Current FDA Initiatives to Integrate Pre- and Post-Market Review

Symposium on the Future of Drug Safety – Challenges for FDA

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IOM Recommendation 3.4:

- ...appoint an OSE staff member to each NDA review team and…

- ...assign joint authority to OND and OSE for post-approval regulatory actions related to safety.

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- CDER is evaluating feasibility of involving OSE staff earlier in reviews
  - Trade name review - done now
  - Risk MAPs - done now
  - For future:
    - data from open-label studies
    - post-marketing data from outside US
    - currently evaluating models for increased role

IOM Recommendation 3.4:

...assign joint authority to OND and OSE for post-approval regulatory actions related to safety.

- CDER is evaluating models for more significant involvement of OSE in postmarketing decision making

4.4: CDER should assure the performance of timely and scientifically-valid evaluations of Risk Minimization Plans (RiskMAPs) (1)

- Plan to identify risk management tools and programs
  - input from academia, industry, and others
- conduct assessments of the effectiveness of identified RiskMAPS, current risk management and risk communication tools

4.4: CDER should assure the performance of timely and scientifically-valid evaluations of Risk Minimization Plans (RiskMAPs) (2)

- conduct annual systematic review and public discussion of the effectiveness of 1 to 2 risk management programs and 1 major risk management tool
- post reports of these discussions on FDA Web site
- hold a public workshop to obtain input from industry and other stakeholders regarding prioritization of the plans and tools to be evaluated

4.5: Develop and continually improve a systematic approach to risk-benefit analysis for use throughout the FDA in the pre-approval and post-approval settings (1)

- new initiatives in quantitative benefit-risk assessment
- Quantitative Safety and Pharmacoepidemiology Group

4.5: Develop and continually improve a systematic approach to risk-benefit analysis for use throughout the FDA in the pre-approval and post-approval settings (2)

- Initiatives from Postmarketing Safety "Process Improvement Team"
- work began in March, 2005

1. improve the safety processes that span post-marketing activities in OND and OSE (the former ODS) to better meet their respective missions

- enhance CDER's responsiveness to post-marketing safety issues

Three (3) Key Policy Concepts:

- Create a PM “Safety Entity” within each OND division
- Create a PM Safety Tracking System
- Initiate periodic (annual) assessments of recently approved New Molecular Entities (IOM recommendation 5.4)

Creation of a PM "Safety Entity" Within Each OND Reviewing Division

- All divisions maintain a staff that focuses on postmarketing safety
- Minimum personnel requirements:
  - "Associate Director of Safety"
  - Safety Regulatory Project Manager
- Staff could be expanded beyond this nucleus

Post-Marketing Safety Tracking System

- Will facilitate timeliness of activity completion

4.13: CDER Review teams regularly and systematically analyze all postmarket study results and make public their assessment of the significance of the results with regard to the integration of risk and benefit information.

- much information is pre-decisional
- release could have adverse public health impact
- decisions to publicly disclose assessments of postmarketing safety studies have to be made on a case-by-case basis

4.13: (make analyses and assessments of postmarketing data public, with B-R assessment)

- plan to publish a newsletter on our Web site containing summaries of the results, including methods, of postmarketing drug reviews.
- no commercial or pre-decisional information
- information on emerging safety issues; recently approved products

5.4: Evaluate all new data on NMEs no later than 5 years after approval

- active process
- joint review by OND & OSE
- periodicity - to be determined (may differ based on priority)
- currently being piloted