

Roche Accepts FDA's Proposal for New Warning Labels on Tamiflu

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BASEL, Switzerland_Swiss drugmaker Roche Holding AG has accepted a recommendation by a U.S. Food and Drug Administration panel to put a stronger warning label on its flu treatment Tamiflu, a spokeswoman said Wednesday.

But Martina Rupp said all patients with full-blown flu should be warned that the illness itself posed a risk of psychiatric problems, not just for those taking the Roche product. She stressed there was no causal relationship between Tamiflu and reported cases of delirium and hallucinations.

"It's important really that the label reflects that influenza itself can trigger such events," she said.

The FDA panel recommended Tuesday that Roche change the warning label for Tamiflu, which has been used by 48 million patients since its launch in 1999.

The drug's label already mentions reports of delirium and self-injury, primarily among children in Japan, but some of the FDA's experts suggested the language should mention that several patients have died as a result of these abnormal behaviors.

Nearly 600 cases of psychiatric problems have been reported in Tamiflu patients, with 75 percent of them coming from Japan. Five children there have died after "falling from windows or balconies or running into traffic," according to the FDA.

Roche presented its own analysis of more than 150,000 patients to the FDA showing no connection between Tamiflu and increased risk of psychiatric problems.

"Over the last year we've been looking at a variety of data and undertaken additional studies that so far have shown no causality between Tamiflu and these events," Roche product director David Reddy said in an interview Tuesday. "In fact, the data increasingly points to the role of influenza in these events."

Rupp said influenza causes fevers that reach 104 Fahrenheit or higher, and people "need to know that this is associated with delirium and hallucination."

Tamiflu sales totaled \$1.1 billion in the first half of 2007. Sales have benefited in recent years from governments stockpiling the drug in case the bird flu virus that has ravaged poultry stocks in Asia mutates into a form that can be easily transmitted among humans, sparking a flu pandemic.