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Health professionals, patients urged to report adverse events

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from the Food and Drug Administration's Office of Pediatric Therapeutics and the Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health

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Health professionals play a critical role in counseling their patients to monitor and report adverse events related to products regulated by the Food and Drug Administration (FDA).

Reports can be made through the MedWatch system regarding adverse events from prescription or over-the-counter medicines, biologics (including blood products), medical devices and special nutritional products such as infant formulas and dietary supplements.

Safety information obtained from pre-market clinical trials may be limited because trials may be of short duration and may enroll small numbers of patients relative to the number who will use the product after approval. Thus, important safety signals, especially those that are rare or emerge after chronic use, may not always be identified at the time of FDA approval or product marketing.

The FDA reviews all reports from health professionals and consumers regarding potential safety concerns and may take regulatory action to protect the public health if a safety concern is identified.

In 2014, for example, the FDA reviewed 22 reports of serious adverse reactions, including death, associated with the use of oral viscous lidocaine 2% solution in infants and children ages 5 months to 3.5 years for mouth pain, including teething and stomatitis. After the review, the FDA issued a Safety Communication (http://bit.ly/2oxZVtm) and added a boxed warning to the product's labeling.

To submit a report through MedWatch, visit http://bit.ly/2ptaPRP. A report should be submitted, even if complete details are not available or there is uncertainty as to whether the product caused the event. Include as much information as possible in the report, which takes about 15 minutes to complete.

Clinicians also can consult MedWatch for timely safety information about products they prescribe.

Resources

- Follow @FDAMedWatch on Twitter.
- http://bit.ly/331kSvQ
- Find information related to reported adverse events on the FDA Adverse Event Reporting System Public Dashboard
- Additional FDA Update columns