厚生労働省
Ministry of Health, Labour & Welfare

Pharmacovigilance Brainstorming

厚生労働省医薬食品局安全対策課
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Mainly ICH－E2C(R)

- Background
- Regulatory consideration
- Framework
- Way forward

Background

- No need to amend E2A, E2D
- Overlap: E2C, E2E, E2F
- EU regulator's Proposal: Target 2012
- Reopen E2F?
- E2E review near future?
- 6 parties position; EC, MHLW, FDA, PhRMA, EFPIA & JPMA?
- RMP, REMS, regional PvP, risk minimisation

Framework of Discussion(1)

- Vision
  - Optimise lifecycle benefit/risk,
  - public health,
  - improved documentation of safety information,
  - B/R evaluation
- Achieving the Vision
  - gap analysis E2C, E2E, E2F
  - Periodic Benefit Risk Evaluation Reporting
  - Transformation (relating E2E, E22F)
  - Priority

Framework of Discussion(2)

- Perceived Problem; ICSR, electronic, new regional regulation, recent advance vs. 1990's
- Scope: benefit/risk evaluation, safety specification
  - no tabulation /line listing,
  - modular approach,
  - Electronic
  - Timing
  - cumulative

Way forward

- If Steering Committee agrees…….

  EWG may start in 2011
- Step 2, 4?
- Seriousness
- What implication and impact of E2C revision ?
  - Japanese regulation?
  - Worldwide?