EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk minimisation measures

PCWP/HCPWP joint virtual meeting, 24 June 2020

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Objectives of today's discussion

- Risk minimisation is a major area of regulatory activity
- Designing and implementing such measures for effective risk minimisation is challenging
- Regulatory guidance on risk minimisation is available and has been strengthened over time
- A guidance review is ongoing now and EMA wants to involve patient and healthcare professional representatives in this review and obtain their input - with a view to strengthen their involvement when developing and reviewing effectiveness of future risk minimisation plans and measures

Structure of today's discussion

- Brief overview on pharmacovigilance guidance
- Overview on the scope of revision regarding risk minimisation measures
- Patients' perspective on risk minimisation
- Healthcare professionals' on risk minimization
- Open discussion on specific topics identified by EMA and patient and healthcare professional representatives
- Discussion outcomes will inform the revised guidance which will be released for public consultation in Q4 2020/Q1 2021

Good pharmacovigilance practices for the European Union (EU-GVP)

- Set of guidelines developed by the EU regulatory network on the practical implementation of legal requirements for pharmacovigilance across the EU for patient and public health protection
- Applies to EU marketing authorisation holders, competent authorities in EU member states and the EMA
- By way of specific agreements with the EU, it also applies in EEA countries (i.e. Norway, Iceland and Liechtenstein)
- Regulatory-scientific content
- Takes into account international standards and guidance
- Developed through internal and external expert dialogue under supervision of the Pharmacovigilance Risk Assessment Committee (PRAC) and public consultation open to all citizens of the EU and parties worldwide
- In force in the EU since 2012, updated regularly and recognised globally

EU-GVP published on a dedicated webpage on EMA website

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Introductory Cover Note

Modules on processes:

Pharmacovigilance system and its quality management
Pharmacovigilance system master file (PSMF)
Inspections
Audits
Risk management plan (RMP)
Individual case safety report (ICSR)
Periodic safety update report (PSUR)
Post-authorisation safety study (PASS)
Signal management
Additional monitoring
Safety communication
Risk minimisation measures (RMM)

Population- or Product-specific Considerations:

Biologicals
Vaccines
Pregnancy & breastfeeding
Paediatrics
Geriatrics

Annex I
Definitions

Annex II
Templates

Annex III
Guidance developed before GVP

Annex IV
International Council for Harmonisation (ICH) guidance

Annex V
Abbreviations

GVP Archive

Links to non-GVP guidance

GVP Module XVI – Scope of guidance

- Legal requirements for risk minimisation measures (RMM)
- Current RMM types: product information (routine), educational programmes, controlled access programmes, pregnancy prevention programmes, direct healthcare professional communications (additional)
- Additional RMM types underpinned by an 'additional RMM toolbox'
- Methods for evaluating RMM effectiveness
- Roles and responsibilities of marketing authorisation holders and the EU regulatory network

GVP Module XVI - Purpose of ongoing revision

- Review of terminology for the additional RMM types and tools (i.e. consistency and clarity of terms)
- Description of additional RMM tools
  - Rev2 included list of tools with some descriptions; rev3 draft now includes exhaustive description of guides, checklists, patient cards, risk awareness forms and diaries.
- Review of RMM effectiveness evaluation
  - New addendum
- Pregnancy and pregnancy prevention programmes
  - Changes to come at a later point

Any questions?

Further information

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