FDA Drug Info Rounds Videos

Title: MedWatch Tips & Tools

Brief description for main page: This short video describes how to report an adverse drug event to FDA's MedWatch program.

Video page description: FDA needs to know when a serious problem with a medical product, such as a drug, is suspected or identified in clinical use. Learn how FDA's MedWatch program makes it easy to get important safety information directly from you to us.

Keywords: FDA Drug Info Rounds, Drug Info Rounds, FDA, Food and Drug Administration, Drug Information, MedWatch, adverse event, adverse reaction

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Video Script:

When you, the health care professional, voluntarily report observed or suspected adverse events to FDA's MedWatch program, you provide a vital source of information to FDA. Voluntary reports are essential for ensuring the continued safety of FDA-regulated products.

All reports received are carefully analyzed by our team of safety evaluators. Your report may be the critical action that prompts a safety change.

Today, resources are available to you, the health care professional, to make reporting to MedWatch easier than ever.

Anyone can submit a report to MedWatch online at www.fda.gov/MedWatch. Start by clicking "Report a Problem."

MedWatch reports can be completed online or printed and completed by hand. You can choose to begin your report as a Health Professional if you are reporting on your patient's behalf, or you can refer your patients to the Consumer/Patient form. The consumer form is now available in English and Spanish.

To submit a report, you must have the following information: name of the drug, description of the adverse event or problem that occurred, and the reporter's name. However, it is important to submit as much detailed information as possible to help FDA understand the adverse event.

A good report includes the following elements.

- Patient identifier
- Name of the drug
- Detailed description of the adverse event
- Time it took for the event to occur
- Clinical outcome and actions taken
- Relevant labs or medical imaging
- Medical history

- Date the drug was administered and if the drug or accompanying drugs were started and then stopped and how that impacted the adverse event

The MedWatch online form also allows you to submit photos with a report. Relevant pictures that can be uploaded include images of the prescription label, product packaging, and the actual product. Upon successful completion of a MedWatch report, you can download or save your completed submission from the confirmation page.

If you don't have enough time to finish your MedWatch report, you have up to three days to continue an incomplete report. Just click "Save and Exit" at the bottom of the page and provide your email address. The Report ID and Report Date will be sent to your email so you can continue your report.

Once FDA receives a report, a safety evaluator will assess the severity of the problem. When needed, a safety evaluator may contact the reporter for more information.

Sign up for MedWatch email alerts, subscribe to the MedWatch RSS Feed, or follow @FDAMedWatch on Twitter to receive up-to-date safety information on FDA-regulated products.

For additional drug information, sign up for the Division of Drug Information's email listserv or follow @FDA_Drug_Info on Twitter.

FDA relies on partners like you, your colleagues, and patients to report adverse event and product problems. Visit www.fda.gov/MedWatch and save it as a favorite website. And please continue to send in well-documented reports. If you or your patients need help with completing a report or have questions, call or email FDA's Division of Drug Information.