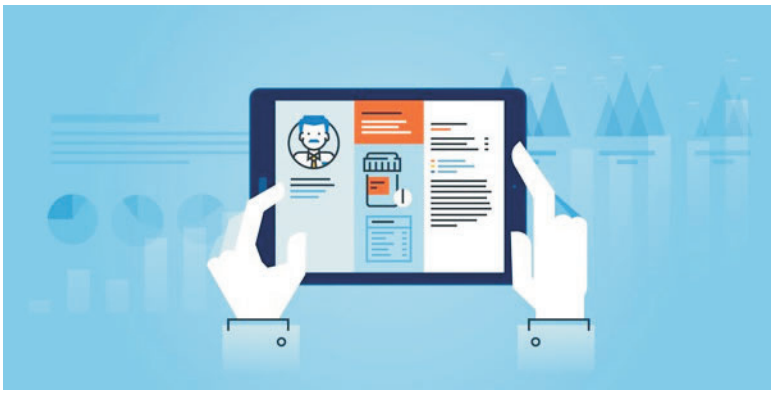
MedWatch



MEDWATCH is a system that provides safety alerts for drugs, biologicals, dietary supplements, and medical devices. MedWatch is a voluntary program that allows people to report a serious adverse event associated with the use of any products approved for use by the FDA. This nationwide central reporting mechanism serves to detect and assess serious adverse medical events. The FDA, working with the Institute of Safe Medication Practices, established MedWatch.

Objective:

Explain the MedWatch system, mission, alerts, and notices.

Key Terms:

- adverse drug reaction (ADR)
- biological
- Center for Drug Evaluation and Research (CDER)
- dietary supplement
- efficacy
- Food and Drug Administration (FDA)
- MedWatch
- over-the-counter (OTC)
- rich site summary (RSS)
- therapeutic

Understanding the MedWatch System

You need to understand the way the MedWatch System works to have some insight on the pharmaceutical industry.

THE SYSTEM AND ITS MISSION

Overview

The **Food and Drug Administration (FDA)** is the agency responsible for ensuring that drugs, vaccines, and medical devices are safe. Because the FDA is the primary governing agency for pharmaceuticals in the United States, the FDA is responsible for investigating and making public any information associated with adverse drug reactions (ADR). An **adverse drug reaction (ADR)** is any negative consequence to a patient from taking a particular drug.

To increase the discovery of adverse events in the general population, the FDA created the MedWatch system. MedWatch is a safety information and adverse event reporting service that is a system to report observed or suspected human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures that include:

- 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)

Adverse events reported to MedWatch include any event that:

- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires/prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage
- Has the potential for harm or close calls

FIGURE 1. Adverse medical events, product quality problems, and medication errors caused by FDA-approved products are reported to MedWatch.

The MedWatch System

The MedWatch system was founded in 1993 to collect data regarding adverse events in healthcare. Before MedWatch, no simple reporting system was in place for healthcare professionals to report adverse events associated with medications or devices directly to the FDA. Many companies and drug manufacturers had their own complicated forms, along with the FDA's separate forms for issues with drugs or devices. Because of the complicated reporting system, many adverse events went unreported.

MedWatch was intended to simplify this process. **MedWatch** is a voluntary program that allows healthcare professionals and the public to report a serious adverse event suspected to be associated with the use of an FDA-regulated drug, biological, or dietary supplement. **Biological** is relating to living organisms (e.g., blood components or human tissues). A **dietary supplement** is a product intended to add nutritional value to the diet. The FDA uses this information to track problems and issues that were not apparent when the medication was initially approved.

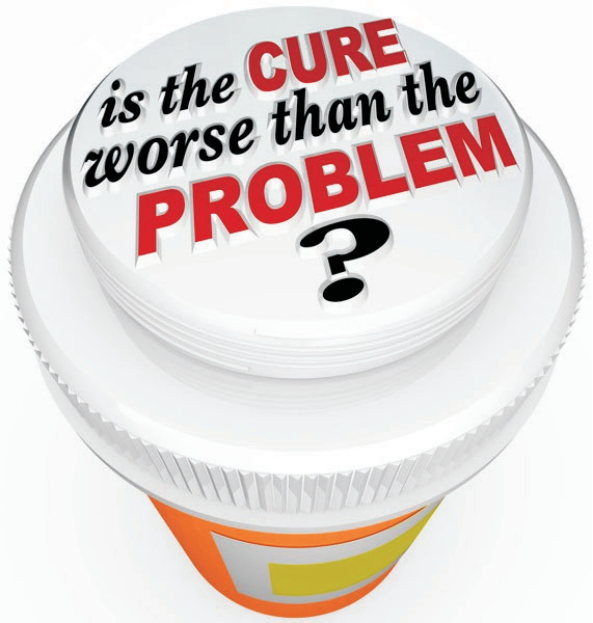


FIGURE 2. Adverse drug events injure an estimated 1.5 million people each year, at a cost of approximately $3.5 billion dollars. "Is the cure worse than the problem?"

The FDA is interested in receiving three types of MedWatch reports: over-the-counter (OTC), quality, and use errors.

Reports are needed on suspected serious adverse events associated with drugs—prescription or over-the-counter. **Over-the-counter (OTC)** are medications sold directly to consumers without a prescription, including:

- Biological products
- Medical devices
- Cosmetics
- Dietary supplements
- Medical foods
- Infant formulas

Reports are needed from pharmacists and nurses of quality problems that might suggest manufacturing or other quality issues with drugs or devices, along with reports of suspected counterfeit products. In addition, reports are needed for medication and device use errors (e.g., the wrong drug/wrong dose errors) that may be caused by product name confusion or confusion resulting from packaging and labeling.

The MedWatch Mission

The mission of MedWatch is to protect the public health by assuring the quality, safety, and efficacy of drugs, biologicals, products, medical devices, cosmetics, and products that emit radiation. **Efficacy** is the ability to produce a desired or intended result. Safe means that risks are managed; quality is assured; health fraud is pursued; and advertising is appropriate. MedWatch helps the public get the accurate, science-based information needed to use medicine and foods to improve health.

SUMMARIZE ALERTS AND NOTICES

MedWatch alerts provide new safety information on drugs, medical devices, vaccines, biologicals, dietary supplements, and cosmetics to the public in a timely manner. These alerts provide information that may impact treatment and diagnostic choices for the healthcare professional and the patient. The following are ways these alerts and notices are delivered to the public.

Website

The MedWatch website, http://www.fda.gov/Safety/MedWatch/default.htm, is the gateway into the product specific safety information for all human medical products. Recalled drugs and **therapeutic** (relating to the healing of disease) biological products are listed in alphabetical order along with the date the alert was issued.

Email

The MedWatch E-list sends clinically important information about medical product safety alerts via email. Information is sent out to subscribers immediately after the FDA identifies a new safety issue and announces it to the public. You can subscribe at http://www.fda.gov/Safety/MedWatch/ucm168422.htm.

Text Message

In addition to the E-list notification, MedWatch distributes safety alerts by RSS feed. **Rich site summary (RSS)** is a format for delivering regularly changing web content. These alerts are sent as short text messages directly to cell phones. This is a convenient way for you to receive immediate safety alerts if you do not wish to receive additional email messages. You can subscribe at http://www.fda.gov/AboutFda/ContactFDA/StayInformed/RSSFeeds/default.htm.

Twitter

You can subscribe to MedWatch Twitter at http://twitter.com/FDAMedWatch to receive updated information about safety alerts.

FURTHER EXPLORATION...

ONLINE CONNECTION: Colored and Decorative Contact Lenses

Decorative contact lenses are meant to change the appearance of your eyes. They include colored lenses and fashion lenses that can make your eyes look like vampires, animals, or other characters. Visit the FDA website at http://www.fda.gov/forconsumers/consumerupdates/ucm275069.htm to read about wearing decorative contact lenses. After reading the article, watch the short video about the improper use of decorative contact lenses. If you see contact lenses being sold by retailers not requiring a prescription, you can report the retailer to the FDA through the MedWatch system.

Colored contact lenses change the appearance of your eyes, and some designer contacts can make your eyes appear as animals, vampires, and other characters.

CDER

Each month, the **Center for Drug Evaluation and Research (CDER)**—the division of the FDA that evaluates new drugs before they can be sold—approves clinically important safety labeling changes for drug products. The information is posted on the MedWatch website in a table format that allows for quick review of the labeling changes.

Partners Program

The Partners Program consists of 170 organizations that work with MedWatch to disseminate new safety information. For example, the American Pharmacists Association includes any safety alerts received from MedWatch in its weekly email bulletin sent to pharmacists across the nation.

FIGURE 3. The MedWatch system provides comprehensive, current information on drug alerts and offers a variety of delivery methods, including email, RSS, and a regularly updated website.

MedWatch Notices

The FDA uses other resources to supplement the alert process. These are not intended to serve as

alerts, but they may provide information in a different format or provide more detail and depth.

- The drug safety newsletter is a quarterly web-based newsletter for health professionals that provides results for certain post marketing drug safety reviews from the CDER.
- The FDA drug safety podcasts provide 2- to 5-minute audio recordings that discuss emerging safety information about drugs.
- The FDA patient safety news is a monthly video presentation for healthcare professionals and features information on new drugs, biologicals, and medical devices. It includes FDA safety notifications and recalls.
- DailyMed is an online collaboration providing current prescribing information for drug products in an easily viewed and searched format.

FIGURE 4. MedWatch supplements its alert process by releasing notifications in a different format as another way of ensuring that the public is notified of potential health hazards.

Summary:

The MedWatch adverse event reporting system allows anyone to report to the FDA any serious health hazard or death caused by an FDA-approved medical product. MedWatch reports sometimes provide the first indication that an investigation is warranted. Submitting a report is easy for the average user and can be completed online. Once a report has been submitted, the FDA can issue a safety alert advising the public and health professionals to monitor a products use, adjust the way it is used, or stop using it.

Checking Your Knowledge:

1. What is MedWatch?
2. Explain the mission of MedWatch.
3. List the seven adverse events that should be reported to MedWatch.
4. List the three types of reports submitted to the FDA.
5. Explain how MedWatch uses technology to alert the public about potential health hazards.

Expanding Your Knowledge:

Contact your local eye care professional. Ask if he or she sells decorative contact lenses. If not, do a search online to find a place that does sell them. Are patients required to receive an eye examination before purchase? What information is given to patients about wearing decorative contact lenses? Report your findings to the class.

Web Links:

Illegally Marketed Diabetes Treatments
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm361487.htm

Licorice Coughing Liquid Warning
http://www.fda.gov/Drugs/DrugSafety/ucm482080.htm

Risks of Using Eye Drops
http://www.fda.gov/Drugs/DrugSafety/ucm490693.htm

Topical Pain Relievers May Cause Burns
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm318674.htm