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## Avandia Label Is Getting Some Additional Contraindications And A New Warning In Europe

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POSTED: Thursday, January 24, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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### January 2008 Revisions Follow An Avandia Safety Review That Was Completed By EMEA In October 2007

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On January 24, 2008 GlaxoSmithKline (GSK) announced that the European label for its diabetes drug Avandia (rosiglitazone maleate) will be revised pursuant to a decision by the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP).

An article published by *Reuters*, "[EU experts add new warnings to Glaxo's Avandia - UPDATE 1](#)", reported what little was known about the Avandia label change in Europe as of noon EST on January 24:

European regulators on Thursday recommended that patients with heart disease or leg pains -- a possible sign of heart problems -- should not take GlaxoSmithKline's (GSK.L: [Quote](#), [Profile](#), [Research](#)) diabetes drug Avandia.

The European Medicines Agency also said in its decision to update Avandia's label that the drug must not be used by people having a heart attack or with conditions such as angina....

In October, Europe's drug watchdog said prescribing information should be updated to include a warning that patients with heart disease should only be given the drug after a careful examination of their individual risk.

A GSK press release issued earlier on January 24, "[GlaxoSmithKline to revise Avandia® \(rosiglitazone maleate\) label in Europe following assessment by CHMP](#)", provided some additional detail about the revisions to the European version of the Avandia package insert, or label:

The label will be revised to state that available data indicate that

rosiglitazone may be associated with an increased risk of myocardial ischaemic events. It will also state that this risk was not confirmed or excluded in three long-term clinical trials and the data in their entirety on myocardial ischaemia are inconclusive.

There are limited clinical trial data in patients with ischaemic heart disease and/or peripheral arterial disease, especially those with myocardial ischaemic symptoms. The revised label will state that as a precaution, the use of rosiglitazone is not recommended in these patients. This information will appear in the warnings and precautions section of the label.

Patients with acute coronary syndrome (unstable angina, NSTEMI and STEMI) require urgent hospital treatment and have an increased risk of developing heart failure. This high-risk patient population has not been studied in rosiglitazone controlled clinical trials, and revised labelling will advise prescribers that rosiglitazone is contraindicated in patients with acute coronary syndrome.

This January 24 GSK press release also specified the affected products:

The label changes will be applied to all approved rosiglitazone-containing products: Avandia® (rosiglitazone maleate), Avandamet® (rosiglitazone maleate and metformin hydrochloride) and Avaglim® (rosiglitazone maleate and glimepiride).

In October 2007 the EMEA concluded that the benefits of Avandia as well as the other diabetes medications in the thiazolidinediones (TZDs) class of drugs outweighed the risks. These Avandia label changes in January 2008, however, are reportedly a result of that earlier safety review.

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