# European Medicines Agency (EMA) Recommends Multaq Use Should Be Restricted For Safety Reasons

## EMA Cites The Increased Risks Of Liver Injury, Lung Side Effects, And Cardiovascular Adverse Events

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 22, 2011; see http://bit.ly/oUhQ9S)

In late September 2011 the European Medicines Agency (EMA) recommended that the use of Sanofi's antiarrhythmic medication Multaq (dronedarone) be restricted to certain patients with paroxysmal or persistent atrial fibrillation.

From the September 22, 2011 *heartwire* news report, "EMA recommends restricting use of dronedarone" (free subscription required):

> [According to the EMA's Committee for Medicinal Products for Human Use (CHMP), Multaq (dronedarone)] should be restricted to patients with paroxysmal or persistent atrial fibrillation when sinus rhythm is obtained and should not be used when atrial fibrillation is still present. It should not be used in permanent atrial fibrillation or in patients with heart failure or those with left ventricular systolic dysfunction. It should also not be used in patients with a previous lung or liver injury following treatment with amiodarone. Patients with nonpermanent atrial fibrillation treated with dronedarone should be monitored by a specialist and have their lung, liver, and heart-rhythm function checked regularly.

As pointed out in this September 22 *heartwire* article by reporter Michael O'Riordan, the FDA is in the midst of its own safety review of Multaq. From that article:

> In an email to *heartwire*, Sandy Walsh, in the FDA Office of Public Affairs, said the FDA still wants to patients and physicians to follow the advice provided in two recent safety communications about [Multaq (dronedarone)].

Somewhat ironically, earlier the same day we had seen this *Wall Street Journal* (*WSJ*) article about the safety controversy surrounding Multaq: "FDA Reviews Heart-Rhythm Drug -- Amid Pressure From Doctors Over Safety, U.S. Regulators May Take Further Steps Concerning Sanofi's Multaq" (paid subscription required). From this September 22, 2011 *WSJ* article by reporter Thomas M. Burton:

> In interviews, several prominent specialists said they recommend against patients taking the drug. "It seems like it's not even safe in intermediate-risk patients," said Sanjay Kaul, a cardiologist at Cedars-Sinai Medical Center in Los Angeles. Dr. Kaul served on an FDA advisory panel about Multaq and voted in favor of approval, but he said he doesn't prescribe the drug.
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> Steven Nissen, chairman of cardiovascular medicine at the Cleveland Clinic, said, "I think the drug is dangerous." Louisville cardiologist John Mandrola said, "I'm surprised that the drug has persisted. I don't know any of my colleagues who would start a patient out on Multaq. It just doesn't work."

Doctors said they based their opinions both on published studies and their own clinical experience.

We will watch for what the FDA decides to do about Multaq and report any use restrictions or other regulatory actions here.

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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