

# Compliance Alert

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August 22, 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 – ZOLOFT®

### ***Issue***

On June 30, 2006, Teva Pharmaceuticals received approval from the U.S. Food and Drug Administration (FDA) for its AB-rated generics to Zoloft® (sertraline) tablets. After a short delay, Teva's generic along with an "authorized generic", or brand manufacturer-approved generic, became available the week of August 14, 2006.

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

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

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

In addition to Zoloft®, 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 Expired  
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  
\*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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