Pharmacovigilance Working Group: Potential Future ICH Topics Update

International Conference on Harmonisation
Brussels, Belgium

Pharmacovigilance Planning Guidance - E2E

- Published -Federal Register, April 1, 2005, Volume 70, Number 62, Pages 16827-16828
- Available on ICH website
- Major features
  - Safety specification
  - Pharmacovigilance plan

Brainstorming Session

- Yokohama - November 2004
- EFPIA, EU, JPMA, MHLW, PhRMA, FDA, WHO, Health Canada, EFTA
- Potential topics
  - Pharmacovigilance
  - Pre- and post-marketing safety assessment
  - Risk communication

Path Forward

- Gap Analysis
- Survey conducted by EU - February 2005
- Topics
  - safety assessment in clinical trials
  - safety communication
  - pharmacovigilance in pediatrics
  - good pharmacovigilance practice
  - risk minimisation

I. Safety Assessment in Clinical Trials

- standardised, consistent annual safety report
- how safety data are interpreted
- how ICSRs are reviewed, assessed and reported
- how institutional review boards (IRBs) and Data Safety Monitoring Boards (DSMBs) operate

II. Safety communication

- standards for the content of various sections of the label
  - precautions, adverse events, etc.
- developing consistent communication approaches with patients and healthcare providers
  - dear health care provider letters
  - patient information

III. Pharmacovigilance in Pediatrics

- European Union
  - Draft Note for Guidance : Conduct of Pharmacovigilance for Medicines used by the Paediatric Population in development
  - Expected date of finalisation : end 2005.

IV. Good Pharmacovigilance Practice

- Guidance published in U.S.
  - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
  - http://www.fda.gov/cder/guidance/5767dft.pdf
- Guidance under consideration in EU and Japan

V. Risk Minimisation

- Draft guidance under consideration in EU
- Guidance published in U.S.
  - Development and Use of Risk Minimization Action Plans
  - http://www.fda.gov/cder/guidance/5766dft.pdf

Guidance “Harmonization”

- US/EU/Japan efforts in pre/post-market risk assessment and risk minimization
  - Good Risk Assessment Practices Guideline (Good Pharmacovigilance Practices)
  - Risk Control/Communication Guideline (Risk Minimization)

Next Steps

- Input from public, stakeholders
- Gap analysis
  - grid, what has been covered, what has not
- Priority topics
  - concept papers
- Further discussion
  - Brussels - May 9-10, 2005