Lääkealan turvallisuus- ja kehittämiskeskus | Säkerhets- och utvecklingscentret för läkemedelsområdet | Finnish Medicines Agency

Guideline on good pharmacovigilance practices (GVP)

Module I Pharmacovigilance systems and their quality systems

Stakeholders Forum, 27 February 2012,
EMA, London

Suvi Loikkanen, Senior Pharmaceutical Officer

Module I Pharmacovigilance systems and their quality systems

- Guidance for the establishment and maintenance of quality assured pharmacovigilance systems:
    - Marketing authorisation holders
    - Competent authorities of Member States
    - Agency
- Describes general application of quality management to pharmacovigilance systems and requirements specific to the operation on EU network

Key elements of the Module I
Structures and prosesses

- Overall quality objectives for pharmacovigilance
- Principles for good pharmacovigilance practices
- Responsibilities
- Training
- Facilities and equipment
- Compliance management

Key elements of the Module I
Structures and prosesses

- Record management
- Documentation
- Critical pharmacovigilance processes
- Monitoring performance and effectiveness
- Preparedness planning

Key elements of the Module I
Operation of the EU network

- Applicant and marketing authorisation holder
    - Overall pharmacovigilance responsibilities (EU)
    - Responsibilities in relation to the QPPV
    - Specific quality system processes
    - Quality system requirements for delegated pharmacovigilance tasks
- Qualified person responsible for pharmacovigilance (QPPV)
    - Qualifications
    - Role

Key elements of the Module I
Operation of the EU network

- EU regulatory network
    - Competent authorities in Member States
    - European Commission
    - European Medicines Agency
    - Pharmacovigilance Risk Assessment Committee (PRAC)
    - Committee for Medicinal Products for Human Use (CHMP)
    - Coordination Group for Mutual Recognition and Decentralised Procedures (CMDh)

Take home messages:

- Quality system is to assure the integrity of the pharmacovigilance system and is an integral part of the pharmacovigilance system

- Produce visibly good pharmacovigilance

  - Public health
  - Overall confidence
  - Public trust

Thank you!

- Questions?
- Comments?
- Public consultation is open until 18 April 2012, contact point: gvp@ema.europa.eu