



January 26, 2009

Medication Safety Review

- MEDICATIONS:** Plavix® (clopidogrel), Bristol-Myers Squibb/sanofi-aventis
- DOSAGE FORMS:** 75 mg tablet
- ISSUE:** The makers of Plavix® (clopidogrel) will work together with the FDA to conduct studies and obtain information regarding the effects of genetic factors and other drugs on clopidogrel.

The following was posted on the FDA Med Watch Web site on January 26, 2009:

“The FDA notified healthcare professionals that the makers of Plavix® have agreed to work with the FDA to conduct studies to obtain additional information that will allow a better understanding and characterization of the effects of genetic factors and other drugs (especially the proton pump inhibitors (PPIs)) on the effectiveness of clopidogrel. The FDA is aware of published reports that clopidogrel is less effective in some patients than it is in others. Differences in effectiveness may be due to genetic differences in the way the body metabolizes clopidogrel or that using certain other drugs with clopidogrel can interfere with how the body metabolizes clopidogrel. These studies should lead to a better understanding about how to optimize the use of clopidogrel. The FDA recognizes the importance of obtaining these data promptly. The drug manufacturers have agreed to a timeline for completing the studies and the FDA will review the new information expeditiously and will communicate its conclusions and any recommendations to the public at that time. It could take several months to complete the studies and analyze the results. Until further information is available the FDA recommends the following:

- Healthcare providers should continue to prescribe and patients should continue to take clopidogrel as directed, because clopidogrel has demonstrated benefits in preventing blood clots that could lead to a heart attack or stroke.
- Healthcare providers should re-evaluate the need for starting or continuing treatment with a PPI, including Prilosec® OTC, in patients taking clopidogrel.
- Patients taking clopidogrel should consult with their healthcare provider if they are currently taking or considering taking a PPI, including Prilosec® OTC.”

A complete copy of the accompanying “Early Communication about an Ongoing Safety Review” dated January 26, 2009 from the FDA may be viewed at:

http://www.fda.gov/cder/drug/early_comm/clopidogrel_bisulfate.htm