance of the next EMA Industry Platform meeting planned on 21 Sep 2016.