FDA to Sharpen Postmarketing Drug Safety Focus

BY ALICIA AULT
Associate Editor, Practice Trends

The Food and Drug Administration said it will beef up oversight of prescription drug safety, with a focus on risks and benefits once a product has been launched into the marketplace.

The initiatives were announced in January in a long-awaited response to September's Institute of Medicine critique of the agency's pharmaceutic safety monitoring.

The FDA said it had taken a close look at the IOM's 25 recommendations, and that it would focus its efforts on three major areas:

1. Strengthening the science used during product reviews and finding new tools to detect safety issues from preclinical testing through postmarketing.

2. Improving communications, especially about risk, to patients, physicians, and other interested parties.

3. Improving management practices.

The IOM criticized an agency culture that it saw as too concentrated on drug approval at the expense of product safety.

Some of the FDA initiatives are underway. Others were published in the Federal Register as part of recommendations for the reauthorization of the Prescription Drug User Fee Act. Under the next PDUFA law, which if enacted would begin in fiscal 2008, the FDA aims to collect $29 million from drug makers over 5 years specifically for postmarketing safety programs.

Key among the initiatives announced in late January is a "report card" on the postmarketing safety of new molecular entities. FDA has proposed a pilot feasibility study this year. These regularly scheduled reports would encompass data from the Adverse Events Reporting System, epidemiologic studies, postmarketing clinical trials, and "mining" of various other databases. The first report would come 18 months after a drug's launch. The goal of this effort is "to identify potential safety concerns early in the product life cycle," according to the FDA.

The FDA also proposed sharing data more often with other agencies, and said it was already collaborating with the Agency for Health Care Quality and Research, the Centers for Disease Control and Prevention, and the Veterans Affairs department. The VA will provide real-world data on how its patients use pharmaceuticals and medical devices.

To address criticism that the FDA has not done a good job of communicating what it knows about a drug's risks on a timely basis, the agency said it could—and would—move quickly to establish a new advisory committee.

The FDA also said it would hold a public meeting in early March to explore the creation of a nationwide public-private medical product safety network. The agency envisions a network that would let both health care providers and regulators rapidly collect and exchange information about adverse events—and would do so at the point of care to help providers make better-informed treatment decisions.

American Medical Association board member Dr. Edward Langston said the AMA generally supported FDA's proposals. "The AMA agrees that the approaches used to communicate information to patients about the risks associated with drug products need significant improvement," Dr. Langston said in a statement.

Long-time FDA critics in Congress, however, said the agency had not gone far enough.

"Today's report is thoughtful, and provides important recommendations for administrative action, but only legislation can give FDA the tools it needs to ensure that the agency is the gold standard for safety," said Sen. Edward M. Kennedy (D-Mass.), who, along with Sen. Michael Enzi (R-Wyo.) soon will introduce a bill to further overhaul FDA's postmarketing safety program.

Sen. Christopher J. Dodd (D-Conn.) said that he and Sen. Chuck Grassley (R-Iowa) were also introducing a bill that would "revamp and prioritize the postmarket surveillance process within the Food and Drug Administration."

That bill, called the Food and Drug Administration Safety Act, would establish a Center for Postmarket Evaluation and Research for Drugs and Biologics. The Center would report directly to the FDA commissioner.

"Congress will act on FDA-related legislation this year, and meaningful structural reforms to the agency need to be a part of what Congress does with regard to drug safety," Sen. Grassley said. ■