Multaq Update: European Safety Review Expanded To Cardiovascular Side Effects Risk In July 2011

EMA And FDA Already Had Sanofi Issue A "Dear Doctor" Letter About Liver Failure In January 2011

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 12, 2011; see http://bit.ly/rt4hKB)

On July 11, 2011 the European Medicines Agency (EMA) announced that it had expanded a safety review of Sanofi's Multaq (dronedarone). This regulatory development came soon after the drug company's announcement that it was discontinuing the late-stage PALLAS study.

From the EMA's July 11, 2011 press release, "European Medicines Agency reviews cardiovascular risk of Multaq":

> The European Medicines Agency is reviewing the cardiovascular risk of the anti-arrhythmic medicine Multaq (dronedarone), from Sanofi Aventis. This follows the company's announcement on 7 July 2011 of its discontinuation of the PALLAS study, because of the occurrence of severe cardiovascular events in some patients taking Multaq.
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> In the PALLAS study Multaq was being investigated in patients over 65 years of age with permanent atrial fibrillation....
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> The study was looking at the rate of major cardiovascular events (stroke or myocardial infarction) or hospitalisations due to cardiovascular events, or death. It found a higher rate of events and hospitalisations with Multaq when compared with placebo.
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> The Agency's Committee for Medicinal Products for Human Use (CHMP) started a review in January 2011 of the overall benefit-risk balance of Multaq following reports of severe liver injury. The scope of this review has now been extended to also assess new information from the PALLAS study and the CHMP will determine the need for any further action at its next meeting of 18-21 July 2011.

We had previously reported on the flurry of activity surrounding Multaq back in January 2011 with this post, "Sanofi-Aventis 'Dear Doctor' Letter Will Warn Heart Drug Multaq Associated With Liver Failure", and have been monitoring this emerging drug safety issue since that time.

In their July 7, 2011 press release, "Sanofi Provides Multaq® Phase IIIb PALLAS Trial Update", the drug company tried to keep the more recently found cardiovascular side effects separate and apart from the earlier liver failure reports, stating: "The decision to terminate the study was not related to any hepatic adverse event."

The same Sanofi press release informed us "Currently approximately 400,000 patients have been treated with Multaq worldwide."

According to a July 11, 2011 Reuters news report by Ben Hirschler, "European regulators launch safety review of Sanofi's Multaq":

> Analysts see Multaq, which won approval from European medicines regulators in September 2009 and was approved in the United States in July 2009, as an important driver for Sanofi to see it through patents expiries on multibillion-dollar drugs like the cancer treatment Taxotere and the blood thinner Plavix.

Returning to our January 2011 post about Multaq and liver failure, we noted that the liver toxicity in addition to the cardiac side effects had caused renowned cardiologist Dr. Steven Nissen to express "concerns about the safety, efficacy and tolerability of dronedarone".

One wonders whether Sanofi will continue to promote Multaq or, instead, move to withdraw it from the market. Only time will tell and, of course, we will let you know if there is a Multaq recall in the U.S. or in the European Union.

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.
http://www.DrugInjuryWatch.com