

NONPRESCRIPTION MEDICINES DIGEST



July 30, 2004

Welcome to the NMA Quarterly Newsletter. This month, we discuss Britain's upcoming release of statins for OTC use, a new joint program to prevent common medication errors associated with home pain reliever use, and the continuing concern of camphor exposure in toddlers. Previously posted articles and updates can be found at <http://www.nmafaculty.org>.

In addition, the FDA has issued an amendment to the final monograph on anti-diarrheal drug products for OTC human use. To view this information, visit <http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/04-10750.htm>.

NMA 2004 Conference applications are due! Please contact Linda.Krypel@drake.edu for information about late applications.

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Britain Ready to Make Statins OTC—Controversy Continues in U.S.

Several sources report that Britain will be the first country to sell statins without a prescription. Multiple factors influenced this decision, but cost-savings proved to be most important. Currently, the National Health Service spends approximately 750 million pounds per year on statins, thus OTC status would reduce the drug bill. Pharmaceutical manufacturers are being encouraged to seek OTC status.

Controversy still surrounds this type of switch in the U.S. Andre Picard, public health reporter for GLOBEMAIL.COM, writes that this change should concern physicians, public-policy makers, and consumers. Like others that oppose the legal move, his concerns are centered upon benefit versus risk. Picard argues that 71 people would have to take a statin for five years in order for one person to benefit. He contrasts this with the potential risk of drug interactions and case reports of muscle disorder (although these occurrences are rare). Additionally, Picard asks if pharmacists are capable of substituting for physicians when prescribing statins, and if this move sets



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an associate.

a precedent for other drugs such as antidepressants and antihypertensives.

In the U.S., the FDA has continued to stand firm on its decision to block OTC status for statins. Their main concern is the lack of a method that would ensure monitoring of cholesterol during treatment. While Britain's plan calls for a point-of-sale assessment by the pharmacist, U.S. manufacturers continue to work on the issue.

Sources:

PharmacyOneSource.com accessed 4/29/04

TheGlobemail.com accessed 5/24/04

<http://www.medscape.com/viewarticle/475448>

New Patient Safety Campaign Targets Safe Use of OTC Pain Relievers

The National Consumers League (NCL) and the FDA have launched "Take With Care", a public education program targeting the need to be careful when taking OTC pain relievers. Evidence provided by multiple recent studies indicates that consumers continue to be unconcerned about side effects (64%), neglect to read package directions (30-66%), take more medication than recommended (60%), or take medication more often than recommended (49%). Another major concern is multi-sourcing—the inadvertent use of multiple prescription and/or OTC products that contain the same ingredient. For example, acetaminophen can be found in over 600 prescription and OTC medications. With a recent study indicating that nearly 80% of American adults say they take OTC pain relievers at least once a week, the high volume of usage is causing alarm in the medical community.

FDA Associate Commissioner for External Relations, Peter J. Pitts, reminds consumers that "OTC pain relievers and fever-reducers are safe when used as directed, but they can cause problems when used by people with certain conditions or those taking specific medicines. We want to remind consumers who take these products that it's important to follow current dosing and label directions carefully."

The campaign hopes to help consumers learn about active ingredients and how to avoid inadvertently taking more than the recommended dosage. Additionally, it will help raise awareness to the fact that people who drink greater than 3 alcoholic beverages per day should talk with their health care practitioner before using any OTC pain reliever.

Sources:

<http://www.natlconsumersleague.org/takewithcare/media/release.htm>

The American College of Emergency Physicians <http://www.ACEP.org>

Emergency Nurses Association <http://www.ena.org>

Are One or Two Dangerous? Camphor Exposure in Toddlers

**J Emerg Med. 2004 Jul;27(1):49-54.
Love JN, Sammon M, Smereck J.**

Authors from the Georgetown University Department of Emergency Medicine remind readers that pediatric exposure to camphor remains a serious toxicity concern. Citing data from the American Association of Poison Control Centers, ingesting as little as 500 mg of camphor has been linked with mortality in the pediatric population. One example suggests that a 10% camphor-containing product contains 500 mg per 5 mL. Despite steps the FDA took in the 1980's to decrease the risk, reports of toxicity persist. The authors conclude that children less than six years-of-age, who are exposed to 500 mg or more of camphor, should be immediately referred to the closest health-care facility. Pharmacists should remind their patients that camphor is found in many OTC products; a few examples include: vaporized or topical cold products, musculoskeletal rubs, and cold sore preparations.