

### **Abbott Laboratories to Reformulate Vicodin Products**

In January 2011, the US Food and Drug Administration announced that they will be requiring manufacturers of prescription drug products to limit the amount of acetaminophen contained in combination products in an effort to decrease the risk of severe liver injury and hypersensitivity reactions due to acetaminophen use. In addition to the decrease in dose, a Boxed Warning is to be included regarding the potential for liver injury, with an additional Warning regarding the chance of rare but serious hypersensitivity reactions. The FDA asked that all prescription combination products contain no more than 325mg acetaminophen per dosage unit. Due to the combination with other pain medications, usually opioids, the efficacy of these medications regarding pain management should not change. The FDA has stated that the reduction in acetaminophen will not change the prescribing directions of these products. The FDA asked that all entities become compliant by January 2014.

To comply with this regulation, Abbott Laboratories, the manufacturer of the popular hydrocodone-acetaminophen combination products Vicodin, Vicodin ES, and Vicodin HP, is planning to reformulate these products. On May 29, 2012, Abbott issued a "Reformulation and Discontinuation Announcement" to healthcare providers regarding this process. In this announcement, Abbott explained that they would discontinue manufacturing and distributing their current products (containing more than 325mg acetaminophen) immediately, ahead of the requested implementation date. This early discontinuation is intended to prevent confusion when the reformulated products are released in the third quarter of 2012.

While Abbott is making a valiant effort to prevent confusion and facilitate this change, there is an area for concern. After the reformulation, Vicodin, Vicodin ES, and Vicodin HP will contain 300mg of acetaminophen, 25mg less than the FDA suggested limit. This may create confusion and unnecessary issues in clinical practice. Prescriptions written for these products will not be substitutable with the readily available generic product that contains 325mg acetaminophen. This will create unnecessary strain on various health care professionals, third party payers, and patients. To combat this, Pharmacist's Letter has constructed a "Dear Doctor" letter that is available to subscribers and intended to be distributed to physicians, detailing the change and requesting that prescriptions should be written for the generic combination product containing hydrocodone-acetaminophen.

### **References**

- Pharmacist's Letter Staff. A Note from Your Pharmacist: Phaseout of High-Dose Rx Acetaminophen Combination Products. Pharmacist's Letter. Available at: <http://pharmacistsletter.therapeuticresearch.com/pl/ArticleDD.aspx?nidchk=1&cs=&s=PL&pt=2&segment=4516&dd=280711>. Accessed on July 27, 2012.
- FDA Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure [updated Jan 21, 2011]. US Food and Drug Administration. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>. Accessed on July 27, 2012.
- Questions and Answers about Oral Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit [updated Aug 01, 2011]. Available at: [www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm239871.htm](http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm239871.htm). Accessed on July 28, 2012.

- Reformulation and Discontinuation Announcement [May 29, 2012]. Abbott Pharmaceuticals. Available at: <http://www.epmonthly.com/whitecoat/wp-content/uploads/2012/06/Abbott-Vicodin-Announcement2.pdf>. Accessed on July 28, 2012.

Heather Hall, PharmD Candidate