EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on new guidance on risk minimisation measures (GVP module XVI RMM)

Session 3 - Impact of pharmacovigilance activities on healthcare and patient safety

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RMM effectiveness evaluation in GVP XVI and Addendum II

GVP XVI.B.5 Effectiveness evaluation of RMM

- Principles
- Objectives and approaches to evaluation
- Assessment of effectiveness and regulatory follow-up

GVP XVI.Add II – Methods for effectiveness evaluation

- Data collection/data sources
- Research methods
  - Qualitative research
  - Survey methods
  - Methods evaluating behaviour and health outcomes
- Reporting results of effectiveness evaluation

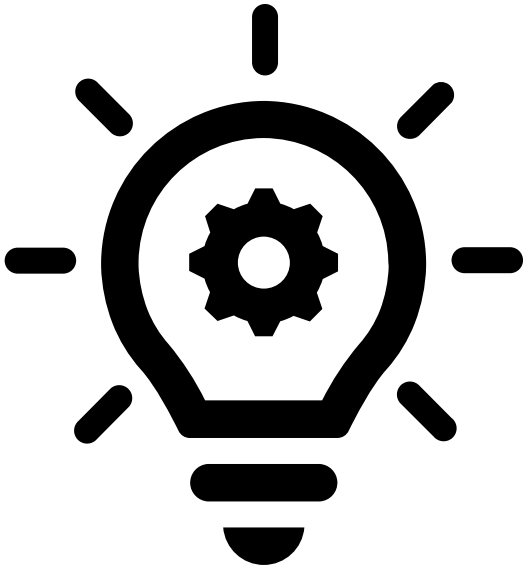
Public consultation feed-back – GVP XVI.B.5

- **Digital RMM methods/tools** collecting real-time data for effectiveness evaluation;
- Need for comprehensive **RMM evaluation framework** (RIMES, Smith et al. 2014);
- **Flexible evaluation timepoints** (principle 2);
- **Reporting** (with RMP update or evaluation report) and adding/removing RMM tools;
- More guidance on **'process measures'** (dissemination metrics)**;**
- **Burden of surveys** on healthcare system;
- **Spontaneous reporting** trends as evidence for negative or positive effectiveness;
- **Patient-reported outcome measures (PROM)** as behavioural change measures;
- Definition of **thresholds of success** for RMM tools and actions if (partially) not reached;
- **MAH engagement** expectations in clinical guidelines and treatment standards;

Public consultation feed-back – Add.II

- **Structure** of methods chapter (qualitative – quantitative);
- **Data sources** chapter **not specific** to effectiveness PASS (separate guidance?);
- Emphasis on **mixed methods approach** (qualitative/quantitative) for RMM evaluation;
- **Human Factors/Usability Engineering techniques** for RMM user needs;
- **Techniques** to investigate **failed RMM** including literature references;
- Further **survey limitations** (limited exposure after initial licensing);
- **RIMES reporting standard** mandatory for MAHs?
- **Barriers to RMM implementation** beyond MAH control (national adaptions to RMM);

Questions or suggestions?



Thank you for your attention

Further information

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