



# Compliance Alert

February 19, 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 ISSUE FROM ESI**

### ***Issue***

Recently, the U.S. Food and Drug Administration (FDA) announced revisions to the prescribing information of Sanofi-Aventis' ketolide antibiotic, Ketek® (telithromycin). Highlights of the changes include:

- **Ketek is no longer indicated for the treatment of *acute bacterial sinusitis* or *acute bacterial exacerbations of chronic bronchitis*.** FDA has determined that the balance of benefits and risks no longer support approval of the drug for these indications.
- Ketek will continue to carry the indications for the treatment of community-acquired pneumonia (of mild to moderate severity).
- A 'BOXED WARNING' will be added to the prescribing information stating that Ketek is contraindicated for use in patients with myasthenia gravis. Previously, this information was described in the 'warnings' section of the prescribing information.
- A Patient Medication Guide will also be provided to patients with each prescription to inform them about the risks of the drug and how to use it safely.
- Other labeling changes include strengthening of the 'WARNINGS' section regarding specific drug-related adverse events including visual disturbances and loss of consciousness. Warnings for hepatic toxicity (rare but severe symptoms of liver disease) were strengthened in June 2006.

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These changes to Ketek's prescribing information are consistent with the recommendations from a joint FDA advisory committee meeting held in December 2006. This panel consisted of FDA's Anti-Infective Drugs and Drug Safety and Risk Management Advisory committees.

**Express Scripts response:**

- In an effort to inform physicians of the changes to Ketek's prescribing information, we have identified physicians who have prescribed the drug within the past 60 days.
- A communication, summarizing the changes to Ketek's prescribing information, will be sent to physicians for those clients enrolled in the physician mailing portion of the Emerging Therapeutic Issues program.

***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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