

Compliance Alert

July 31, 2006

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 FROM ESI – ZOCOR®

Issue

The U.S Food and Drug Administration (FDA) recently approved AB-rated generics to Zocor® (simvastatin) tablets. Teva® has been granted 180 days of generic exclusivity for the 5mg, 10mg, 20mg and 40mg tablets while Ranbaxy® was granted this exclusivity for the 80mg tablets. In addition to these FDA approved generics, an "authorized generic", or brand manufacturer approved generic, is also available.

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

Take-Away Points

- Generic simvastatin tablets are AB-rated generics to Zocor® and are now available in the marketplace.
- The brand-name product, Zocor®, will be converted to non-formulary status on September 1, 2006.
- This procedure is being enacted because Zocor® is marked with an '*' on the formularies, indicating a potential for conversion.

In addition to Zocor, several other drugs are scheduled to lose patent protection in 2006. 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.

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Adderall XR (amphetamine salts - Shire) - ADHD –Expired
Allegra® D (fexofenadine - sanofi-aventis) - Allergies – Expired
Concerta (methylphenidate, e.r. - McNeil PPC) – ADHD – Expired
Ditropan XL (oxybutynin, e.r. - Ortho McNeil) - Overactive Bladder –Expired
Emadine (emadastine - Alcon) - Ophth. Antiallergic – Expired
Metadate CD (methylphenidate e.r. - UCB) – ADHD – Expired
Metrogel (metronidazole 0.75% gel - Galderma) - Topical antibiotic - June 6, 2006
Skelaxin (metaxalone - King) - Muscle Relaxant – Expired
Toprol XL (metoprolol, e.r. - AstraZeneca) - Blood pressure – Expired
Uniphyl (theophylline, c.r. - Purdue Frederick) - Asthma/COPD – Expired
Wellbutrin XL (bupropion, e.r. - GlaxoSmithKline) – Depression – Expired
Zofran (ondansetron - GlaxoSmithKline) - Nausea/vomiting - December 23, 2006
Zoloft (sertraline - Pfizer) – 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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