EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance System Master File

Discussion of the need to revise GVP guidance

8th industry stakeholder platform – operation of EU PV legislation

Presented by Sophia Mylona on 1 July 2016
Compliance and inspections department

GVP Module II – pharmacovigilance

exploring the possibility for revision

The Agency, with the Pharmacovigilance Inspectors Working Group (PhV IWG) and the Pharmacovigilance Risk Assessment Committee (PRAC) is exploring the possibility for revision of Good Vigilance Practice (GVP) module II on pharmacovigilance system master file, gathering:

- pharmacovigilance inspection experience;
- common pharmacovigilance inspection findings and queries received by the Agency;
- call for industry feedback on the use of the PSMF and any proposals for revision of the GVP Module II guidance text.

GVP Module II – pharmacovigilance

exploring the possibility for revision

Feedback received by industry stakeholders will be considered in order to decide:

- whether there is a need for change in GVP text;
- the areas / GVP Module II sections to be revised, if applicable;
- whether for some topics it is best to provide further guidance by creating a specific Q&A / practical document instead of revision of GVP Module II text.

Following the call for industry feedback on the PSMF use and proposals for GVP Module II revision, responses were received by two organisations. Reminder to be sent with new deadline on 15 July 2016.

Thank you for your attention

Further information

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