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

Guideline on good pharmacovigilance practices (GVP)

Module III Pharmacovigilance inspections

Stakeholders Forum, 08 November 2012,
EMA, London

Suvi Loikkanen, Senior Pharmaceutical Officer

Module III Pharmacovigilance inspections

- Overview of the public consultation

- Next steps

Module III Pharmacovigilance inspections

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Overview of the public consultation
GVP module III - Pharmacovigilance inspections

- Feedback received from 17 organisation
  - National pharmaceutical industry associations
  - European pharmaceutical industry associations
  - Pharmaceutical companies
  - Regulatory authorities

- ”Module provides transparency to the inspection process and gives MAH and NCA alike guidance on the expectations during inspections.”
- ”With regards to a comparison between this guidance and Vol 9a, this represents clarification on existing inspection guidance as opposed to new requirements.”
- ”We fully understand and support the intention of proposed module… have few comments.”

Overview of the public consultation
GVP module III - Pharmacovigilance inspections

- New concepts in addition to the elements included in vol. 9A:
  - Supervisory Authority
    - PSMF location
  - Pre-authorisation inspections
    - Performed by Supervisory Authority
  - Information sharing on inspections planned and conducted
  - Communication of non-compliance

Overview of the public consultation
GVP module III - Pharmacovigilance inspections

- Clarification/definition requested

  - Non-compliance
    - Critical and/or major findings according to the EU grading definitions

  - Alignments with legislation
    - PSMF
    - Contac person for pharmacovigilance issues at national level
    - Relevant third parties, multiple contracting partners
      - Any firms employed to perform pharmacovigilance activities

Overview of the public consultation
GVP module III - Pharmacovigilance inspections

- Structures and processes and operation of EU network
  - Requests to harmonise minimum timelines and specific proposals regarding inspection announcements and provision of the agenda
  - Inspection follow-up and communication between inspectors and assessors need clarification
  - Concerns about publication of information on the conduct of pharmacovigilance inspections and their follow-up

Next steps
GVP module III - Pharmacovigilance inspections

- Module finalisation through the project governance structure and formal approval process
- Final Module III publication in December 2012
- Preparation of community procedures on pharmacovigilance inspections - work in progress

Thank you!

- Questions?
- Comments?