U.S. Department of Health and Human Services
Agency for Healthcare Research and Quality
Food and Drug Administration

Summary of Public Workshop

Implementation of Risk Minimization Action Plans (RiskMAPs) to Support Quality Use of Pharmaceuticals: Opportunities and Challenges

June 25-26, 2007

Workshop participants agreed on the goal of preserving patient access to certain medicines with unusual safety or patient monitoring concerns through implementation of necessary and practical RiskMAPs that assure appropriate use. They urged more standardized—as well as adaptable and flexible—approaches to risk minimization that were still sensitive to the unique risks of each drug. RiskMAPs were seen as a leverage point to develop consensus on system-wide solutions to improving health care by reducing significant known risks of a medicine and preventing medication errors.

The public workshop on RiskMAPs sought input from patients and consumer advocates, clinicians, pharmacists, distributors, third-party payers of care, the pharmaceutical and biotechnology industries, researchers and innovators in health information technology. The two-day meeting was another step in FDA's effort to systemically monitor the performance of RiskMAPs and perform regular follow-ups of these plans.

RiskMAPs are strategic safety programs designed to meet specific goals and objectives and minimize the significant known risks of a medicine. RiskMAPs employ one or more risk minimization tools in addition to the FDA-approved labeling and routine reporting of adverse events, including:

- *Targeted education and outreach* to inform patients and health-care practitioners about a product's risks and steps that can prevent or mitigate the risks.
- *Reminder systems* to prompt or guide health-care practitioners or patients in prescribing, dispensing or using a product in ways that minimize risk.
- *Performance-linked access (PLA) systems* that tie physician and patient access to a medication to required laboratory testing or other documentation. These systems may include a restricted distribution channel.

As of February, 2007 about 30 drugs on the market have RiskMAPs. All have targeted education and outreach as a component and 10 RiskMAPs include performance-linked access or reminder systems. Nine plans were developed after the drug was marketed.

Common themes emerging from conference attendees were:

- *Collaborative development.* More collaboration among stakeholders in developing, testing and evaluating RiskMAPs was urged to make them more acceptable to patients and health-care providers, adaptable to existing professional practices, consistent with privacy requirements, and supportive of current business models.
- *Balancing benefit and risk.* Some approaches to minimizing or preventing a drug's risks were faulted for failing to maintain awareness of and access to the drug's benefits.

- *Standardization.* Because performance-linked access systems disrupt clinical practice, pharmacy routines, established distribution channels, and business relations, many participants urged standardized approaches.
- *Evaluation.* RiskMAPs are therapeutic interventions and should be held to the same standards of efficacy, medical ethics and personal privacy as other interventions.
- *A key to unlock larger problems.* Current RiskMAPs are the "tip of the iceberg" and improved systems to handle them may be the key to solving such problems as high levels of medication errors, inappropriate medication use, distribution tracking, and delivering on the promise of personalized medicines.
- *Transparency.* Information about RiskMAPs is not readily available. Participants want greater access to the RiskMAP documents and procedures. The pharmaceutical industry wants greater clarity on the criteria for RiskMAPs and more systemic policy around RiskMAPs.

Patient and consumer groups understand the need for RiskMAPs but find that they are limiting access to some efficacious drugs, either because of administrative burden or the focus on risk to the exclusion of benefit. From a patient perspective, many RiskMAPs pose scheduling difficulties with physicians, laboratories and pharmacies. They felt the best risk management may be undermined by overzealous promotion by marketers. One consumer group noted that medication errors are a large problem and that the system needs to embrace zero tolerance.

Providers and payers demonstrated how large integrated health systems that link prescribers, health records and pharmacists can improve medication safety. Electronic health records can also help prescribers do the right thing and harder to do the wrong thing, although developing effective clinical decision support is challenging. Payers noted that they are able add a level of control in addition to that provided by the RiskMAP. A representative of family practice physicians in small practices noted that while the use of electronic health records is expanding rapidly, the evidence-base for clinical decision support is missing. Payers and clinicians agreed that additional transparency and flexibility in the RiskMAP program are needed. They noted that large clinical databases should be used to deepen our understanding of the benefits and risks of medications and to evaluate the effectiveness of RiskMAP programs

Pharmacists and distributors want to be involved in the process of designing and developing the RiskMAPs. Pharmacists want the flexibility to incorporate drugs with RiskMAPs efficiently into their workflow for dispensing and ordering systems. They believed that standardizing the process for distribution and dispensing among RiskMAP drugs would helpful. The distributors association noted that any large increase in the number of RiskMAPs employing limited distribution has the potential to disrupt existing business relations which in turn could disrupt access.

Three companies who sell pharmaceutical products with performance-linked access systems demonstrated how their RiskMAPs have maintained the benefits of the product for selected patients while limiting risk or preventing it entirely. Because of the fractionated U.S. health-care delivery system, their plans involve multiple checks and balances among prescribers, patients, pharmacists and distributors to ensure controlled delivery of the right medicine to the right patient.

Researchers and regulators discussed RiskMAP evaluations and how they have allowed important program modifications as well as revealed unintended adverse consequences. Also discussed were possible *future directions* in risk management based on practices of the European Medicines Agency and the results of AHRQ-funded research using health information technologies to promote quality medication use. Here technologies such as computerized reminder and alert systems were shown to have promising benefits, but to be prone to "alert/warning fatigue" and inappropriate design.

A *summary wrap-up* echoed the comments and recommendations of previous panels and added calls for more interaction with stakeholders, increased collaborations, the development of curricula in pharmacoepidemiology, and additional funding of risk management and medication quality efforts.