Safety Developments Regarding Pradaxa: Boehringer Starts Drug Registry; EMA Wants Label Change; Study Compares Pradaxa Use To Coumadin As Regards Side Effects

Pradaxa Adverse Reactions And Serious Bleeding Events More Common In Older Patients And Females, With Reduced Renal Function Also Being A Factor

(Posted by Tom Lamb at www.DrugInjuryWatch.com on June 5, 2012; see http://bit.ly/KMfgda)

In April 2012 the manufacturer of Pradaxa (dabigatran), Boehringer Ingelheim, announced it is launching the GLORIA ™-AF Registry Program, which is designed to gather real-world data on patient demographics, disease characteristics, treatment decisions, and the safety and efficacy of Pradaxa as well as various other antithrombotic therapies such as Coumadin (warfarin) and Xarelto (rivaroxaban). This Boehringer registry for Pradaxa aims to enroll more than 50,000 newly diagnosed atrial fibrillation (AF) patients from 50 countries and follow them until 2020.

In May 2012 we learned that the European Medicines Agency (EMA) wants the Pradaxa prescribing information, also called the package insert or label, revised to give clearer guidance to European doctors and patients about how they might reduce and manage the risk of serious bleeding events that have associated with this relatively new anticoagulant medicine from Boehringer.

Next, a news report published online by ***theheart.org***, "More adverse events seen on dabigatran vs warfarin", seems to give more support to the contention that the risk of side effects with Pradaxa is highest in elderly patients and in patients with reduced renal function.

From that news report we get these significant findings from a study which was presented as a poster at the Thrombosis & Hemostasis Summit of North America 2012 by Dr. Mark Wurster.

> Results showed that during the warfarin treatment period, there was one event (0.88%) necessitating drug discontinuation—the patient was hospitalized because of a high INR. This compared with 13 events (11.5%) in the dabigatran treatment period. These included one treatment-related death (GI bleed), four other bleeding episodes (two GI bleeds, one rectus sheath hemorrhage, one intracranial hemorrhage associated with trauma), one deep venous thrombosis, one atrial thrombus, one transient ischemic attack, one skin rash, and four patients with GI symptoms.
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> These adverse reactions were more common in older patients and in females. The mean age of patients experiencing complications on dabigatran was 73.4 years, compared with 66.5 years for the whole population. And women represented 29% of the overall population, but 71% of patients with complications.

In an earlier article, "Pradaxa Hemorrhage Cases May Occur In Oldest Patients Due To Age-Related Decline In Renal Function", we pointed out that reduced renal function also seems to be a factor in gastrointestinal bleeding (GI bleeds), intracranial hemorrhages, and other serious bleeding events associated with Pradaxa use.

Lastly, the FDA's investigation of possible higher than expected incident rate of serious bleeding side effects is still underway.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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