



# Compliance Alert

November 28, 2007

***Compliance Alert, provided by Group Benefit Services, gives you the most up to date information regarding industry news as well as legislation and regulatory activities affecting your health plan.***

## **TOPIC: EMERGING THERAPEUTIC ISSUES COMMUNICATION**

On November 14, 2007, the U.S. Food and Drug Administration (FDA) and GlaxoSmithKline informed healthcare professionals that the BOXED WARNING in Avandia's label now includes information about a potential increased risk for myocardial ischemia, such as angina (chest pain) and heart attacks. Here is some important information included in the recent labeling change:

- **A meta-analysis of 42 clinical studies, most of which compared Avandia to placebo, showed Avandia to be associated with an increased risk of myocardial ischemic events such as angina (chest pain) or myocardial infarction (heart attacks).**
- **Three other studies comparing Avandia to some other approved oral antidiabetic agents or placebo have not confirmed or excluded this risk.**
- **In their entirety, the available data on the risk of myocardial ischemia are inconclusive.**

At this time, FDA has concluded that there isn't enough evidence to indicate that the risk of heart attacks or death is different between Avandia and some other medications to treat type 2 diabetes. As a result, GlaxoSmithKline has committed to conducting a long-term study to evaluate the potential cardiovascular risk of Avandia.

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For additional information about these changes or to report an adverse event, please access FDA's MedWatch website at: [www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm). You can also call FDA at 1-888-INFO-FDA (automated) or 301-827-4570.

**Express Scripts response:**

- In an effort to inform physicians of the significant changes to the product labeling, we have identified physicians who have prescribed Avandia containing product within the past 60 days.
- A communication, summarizing the changes to the prescribing information, will be sent to physicians for those clients enrolled in the physician-mailing portion of the Emerging Therapeutic Issues program. The communication will also contain patient profiles to help identify impacted patients.

***If you have any questions regarding this information, please contact your Group Benefit Services Account Manager at 1.800.638.6085.***

***This communication is not intended to be legal advice and should not be construed as legal advice. If you have any legal questions or concerns about your plan, GBS recommends seeking counsel from an ERISA attorney.***

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