MedicalXpress

Diabetes drug Avandia gets new setback ahead of US decision

July 10 2010

GlaxoSmithKline's blockbuster diabetes treatment Avandia suffered a new setback Friday when US health officials offered more evidence of the drug's increased link to heart problems.

A document released by the Food and Drug Administration came as an FDA panel of experts prepares to meet next week to consider withdrawing the popular drug because of concerns about its links to cardiovascular ailments.

The document cited Thomas Marciniak, an FDA expert on cardiovascular treatments, who indicated that clinical trials of the drug, whose generic name is rosiglitazone, were "inadequately designed" and that the record "suggests the rosiglitazone increases the risk" of heart attacks.

"Half of the errors were substantial," Marciniak said in the document. "If consulted in advance, I would have rejected this study design as inappropriate and biased."

The report came after two studies released in recent weeks concluded patients taking Avandia faced a higher risk of heart attacks and strokes, emboldening critics who have asked that it be withdrawn from the market.

The FDA often follows the advice of its panels of experts, which will make its recommendation after the talks on Tuesday and Wednesday.

In addition to Marciniak's comments, the FDA also released some 700 pages of documents examining studies on Avandia and its safety compared with other treatments.

Last year sales of Avandia, which has been on the market since 1999, were about 800 million dollars worldwide, making it one of the top selling diabetes treatments and overall drugs.