Drugs

medication error reports

Medication errors cause at least one death every day and injure approximately 1.3 million people annually in the United States. Medication mishaps can occur anywhere in the distribution system:

- prescribing,
- repackaging,
- dispensing,
- administering, or
- monitoring.

Common causes of such errors include:

- poor communication,
- ambiguities in product names, directions for use, medical abbreviations or writing,
- poor procedures or techniques, or
- patient misuse because of poor understanding of the directions for use of the product.

In addition, job stress, lack of product knowledge or training, or similar labeling or packaging of a product may be the cause of, or contribute to, an actual or potential error.

CDER began receiving reports of medication errors in January 1992, when the U.S. Pharmacopeia began forwarding reports to the FDA. To evaluate and recommend appropriate action on these reports, the Medication Errors Subcommittee was formed in June 1992. In November 1993, the Agency began evaluating and coding MedWatch reports for medication errors and publicly stated that physicians and other health care professionals could report medication errors directly to the FDA through the MedWatch program.

CDER responsibilities are not completed when the safety and effectiveness of a drug product are determined. The Center also has the responsibility for helping to ensure the safe use of the drugs it approves by identifying and avoiding proprietary names that contribute to problems in the prescribing, dispensing, or administration of the product. Because early identification of a potential confusing proprietary name is crucial, CDER reviews these proposed names, prior to approval of a new drug application, by means of the Office of Postmarketing Drug Risk Assessment (OPDRA)

CDER's approach to medication errors is as follows:

- Prevent medication errors prior to a drug's approval;
- After approval, evaluate, monitor, and take appropriate action on reports of medication errors;
- Educate and provide feedback to health professionals; and
- Share information with outside organizations involved in preventing medication errors.

For more information, see:

- Federal Food, Drug and Cosmetic Act, as Amended Section 502 (e)
- Code of Federal Regulations 21 CFR 201.10 (c); 201.56(b); and 299.4
- American Society of Health System Pharmacists (ASHP) guidelines on the prevention of medication errors, 1993

Page Last Updated: 03/05/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA