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FDA reviewing risks of Glaxo drug

By Lisa Richwine

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WASHINGTON (Reuters) - U.S. regulators are reviewing the safety of [GlaxoSmithKline](#)'s Plc's diabetes drug Avandia but have not yet

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determined the significance of risks reported in a study released on Monday, a U.S. Food and Drug Administration official said.

A study published in the New England Journal of Medicine said Avandia increased the risk of cardiac-related deaths by 64 percent and heart attacks by 43 percent. Dr. Robert Meyer, head of the FDA office that reviews diabetes drugs, said other data contradicted those findings.

"FDA has not confirmed the clinical significance of the reported increased risk in the context of other studies," Meyer told reporters during a conference call.

"Further, the FDA does not know whether the other approved treatments in the same class of drugs ... have less, the same, or other greater such risks," he said.

The agency said it was not asking GlaxoSmithKline to take any action at the present time but would ask a public advisory committee to weigh in at a later date.

"Patients who are taking Avandia, especially those who are known to have underlying heart disease or who are at high risk of heart attack should talk to their doctor about this new information as they evaluate the available treatment options for their type 2 diabetes," the FDA said.

GlaxoSmithKline said it strongly disagreed with the study findings and believed Avandia's benefits outweighed its risks.

Members of Congress, however, questioned the actions of the FDA and GlaxoSmithKline.

"What we are learning about the handling of Avandia by both GlaxoSmithKline and the FDA is appalling and unacceptable. Both the drug company and the FDA have some major explaining to do about what they knew about Avandia, when they knew it, and why they didn't take immediate action to protect patients," said Sen. Max Baucus, a Montana Democrat who chairs the Senate Finance Committee.

In a letter to Glaxo, Baucus and Sen. Charles Grassley, the committee's leading Republican, said they are concerned about reports "that GSK employees silenced one or more medical professionals who attempted to speak out about the potential for cardiovascular problems with Avandia. This allegation is very serious and warrants further investigation."

Glaxo said it had shared data on Avandia with the FDA and other regulators as quickly as possible.

"The suggestion that GlaxoSmithKline has placed patients at risk and attempted to silence independent investigation of data is absolutely false," the company said.

"Any fair examination of the company's record will show that GSK has been fully transparent in its efforts to

thoroughly study the safety and effectiveness of Avandia, and to widely communicate that information," Glaxo added.

Another congressional panel, the U.S. House of Representatives Oversight and Government Reform Committee, scheduled a hearing for June 6 on the FDA's handling of the drug and said it would invite the agency commissioner and Glaxo's chief executive to testify.

Glaxo said it provided its own analysis to the FDA in August 2006 that found a cardiovascular risk with Avandia of about 30 percent, but the finding was not borne out by other long-term studies.

The FDA's Meyer said the agency had been reviewing the conflicting data. An FDA analysis showed some increased heart risk but it is not yet completed, he said.

Avandia's label had already been updated to include findings from a study that showed more people with preexisting heart disease who took Avandia had cardiovascular problems, Meyer said.

FDA officials felt that language "would stand until we could get a better handle on all the existing data to make a more informed regulatory decision," Meyer said.

Shares of Takeda Pharmaceutical Co. Ltd. (4502.T) rose in early Tokyo trading after the study. Takeda's main earnings driver, Actos, competes directly with Avandia and belongs to the same class of drugs.

(Additional reporting by Susan Heavey)

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