FDA Revamps Drug Info, Aims to Improve Safety

BY SHARON WORCESTER
Southeast Bureau

Prescription drug package inserts will soon have a new format that U.S. Food and Drug Administration officials believe will reduce the risk of medical errors.

A goal of the "major revisions" recently announced by the FDA is to prioritize warning information and provide user-friendly access to the most important prescribing information. The new inserts will contain a "Highlights" section prominently displayed at the top of the first page, Dr. Andrew von Eschenbach, acting FDA commissioner, explained during a press briefing sponsored by the agency.

The new format will provide the most up-to-date information in a clearly organized, concisely written, easily accessed format so doctors can convey this vital information to patients, he said.

Other key features of the new inserts will include a table of contents that provides reference to detailed safety and efficacy information, the date of initial product approval and information about any changes to the label in the past year, a patient counseling information section, and a toll-free number and Web site for reporting adverse events.

'We made great strides today that will benefit providers and the American public by increasing the health literacy of all those who desperately need this information.'

The revisions also were designed to make prescription information more accessible via the Internet: Information will be updated in real-time to DailyMed, an interagency online health information clearinghouse, which can be accessed at http://dailymed.nlm.nih.gov, Dr. Scott Gottlieb, FDA's deputy commissioner of medical and scientific affairs, said during the briefing.

This information will also be made available soon at a new Web site called Facts@FDA, which will provide comprehensive information about all FDA-regulated products, he noted.

The electronic capability aspects of the new package insert requirements are one of the most "potentially exciting opportunities" created by the new system, he said, adding that the electronic information will allow physicians to access the most up-to-date prescribing information at the point of care.

This is particularly important in this age of 12-minute patient visits, said U.S. Surgeon General Richard H. Carmona during the briefing. "We made great strides today that will benefit providers and the American public by increasing the health literacy of all those who desperately need this information."

The final rule providing for the changes—the first changes to prescription drug package inserts in 25 years—has been in the works since 2000 when a draft rule was released. The final version, released along with two guidance documents and two draft guidance documents to assist drug companies with implementing the revisions, differs little from the early draft, and was based largely on information from focus groups, physician surveys, a public meeting, and written comments.

The revisions will be phased in gradually and apply only to drugs approved in the last 5 years, as well as newly approved drugs and those that receive new indications. However, FDA officials are encouraging voluntary industrywide application of the rule for existing drugs.

The American Medical Association applauded the rule as one that will simplify the prescribing process for physicians, but some consumer advocates, such as Washington-based Public Citizen, are critical, saying the revisions fail the patients they are purported to ultimately protect.

A preamble added to the rule is a "sneak attack" on patients' rights designed to preempt lawsuits filed by patients under state law, Public Citizen said in a statement.

Further, although the revisions simplify and prioritize labeling for doctors and patients, they don't go far enough, according to Public Citizen. In many cases, patients will receive this information only if they request it. Otherwise they will receive only nonregulated patient information leaflets; these have been shown to lack scientifically accurate drug information, the group argues. ■