Pradaxa Named in Most FDA Adverse Event Reports for Deaths, Hemorrhage, Kidney Failure and Stroke

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The controversial blood thinner, Pradaxa, surpassed all other drugs monitored by the U.S. Food & Drug Administration (FDA) in adverse event reports made to the agency last year. According to the Institute for Safe Medicine Practices' (ISMP) latest QuarterWatch report, Pradaxa also topped the list for reports of deaths, hemorrhage, acute renal failure, and stroke.

According to QuarterWatch, the FDA received 3,781 adverse event reports associated with Pradaxa in 2011. These included 541 deaths, 2,367 reports of hemorrhage, 291 reports of kidney failure and 644 reports of stroke. Pradaxa was also a suspect in more than 15 cases of liver failure reported to the FDA.

Pradaxa, approved by the FDA in October 2010, is one of a number of new blood thinners that have been positioned as a superior alternative to warfarin, an anti-coagulant that has been marketed for decades. Warfarin, known by the brand name Coumadin, was associated with the second highest number of adverse event reports in 2011, according to ISMP with more than 1,100. That included 731 reports of hemorrhage and 72 deaths.

Like any blood thinner, both Pradaxa and Coumadin are associated with the risk of serious and sometimes fatal bleeding. However, as we've reported previously, there are antidotes for Coumadin bleeding, such as the administration of vitamin K. There is no readily available antidote for Pradaxa bleeding. In a number of reported cases, Pradaxa patients have apparently died from serious internal bleeding following a minor trauma, such as a fall that resulted in a bump to the head.

The FDA launched a review of Pradaxa in December over reports of bleeding-related side effects, while regulators in Europe and Japan have directed Boehringer Ingelheim to strengthen warnings for the drug. Most recently, European regulators asked Boehringer Ingelheim, the manufacturer of the Pradaxa, to update the drug's label with additional information regarding its bleeding side effects. As we reported, the European Medicines Agency (EMA) wanted the label to include more specific information regarding when Pradaxa must not be used, as well as advice on managing patients and reversing the anticoagulant effect if Pradaxa bleeding occurs. The request followed one the EMA had made in November, when it asked Boehringer Ingelheim to add more information about bleeding to Pradaxa's label, including a caution that it be prescribed at lower doses to older patients and those with kidney problems.

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