EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk Management Planning

Follow-up from the previous meeting

Industry Stakeholder platform meeting on the operation of EU pharmacovigilance legislation

12 January 2015

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An agency of the European Union

Update on the review of the GVP Module V including RMP templates

- Work on the revision of GVP Module V has started
  - **Public consultation planned for Q2 2015**
- The revised template for RMPs has been drafted, additional input from Stakeholder Forum discussions to be considered
  - **Template will be piloted in Q1 2015 with nominated companies for testing ahead of wider consultation**
- Training to be provided on revised GVP Module V and related RMP template
  - **RMP InfoDay planned for Q2 2015**

Revision of the RMP review process during the assessment of initial MAAs

Background: based on experience with the RMP review process as part of the implementation of the pharmacovigilance legislation, aspects were identified to improve the scientific review process across committees

Key aspects: roles and responsibilities of Rapporteurs (CHMP: safety specification; PRAC: prospective risk management planning); timing of detailed PRAC plenary discussion

Practical arrangements (business process and assessment template) currently being put in place, in collaboration with PRAC and CHMP → implementation expected later in Q1 2015

➢**No direct impact on applicants; communication to follow**