



# Compliance Alert

March 9, 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: FORMULARY UPDATE – ZOFRAN® - PATENT EXPIRATION AND FORMULARY CHANGES**

### ***Issue***

In late 2006, generic manufacturers received approval for AB-rated generics to GlaxoSmithKline's Zofran (ondansetron) tablets, orally disintegrating tablets and oral solution. In addition, AP-rated generics to Zofran injections were also approved. An 'AP' rating is the equivalence designation for injectable products, similar to the 'AB' rating assigned to oral drugs. Zofran was originally approved in 1991 for the prevention of nausea and vomiting.

Now that generics to Zofran are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand Zofran from Express Scripts formularies, replacing it with the generic ondansetron products. This procedure is being enacted because Zofran is marked with an '\*' on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

### ***Take-Away Points***

- ✓ Generic ondansetron products are AB-rated generics to Zofran tablets, orally disintegrating tablets and oral solution, and AP-rated generics to Zofran injection. These products are now available in the prescription market.
- ✓ An 'AP' rating is the equivalence designation for injectable products, similar to the 'AB' rating assigned to oral drugs.
- ✓ The brand-name product, Zofran, will be converted to non-formulary status on April 1, 2007.

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### ***Take-Away Points (continued)***

- ✓ This procedure is being enacted because Zofran is marked with an '\*' on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

In addition to Zofran, several other drugs are scheduled to lose patent protection in 2007. The drugs listed in the table below will also be designated as “non-formulary” when generics are established in the market. However, keep in mind that although a key drug patent expires, generic products are not always readily available. There are many issues that may delay their availability, including litigation, final approval from FDA, and additional patents and granted exclusivities.

Allegra-D® (fexofenadine/pseudoephedrin - sanofi-aventis) Allergies Expired#  
Ambien® (zolpidem – sanofi-aventis) Sleep April 21, 2007  
Cognex® (tacrine – Sciele Pharma) Alzheimer’s Disease September 9, 2007  
Colazal® (balsalazide disodium – Salix) Ulcerative colitis January 8, 2007  
Concerta® (methylphenidate, e.r. – McNeil PPC) ADHD Expired#  
Coreg® (carvedilol – GlaxoSmithKline) Blood pressure/CHF September 5, 2007  
Emadine (emadastine – Alcon) Ophth Antiallergic Expired#  
Lamisil® (terbinafine – Novartis) Fungal infections June 30, 2007  
Metadate CD® (methylphenidate e.r. – UCB) ADHD Expired#  
Omnicef (cefdinir – Abbott) Bacterial infections May 06, 2007  
Ortho Tri-Cyclen Lo (norgestimate/EE – J&J) Oral contraceptive Litigation  
Requip (ropinirol – GlaxoSmithKline) Parkinson’s disease December 7, 2007  
Skelaxin (metaxalone – King) Muscle Relaxant Expired#  
Toprol XL (metoprolol, e.r. – AstraZeneca) Blood pressure Expired#  
Wellbutrin XL (bupropion, e.r. – GlaxoSmithKline) Depression Expired#  
# - Generics not yet available

***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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