



Compliance Alert

June 30, 2008

Express Scripts – Emerging Therapeutic Issue and Two Formulary Updates

Emerging Therapeutic Issue

ETHEX Corporation has announced a voluntary recall of several lots of its 30mg and 60mg morphine sulfate extended-release tablets. The recalled lots were distributed between June 2006 and May 2008. They are being recalled because it is possible that oversized tablets, with as much as twice the labeled amount of active morphine sulfate, have been distributed. This possibility leads to a concern that the abnormal tablets may cause overdoses. Overdoses from opioids like morphine can have life-threatening consequences such as respiratory depression (difficulty or lack of breathing) and low blood pressure. So far, there have been no reports of adverse events stemming from this recall.

Questions regarding this recall can be directed to ETHEX Customer Service at 1.800.321.1705 Monday through Friday, 8 a.m. to 5 p.m. CST. Additional information can be found on FDA's MedWatch website at: www.fda.gov/medwatch/safety.htm. You can also call FDA at 1.888.INFO.FDA (automated) or 301.827.4570.

Express Scripts response:

- In an effort to inform members of this recall, we have identified members who have received a prescription for 30mg or 60mg morphine sulfate extended-release tablets within the past 120 days. A communication summarizing the information provided by the manufacturers will be sent to these members.
- The above communications will be distributed for those clients enrolled in the member and physician portions of the Emerging Therapeutic Issues Patient Safety Program., respectively.

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Formulary Updates

Wellbutrin XL® Tablets

Generics to all strengths of GlaxoSmithKline's antidepressant Wellbutrin XL® (bupropion extended-release) tablets are now available. Recently, Teva Pharmaceuticals launched AB-rated generics to the 150mg tablet strength. Generics to the 300mg tablet have been available since early 2007.

Now that generics are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand Wellbutrin XL tablets from Express Scripts formularies, replacing them with equivalent generic bupropion extended-release tablets. This procedure is being enacted because Wellbutrin XL is marked with an '*' on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

Verelan® PM Capsules

The U.S. Food and Drug Administration (FDA) approved AB-rated generics to Elan's blood pressure medication, Verelan® PM (verapamil extended-release) capsules. Mylan Pharmaceuticals is now supplying generics to all strengths of Verelan PM to the market.

Now that generics are established in the marketplace, Express Scripts will enact a procedure that will result in the removal of the brand Verelan PM capsules from Express Scripts formularies, replacing them with equivalent generic verapamil extended release capsules. This procedure is being enacted because Verelan PM is marked with an '*' on the formularies, indicating a potential conversion to non-formulary status with the availability of generics.

Take Away Points for above Formulary Changes

The brand-name products, Wellbutrin XL tablets and Verelan PM capsules, will be converted to non-formulary status on July 15, 2008.

Several other drugs are due to lose patent protection in 2008. The drugs listed in the table below are some of the drugs that will 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, patent settlements, final approval from FDA, and additional patents and granted exclusivities.

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Drug – Therapeutic Class – Patent Expiration

Allegra-D® (fexofenadine/pseudoephedrine – sanofi-aventis) Allergies	Litigation
CiproDex (ciprofloxacin/dexamethasone Otic – Alcon) Infection	Expired*
Concerta® (methylphenidate, e.r. – McNeil PPC) ADHD	Litigation
Cosopt (dorzolamide/timolol – Merck) Glaucoma	October 28, 2008
Depakote (divalproex – Abbott) Seizures	July 29, 2008
Dynacirc CR (isradipine e.r. – Reliant) Blood Pressure	July 9, 2008
Imitrex (sumatriptan – GlaxoSmithKline) Migraines	4 th Quarter 2008
Lamictal (lamotrigine – GlaxoSmithKline) Seizures	2 nd half of 2008
Metadate CD® (methylphenidate e.r. – UCB) ADHD	Litigation
Ortho Tri-Cyclen Lo (norgestimate/EE – J&J) Oral contraceptive	Litigation
Protopic (tacrolimus topical – Astellas) Atopic dermatitis	April 8, 2008
Risperdal (risperidone – Johnson & Johnson) Antipsychotic	June 29, 2008
Trusopt (dorzolamide – Merck) Glaucoma	October 28, 2008

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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