FDA Guidance for Industry Development and Use of Risk Minimization Action Plans

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FDA

Guidance

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- /5766dft.pdf RiskMAPs
- /5765dft.pdf Premarketing
- /5767dft.pdf Pharmacovigilance

Risk Management

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Risk Assessment

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Risk Minimization

Risk Assessment and Risk Minimization

Highly inter-related

- Occur both pre- and post-marketing
- Best if both are evidence-based

Risk minimization efforts are based upon good risk assessment

Key Points about Guidance

- Two rounds of commentary valuable
  - Concept paper and draft guidance
- Framework, nomenclature will aid FDA and Industry discussions
  - Common terminology
  - Recommendations for when, how, what of discussions and submissions

Key Points about RiskMAPs

- Start with good risk and benefit assessments
- Seek stakeholder input, transparency
- Set clear goals for health outcomes
- Define intermediate objectives
- Pick tools from 3 categories
  - Targeted education and outreach
  - Reminder systems
  - Performance-Linked Access Systems
- Evaluate and communicate with FDA about progress, possible changes

Final vs. Draft Guidance

- Evaluation strengthened and clarified
- Decision-making and consistency questions addressed
  - Public advisory committees
  - CDER clearance of RiskMAPs with reminder or restricted distribution tools

For Reference

Risk Minimization Action Plan (RiskMAP) Definition

- A strategic safety program designed to meet specific *goals* and *objectives* in minimizing known risks of a product while preserving its benefits
- Uses one or more *tools* to accomplish these ends

RiskMAP Definitions

- Goal – End result, expressed in terms of one or more health outcomes to be achieved (or avoided)
- Objective – Intermediate step to achieving the goal(s)
- Tool – System or process other than product labeling

Definitions Applied to a Fictional Example

- Goal: A dangerous drug-drug interaction should not occur
- Possible Objectives:
  - Physicians won't co-prescribe 2 drugs
  - Pharmacists won't co-dispense
  - Patients won't take 1 drug with the other
- Tools: Education, pharmacy alert screens, or restrictions on physicians or others

Categories of RiskMAP Tools

- Targeted Education & Outreach
  - *–to inform*
- Reminder Systems
  - *–to alert or reinforce*
- Performance-Linked Access Systems
  - *–to block unsafe use*

Summary: RiskMAPs

- Apply to a small number of products
- Have clear goals and objectives
- Use tools that
  - are evidence-based
  - allow appropriate product access
  - consider stakeholder input, technology, use settings, other factors
- Are evaluable and monitored