U.S. Food and Drug Administration • Center for Drug Evaluation and Research

Medication Errors

Search

About

Drug Information

Regulatory

CDER

Specific

CDER

Medication Errors

- Introduction
- Drug Products Associated with Medication Errors UPDATED 8/5/2003
- Medication Errors Reports and Articles
- Name Differentiation Project
- Federal Regulations and Guidances
- How to Report a Medication Error
- Other Resources

Introduction

FDA receives medication error reports on marketed human drugs (including prescription drugs, generic drugs, and over-the-counter drugs) and nonvaccine biological products and devices. The National Coordinating Council for Medicat Error Reporting and Prevention defines a medication error as "any preventable ev that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. events may be related to professional practice, health care products, procedures, a systems, including prescribing; order communication; product labeling, packagin and nomenclature; compounding; dispensing; distribution; administration; educat monitoring; and use."

The American Hospital Association lists the following as some common types of medication errors:

- incomplete patient information (not knowing about patients' allergies, othei medicines they are taking, previous diagnoses, and lab results, for example
- unavailable drug information (such as lack of up-to-date warnings);
- miscommunication of drug orders, which can involve poor handwriting, confusion between drugs with similar names, misuse of zeroes and decima points, confusion of metric and other dosing units, and inappropriate abbreviations;
- lack of appropriate labeling as a drug is prepared and repackaged into smal units; and
- environmental factors, such as lighting, heat, noise, and interruptions, that (distract health professionals from their medical tasks.

In 1992, the FDA began monitoring medication error reports that are forwarded t(FDA from the United States Pharmacopeia (USP) and the Institute for Safe

Medication Practices (ISMP). The Agency also reviews MedWatch reports for possible medication errors. Currently, medication errors are reported to the FDA manufacturer reports (adverse events resulting in serious injury and for which a medication error may be a component), direct contact reports (MedWatch), or rep from USP or ISMP.

The Division of Medication Errors and Technical Support includes a medication prevention program staffed with pharmacists and support personnel. Among their many duties, program staff review medication error reports sent to the USP-ISMF Medication Errors Reporting Program and MedWatch, evaluate causality, and an: the data to provide feedback to others at FDA.

▲ Back to Top

Drug Products Associated with Medication Errors

Medication safety information from *Drug Topics* FDA Safety Page

- Bextra: Valdecoxib or bucindolol? ↗
- Curbing med errors involving Anzemet, Bentyl ↗
- Confusion between methylphenidate and methadone ↗
- Drug errors associated with opium tincture and paregoric ↗ **New!!** (Posted 8/5/2003)
- Fatal medication errors associated with Temodar ↗
- Transdermal patches: High risk for error? ↗
- Medication errors associated with serzone and seroquel ↗
    - o MedWatch Safety Alert for Seroquel
    - o MedWatch Safety Alert for Serzone

Medication errors information from FDA

- Dispensing errors associated with lamictal (lamotrigine) tablets
- Medication errors associated with flomax and volmax
- Medication errors associated with zantac and zyrtec

Medication Safety Alerts from Institute for Safe Medication Practices

- Medication errors associated with levothyroxine products
- Misuse of liquid phosphate laxatives used for bowel preps
- Medication errors associated with taxotere and taxol

▲ Back to Top

Federal Regulations and Guidances

- FDA proposes bar codes for drugs, blood; new adverse reaction reporting.
    - o FDA Public Meeting On Bar Code Labeling For Drugs. Remarks by

Lester M. Crawford, Jr., D.V.M., Ph.D.
Deputy Commissioner, FDA. (Posted 7/31/2002)

- Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities -
  FDA Public Health Advisory. (Issued and Posted 4/5/2001). This guidan(
  intended to alert hospitals, nursing homes, and other health care facilities t(
  hazards of medical gas mix-ups.

- Flyer on FDA Public Health Advisory: Medical Gas Mix-Ups Can Cause I
  and Serious Injury Optional format: HTML (Posted 10/10/2001). This
  page, color flier is intended to alert people who handle medical gases abou
  hazards of mix-ups. Please feel free to copy and distribute this flier. Comm
  and suggestions are welcome.

- FDA Proposed New Format for Physician Prescription Drug Labeling. FD/
  has proposed a new, user-friendly format for the labeling information doct(
  get about prescription drugs. FDA believes that this new, user- friendly fo1
  will reduce errors in drug prescribing.

- *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.

Other Resources

- *Drug Topics* FDA Safety Pages
  o Stemming drug errors from abbreviations
  o How FDA reviews drug names
  o Med error reports to FDA show a mixed bag
- Strategies to Reduce Medication Errors: How the FDA is working to impr(
  medication safety and what you can do to help. Article from FDA Consum(
  magazine, May-June 2003.
- FDA Patient Safety News. FDA Patient Safety News is a televised series f
  health care professionals, aimed at hospitals and other medical facilities ac1
  the country. It features information on new drugs, biologics, and devices, o
  FDA safety notifications and product recalls, and on ways to protect patien
  when using medical products.

- American Society of Health-System Pharmacists: Center on Patient Safety

- Healthfinder: Medical Errors. Links to specific resources and organization
  medication errors.

- Quality Interagency Committee (QuIC) Task Force. The QuIC Task Force ·
  established in response to the final report of the President's Advisory
  Commission on Consumer Protection and Quality in the Health Care Indus
  In response to the Institute of Medicine's report on medication errors, QuIC
  issued a report called *Doing What Counts for Patient Safety: Federal Acti(*
  to Reduce Medical Errors and Their Impact

- National Patient Safety Foundation

- Agency for Healthcare Research and Quality: Medical Errors and Patient Safety.

- Institute for Safe Medication Practices

Back to Top   Back to Drug Information

FDA/Center for Drug Evaluation and Research
Last Updated: August 5, 2003
Originator: OTCOM/ODS
HTML by SJW