

FDA's Safe Use Initiative

Reducing harm risk from acetaminophen

Today, tens of millions of people in the United States depend on prescription and OTC medications to sustain their health. As many as 3 billion prescriptions are written annually; however, too many people suffer unnecessary injuries, or even die, as a result of preventable medication errors or misuse.

On November 4, 2009, FDA announced the Safe Use Initiative to reduce the likelihood of preventable harm from medication use.



The mission of the Safe Use Initiative is to create and facilitate public and private collaborations within the health care community. The goal is to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing, and evaluating cross-sector interventions with partners that are committed to safe medication use. The following are potential partners in the Safe Use Initiative:

- Federal agencies
- Health professionals and professional societies
- Pharmacies, hospitals, and other health care entities
- Patients, caregivers, consumers, and their representative organizations

The Safe Use Initiative sets priorities for involvement in activities by analyzing and evaluating the FDA-regulated drug, drug class, and therapeutic area for the following:

- Degree of preventable, public health harm
- Potential that interventions will help manage the risks of medication use, complement ongoing regulatory actions, and reduce preventable harm
- Ability to engage with stakeholders for collaboration
- Ability to measure outcomes and impact

One Safe Use Initiative activity is to reduce preventable harm (liver injury) associated with unintended overdose of acetaminophen, as described below.

Acetaminophen toxicity

In June 2009, FDA held an advisory committee meeting on mitigating the risks of acetaminophen liver toxicity. Although it may occur rarely with appropriate use, most toxicity is linked to unintended or deliberate overdose. FDA is considering a variety of steps from a regulatory perspective. Much will need to be done, in collaboration with various stakeholders, to improve communication about inadvertent overexposure and to discourage intentional overdose.

Patients and consumers can increase medication risks through misinformation. An estimated 5,000 visits to emergency departments each year are by patients who deliberately increased the dose of acetaminophen in a misguided attempt to obtain additional symptom relief. Others unknowingly may take multiple versions of the same drug at the same time. Harm could be prevented if consumers had access to current, easy-to-understand information about how to use the medication safely.

To reduce acetaminophen toxicity, the Safe Use Initiative is working with health care stakeholders to

- Decrease confusion by encouraging the elimination of "APAP" as an abbreviation for acetaminophen.
- Increase awareness and education surrounding this activity.
- Broaden the reach of the audience.
- Support existing efforts.

Preventing overexposure

FDA recently collaborated with the National Association of Boards of Pharmacy (NABP) to address acetaminophen toxicity. On July 8, NABP sent a letter to the executive officers of state boards of pharmacy recommending that the boards prohibit use of the APAP abbreviation

on prescription labels and require that "acetaminophen" be spelled out to help prevent the well-recognized danger of acetaminophen-induced liver injury.

The FDA Safe Use Initiative and NABP will work with interested organizations to identify best processes to eliminate the use of "APAP" and, in its place, spell out "acetaminophen." The stakeholders wish to address concerns related to limited space on prescription labels to avoid abbreviating other important information, such as the name of any narcotic contained in the product. In addition, FDA and NABP will work with pharmacy and other organizations to incorporate a reasonable implementation period for new requirements or recommendations related to this issue.

APhA, along with the Consumer Healthcare Products Association, is developing a consortium of stakeholders to address the proper use of acetaminophen. The goal of the consortium is to educate health professionals through clear and consistent messaging, which they can share with patients and consumers, on the safe, effective use of acetaminophen.

What can pharmacists do?

During the transition phase, pharmacists should counsel patients who receive prescriptions with "APAP" on the label, emphasizing that it is an abbreviation for acetaminophen.

Because acetaminophen is the active ingredient in a number of OTC and prescription products, pharmacists should encourage patients to read medication labels carefully. Combining prescription or OTC medications that contain acetaminophen may result in liver injury.

For more information, see FDA's Safe Use Initiative Web page at www.fda.gov/safeuseinitiative. Public comments can be submitted to the open docket. Go to www.regulations.gov and enter FDA-2009-N-0526.

—**Beth Fritsch, BPharm, MBA**
Contributing writer

Beth Fritsch, BPharm, MBA, is a member of the Health Professional Liaison Program in FDA's Office of Special Health Issues.