Measuring the Effectiveness of Risk Minimisation Measures

The Risk Minimisation Plan

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Risk Minimisation Measures

Safety concerns

Prevent or Minimise!

Risk Minimisation Measures

Routine Risk Minimisation
- Legal status
- Pack size
- SPC
- Package leaflet
- Labelling

Additional Risk Minimisation
- Educational programme
  - Patients/carers
  - Health care professionals
- Controlled access programme
- Pregnancy prevention programme

Risk minimisation Plan

Effectiveness of RMMs
Additional RMMs

1. Educational Programme
   - *For HCP:* e.g. Prescribing Guide/checklist; Safety Guide
   - *For Patients/Carers:* e.g. Alert Card; Reminder Card

2. Controlled Access Programme
   - Access subject to compliance with specific RMMs applied at the level of prescribing, dispensing, or use of a medicinal product. E.g:
     - Specific testing and/or examination of the patient to ensure compliance with strictly defined clinical criteria
     - Patient enrolment in a registry

3. Pregnancy prevention programme:
   - A set of interventions to prevent pregnancy during treatment with a product with potential/known teratogenicity
   - Male fertility: Interventions may involve the father
RMMs: Why To Assess the Effectiveness

- Legislation requires **active monitoring of the outcome** of risk minimisation measures
- Crucial aspect of continuous pharmacovigilance
Risk Management Cycle

- Clinical Trials Phase I-III/IV
- Spontaneous Reporting
- Scientific Literature
- Epidemiological Studies - Registries

Risk Identification

- Effectiveness Measurement
- Risk Management
- Risk Minimisation Intervention
- Risk Assessment
RMMs: How To Assess The Effectiveness

- Quantify risk reduction
- Assess how drug is used

Effectiveness Measure

- Define milestones for assessment
- Consider burden on patients/prescribers and performance in healthcare system

Risk of ADRs

Performance measures
- received, perceived, understood
- impact on behaviour

Attainment of RMM objectives
Dual Approach to assess effectiveness

- Risk
  - Risk Management Plan
  - Risk Minimisation Measures (RMM)

  **Tools for RMP**

  - Implementation of RMM
    - Process Indicators: successful implementation of RMM according to plan
    - Research protocol (survey methods, psychometrics, etc)

  - Attainment of the RMM objectives (effects of the RMM)
    - Final Outcomes Indicators: ADR occurrence or severity
    - Post Authorisation Safety Studies (PASS)

  - Dual evidence of RMM effectiveness
    - Clinical Knowledge
      - Clinical Actions
    - Pre-Post comparison of ADRs
    - Post intervention ADR compared to reference value

Patients Contribution

- Survey targeting patients and/or HCPs
  - To monitor understanding and knowledge by means of appropriate psychometric measures (e.g. was an educational intervention received, perceived, understood?)
  - To evaluate the impact of interventions on behavior
- Prospective observational studies
  - Pregnancy registry
  - Disease/product registry
- Spontaneous report of ADR
- Studies conducted by mean of secondary use of electronic records:
  - Anonymised electronic databases across EU
Thank you!