EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on pharmacovigilance guidances

8th Industry Platform meeting on the Implementation of EU Pharmacovigilance Legislation - 1 July 2016

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Pharmacovigilance guidance – status update

EUROPEAN MEDICINES AGENCY

Revisions finalised and publication is imminent:

- GVP Module VIII – Post-authorisation safety studies (Rev2) and its addendum I will be published in July 2016.

Ongoing revisions:

- GVP Module XV – Safety communication (Rev 1) and Annex II is expected in Q3 2016;
- GVP Module VI – Management and reporting of adverse reactions to medicinal products (Rev 2) and addendum I will be released for public consultation in Q3 2016;
- GVP Module IX – Signal management (Rev 1) and revised guidance on statistical methods (addendum I) will be released for public consultation in Q3 2016;
- GVP Module V – Risk management systems (Rev 2), public consultation closed in May 2016;
- GVP Module III – Pharmacovigilance inspections (Rev 2) drafting is ongoing;
- GVP Module II – Pharmacovigilance system master file (Rev 2) drafting is ongoing;
- GVP - Annex I - Definitions (Rev 4) drafting is ongoing.

Guidance under development:

- Publication of final Pharmacovigilance guideline for biological medicinal products is expected in Q3 2016;
- The Pharmacovigilance guideline for paediatric medicines – drafting is ongoing;
- The Pharmacovigilance guideline for pregnancy is planned to be released for public consultation in late 2016;
- The Pharmacovigilance guideline for medicines used by the older population is planned to be released for public consultation in late 2016.

Thank you for your attention

Further information

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