Enhancing Post Marketing Safety Monitoring – FDA Initiatives for Improving Drug Safety Monitoring

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March 12, 2007

IOM Recommendation 4.1

- The committee recommends that in order to improve the generation of new safety signals and hypotheses, CDER
  - A) conduct a systematic, scientific review of the AERS (adverse event reporting system) system,
  - B) identify and implement changes in key factors that could lead to a more efficient system, and
  - C) systematically implement statistical-surveillance methods on a regular and routine basis for the generation of new safety signals.

IOM 4.1 - FDA Actions

- Upgrade AERS II
  - Improve and expand functionalities
  - Allow for more efficient use of the database
- Publish RFP on AE reporting
  - Study AE reporting through a drug's lifecycle
  - Maximize public health impact of AE reporting

IOM 4.1 - FDA Actions (cont.)

- Pilot program to review New Molecular Entities after one year
  - Evaluate utility of scheduled systematic review of NMEs
  - Gather data on resources estimates

- Sentinel Network Meeting
  - March 7-8, 2007
  - Ideas for integration of public and private sector postmarketing safety monitoring systems

IOM Recommendation 4.2

- The committee recommends that in order to facilitate the formulation and testing of drug safety hypotheses, CDER
  - A) increase intramural and extramural programs that access study data from large automated healthcare databases, and
  - B) include these program studies on drug utilization patterns and background incidence rates for adverse events of interest, and
  - C) develop and implement active surveillance of specific drugs and diseases as need in a variety of settings.

IOM Recommendation 4.6

- The committee recommends that CDER build internal epidemiologic and informatics capacity in order to improve the postmarket assessment of drugs.
  - Hire additional epidemiologists, statisticians, and programmers
  - Development of guidance document on observational pharmacoepidemiologic studies

IOM 4.2/4.6 - FDA Actions

- Expand capabilities using observational data
  - Strengthen intramural program:
    - Access additional databases (eg, CMS)
    - Hire additional epidemiologists and programmers
  - Strengthen extramural program
    - Increase contract capacity
    - Increase internal FDA resources to manage these programs
    - Increase partnerships with other Federal agencies
      - AHRQ, VA, DoD
  - Develop guidance on best practices for observational pharmacoepidemiological studies

IOM 4.2/4.6 - FDA Actions (cont.)

- Drug utilization patterns
  - Expand range of drug utilization databases
    - Acquire data on settings of care not already available to FDA
- Active surveillance
  - Need testing and validation
  - Implementation to follow, based on results of testing