Medication Error Reporting

FDA MedWatch - Healthcare Professionals

FDA MedWatch - For Patients/Consumers

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

FDA Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events (possible side effects) following vaccination. You should report adverse events even if you are unsure whether a vaccine caused them. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

ISMP Voluntary Reporting - Healthcare Professionals
ISMP Voluntary Reporting - Consumers

ISMP encourages healthcare practitioners and consumers to report medication errors, vaccine errors, preventable adverse drug reactions, close calls, and hazards to ISMP. Examples include, but are not limited to:

- Errors when prescribing, transcribing, dispensing, and administering medications/vaccines
- Errors related to patient monitoring of the effects of medications and vaccines
- Errors with medications or vaccines that are captured before they reach the patient
- Potential or actual confusion regarding look- and sound-alike drug or vaccine names, packaging similarities, or label ambiguity
- Misuse, nonuse, or malfunction of medication-related tools (e.g., syringes, needles), equipment (e.g., tubing, infusion pumps), and technology (e.g., computerized order entry systems, barcode scanning)

ISMP Voluntary Reporting - Healthcare Professional - Vaccines

- Tell the story of what went wrong or could go wrong, the causes or contributing factors, how the event or condition was discovered or intercepted, and the actual or potential outcome of the involved patient(s).
- Answer the specific questions as best you can.
- Be sure to include the names, dosage forms, and dose/strength of all involved products. For product-specific concerns (e.g., labeling and packaging risks), please include the manufacturer.
- Share your recommendations for error prevention.
- If possible, submit associated materials (e.g., photographs of products, containers, labels, de-identified prescription orders) that help support the report being submitted.