



Compliance Alert

June 6, 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 – AMBIEN® AND OMNICEF® – PATENT EXPIRATION AND FORMULARY CHANGES

Issue – Ambien®

On April 23, the U.S. Food and Drug Administration (FDA) approved AB-rated generics to sanofi-aventis' Ambien (zolpidem) 5mg and 10mg tablets. In addition to the FDA approved generics, an "authorized generic", or brand manufacturer approved generic, is also available.

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

Take-Away Points

- ✓ Generic zolpidem tablets are AB-rated generics to Ambien® and are now available in the marketplace.
- ✓ The brand-name product, Ambien, will be converted to non-formulary status on June 15, 2007.

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Issue – Omnicef®

On May 7, 2007 the first AB-rated generics to Omnicef capsules and suspensions were made available. Currently, three manufactures are supplying generics to the market in addition to an “authorized generic” from Dava Pharmaceuticals. As a result, all formulations of brand Omnicef are now available generically from several manufacturers.

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

Take-Away Points

- ✓ Generic cefdinir capsules and suspensions are AB-rated generics to Omnicef® and are now available in the marketplace.
- ✓ The brand-name product, Omnicef, will be converted to non-formulary status on July 1, 2007.
- ✓ This procedure is being enacted because Omnicef is marked with an '*' on the formularies, indicating a potential for conversion to non-formulary status with the availability of generics.

In addition to Omnicef and Ambien, 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/pseudoephedrine – sanofi-aventis) Allergies Expired#
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#

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Coreg® (carvedilol – GlaxoSmithKline) Blood pressure/CHF September 2007
Emadine® (emadastine – Alcon) Opth. 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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