Pediatric Information Out in Front on New Label

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ROCKVILLE, MD. — Pediatric information in drug labels should be easier to find and understand thanks to a new way of incorporating pediatric information into a revised drug label design, required for all new drugs approved since June last year.

At a meeting of the Food and Drug Administration's Pediatric Advisory Committee held to review pediatric adverse event reports for several drugs, Iris Masucci, Pharm.D., of the FDA's Center for Drug Evaluation and Research (CDER), provided an overview of the elements of the revised drug label.

A physician labeling rule implemented in June 2006 requires that drug labels be more user friendly. The label, or package insert, of any newly approved drug or biologic or supplemental efficacy approval of a drug submitted to the FDA after June 30, 2006, is required to be in the new format. Drugs approved in the 5 years before this date must update their labeling to the new format according to a stepped timeline.

If a pediatric indication is not approved, all pediatric data on the new labels will appear in the section, 'Use in specific populations-Pediatric Use.'

Drugs approved before that time are not required to make the change, but may do so voluntarily. The new labeling requirements also apply to biologics.

The approach on where to incorporate pediatric information into labels is a separate initiative from the new labeling format requirements. Rather, it is a more clearly defined paradigm than what has been used in the past, which will make labels more consistent in terms of how and where pediatric information is added, Dr. Masucci said in an interview .

A major change in the newly designed label is the highlights section, designed in response to feedback from physicians on what they wanted in a drug label, which appears at the beginning of the label. This is a half-page summary that provides the main information on a drug in a simple format with bullets and tables, Dr. Masucci said at the meeting.

This section includes the name of the product with the date of the initial U.S. approval; a boxed warning (if there is one); indications (which include the pharmacologic class of the drug); usage, dosage, and administration information; major changes recently made to the label; as well as dosage forms and strengths, contraindications, warning and precautions, adverse reactions, and drug interactions. Also included is a patient counseling information statement and a section on use in specific populations, such as children.

The contents of the label include numbered sections with a specific number that corresponds to a particular section, which will be consistent for all drugs. For example, section 2 will always pertain to dosage and administration, and section 8 will always pertain to use in specific populations, which includes pediatric patients.

Other features of the new label include the consolidation of the warnings and precautions sections. Sections on drug interactions, use in specific populations, and patient counseling information—which appears in the precautions section in the old label—are now separate sections. Also, sections on clinical studies and nonclinical toxicology, previously optional, are now required, she said.

Contact information for the FDA's adverse event reporting program, MedWatch, and the drug's manufacturer for reporting adverse events are now also included in the label.

With the old format, it is difficult to know if a drug is actually approved for pediatric use, Dr. Masucci said, noting that in some tables, a pediatric dose but no pediatric data are listed.

If the new data warrant a pediatric indication, the pediatric information is included in the applicable sections: indications and usage, dosage and administration, adverse reactions, use in specific populations, pharmacokinetics and pharmacodynamics, and clinical studies. However, if the data do not support pediatric approval, all pediatric information on the drug appears in the section "Use in specific populations-Pediatric Use," which she said "will avoid the implication of approval." ■