The Weekly Mortar & Pestle

A Publication of Walgreens Health Initiatives

May 1, 2008

A publication created especially for our clients and associates, delivering up-to-date information about brand-name and generic medication, medical products, and other pharmaceutical-related information collected from key government and industry sources.

Recent Food and Drug Administration (FDA) warnings and health news for patients and healthcare professionals

(Updates to previously printed news are noted in blue.)

Drug/Issue	Date	News Event(s)	Member/ Client Impact	Strategic Rationale	Action Needed to Implement
atenolol 50 mg/ chlorthalidone 25 mg tablets/ Major Pharmaceuticals **Issue:** Drug recall	04/21/08	• Major Pharmaceuticals has issued a patient-level recall of its bottles of 100-count atenolol 50 mg/chlorthalidone 25 mg tablets (lot #: L-1456; exp date: 08/2009) because the bottles actually contained gabapentin 100 mg capsules, a medication used to treat epilepsy and other conditions.	Low	• Low utilization. • Pharmacies have been notified of this recall.	• Communication to clients via *Weekly M&P* newsletter. • This event does not meet Industry Events Quick Response Team criteria for member communication.

Drug/Issue	Date	News Event(s)	Member/ Client Impact	Strategic Rationale	Action Needed to Implement
		• Pharmacists and other healthcare professionals are being asked to stop distribution and quarantine the recalled product while immediately notifying their customers of this recall. • Healthcare professionals with additional questions and concerns about the medication recall are asked to call Major Pharmaceuticals at 734-743-6181.			
Budeprion XL™ and **Wellbutrin XL®** (bupropion) extended-release (ER) tablets/ GlaxoSmithKline and Teva **Issue:** FDA review	04/16/08	• Between January 1, 2007 and June 30, 2007, the FDA received 85 post-marketing reports in which patients who switched from Wellbutrin XL 300 mg to Budeprion XL 300 mg experienced undesirable effects. • In 78 of these cases, there was reported loss of antidepressant effect following a switch from the branded to the generic product. A number of cases also reported the new onset or worsening of side effects. The reported side effects were consistent with the adverse effects in labeling for bupropion products. • More than half of the patients who switched back to Wellbutrin XL 300 mg reported improvement of depression or abatement of side effects. • Given the relationship between the switch to the generic product and the recurrence of depression or onset of side effects, these patients and physicians attributed these effects to poor performance of the generic product.	Low	• Whether or not these effects are due to bioequivalence is unknown at this time. • The generic has met FDA bioequivalence standards.	• Communication to clients via *Weekly M&P* newsletter. • Wellbutrin XL is nonpreferred. No changes planned. • Wellbutrin SR® and Wellbutrin XL Step Care in place.

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Drug/Issue	Date	News Event(s)	Member/ Client Impact	Strategic Rationale	Action Needed to Implement
		• Generic drug products approved by the FDA are therapeutically equivalent to the branded product, and therapeutically equivalent drugs generally may be substituted for each other. • The FDA approved Budeprion XL based on evidence demonstrating bioequivalence to Wellbutrin XL, and considers the generic to be interchangeable with Wellbutrin XL 300 mg. The FDA will continue to closely monitor reports of adverse events and therapeutic equivalence of bupropion products.			
Digitek® (digoxin) tablets/ Actavis Pharmaceuticals **Issue:** Drug recall	04/25/08	• Actavis Pharmaceuticals has recalled all lots of Digitek as a precaution. • Digitek is used to treat heart failure and abnormal heart rhythms, and it is an AB-rated generic equivalent of Lanoxin® tablets. Generic digoxin tablets are available from other manufacturers. • The voluntary recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released and may contain twice the approved level of digoxin. • Double-strength tablets pose a risk of toxicity such as nausea, vomiting, dizziness, low blood pressure, and cardiac abnormalities especially in patients with compromised kidney function.	High	• Moderate utilization of Digitek, but potential for serious adverse effects is high. • Patients should contact their physicians and pharmacy in order to have their Digitek supply replaced with an appropriate alternative.	• According to policy, Industry Events Quick Response Team has determined that alert letters will be sent to affected members and their prescribers. The letters will be sent on May 1, 2008. • Members will be directed to contact their physicians and pharmacy for alternatives.

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		• Retailers who have this product are urged to return the product to their place of purchase. If consumers have medical questions, they should contact their health care providers.			• Alternative preferred and generic forms of digoxin are available on the WHI PML.
Sodium chloride 1 gram tablets/ Consolidated Midland **Issue:** Drug shortage	04/17/08	• Sodium chloride tablets are on back order due to manufacturing problems. • Consolidated Midland, the sole supplier of sodium chloride tablets, cannot estimate when supplies will be available.	Low	• Very low utilization. • Affected patients should contact their healthcare professionals for alternatives.	Communication to clients via *Weekly M&P* newsletter.

New Products*

Drug/ Manufacturer	Therapeutic Class	Indication(s)	Date	Projected Launch	Comments	Programs Planned
New FDA-Approved Agents						
Aplenzin™ (bupropion hydrobromide) ER tablets/Biovail	Antidepressant agent	Treatment of depression in adults	04/23/08	Unknown	Aplenzin is an alcohol-resistant formulation of new bupropion salt and has been approved in 174 mg, 348 mg and 522 mg ER tablets.	• P&T review planned. • MedMonitor® will review for conflict edits when Aplenzin becomes available.
Cimzia® (certolizumab pegol) injection/UCB	Biologic response modifier (BRM)	Treatment of moderate to severe Crohn's disease	04/22/08	Unknown	• Cimzia is for patients with inadequate response to conventional therapy.	• P&T review planned. • BRM SPA is in place.

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					• Treatment includes an injection every two weeks for the first three injections, then every four weeks once benefit is established. • UCB is developing Cimzia for rheumatoid arthritis and other autoimmune disease indications.	
New Dosage Forms & Combinations						
None to report						
New FDA-Approved Indications						
Vyvanse™ (lisdexamfetamine) capsules/Shire	Attention deficit hyperactivity disorder (ADHD) agent	Treatment of ADHD in adults	04/23/08	Available	• Vyvanse was introduced in July 2007 for the treatment of ADHD in children age 6 to 12. • Vynase is now the first and only once-daily stimulant approved to treat adults with ADHD.	• Vyvanse is nonpreferred. No changes are planned. • ADHD and Narcolepsy CPA is in place. • MedMonitor® will review for conflict edit updates.
New First-Time Generic Drug Approvals						
Sumatriptan injection/ Wockhardt	Migraine agent	Treatment of migraine headaches	04/22/08	Unknown	The medication is the generic equivalent of Imitrex® injection by GlaxoSmithKline.	• It will be added to the lowest copay tier when available. • MedMonitor® will review for conflict edit and drug list updates.

* Note: If FDA-approved, agents are under P&T review and reside on the 3rd tier.

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Pipeline Analysis

Drug/ Manufacturer	Therapeutic Class	Indication(s)	Status	Comments
CloniBID™ (clonidine), oral/ Sciele	Antihypertensive agent	Treatment of hypertension	New Drug Application accepted.	• CloniBID is a 12-hour, sustained-release formulation of clonidine. • Upon FDA approval, Sciele expects to launch CloniBID in early 2009.
First-Time Generic Drugs in the Pipeline				
Raloxifene tablets/Teva	Selective estrogen receptor modulator	Treatment and prevention of osteoporosis	Tentative approval received.	• Patent litigation is ongoing, and trial date has not been set. • Raloxifene is a generic equivalent of Evista®. • Evista's patent protection expires on July 28, 2012.

New Generics Log

(Recent updates are noted in blue.)

Generic Name	Therapeutic Class	For Brand Name	Pipeline Stage	FDA ANDA Approval Date	Release Date*	Comments
Albuterol extended-release tablets/Mylan	Beta-adrenergic agent (bronchodilator)	VoSpire ER®	Approved	01/29/07	02/02/07	
Alendronate tablets/ multiple manufacturers	Osteoporosis agent	Fosamax®	Approved	02/06/08	02/06/08	• Patent expired February 6, 2008. • Merck will launch an authorized generic.
Amlodipine tablets/Mylan	Antihypertensive (calcium channel blocker)	Norvasc®	Approved	03/23/07	04/03/07	
Amlodipine/ benazepril capsules/Teva	Antihypertensive (ACE-inhibitor/ calcium channel blocker combination)	Lotrel®	Approved, with the exception of Lotrel 5/40 and 10/40 strengths.	05/18/07	05/22/07	• Shipments resumed after temporary injunction, but Sandoz plans its own generic. • Litigation is ongoing. • Lotrel 5/40 and 10/40 remain preferred.

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Atorvastatin tablets	Cholesterol agent	Lipitor®	Early	TBD	TBD	• Anticipated availability in 2010. • Patent expires March 2010.
Budesonide/formoterol inhalation	Antiasthmatic agent	Symbicort®	Early	TBD	TBD	Patent expires December 2012.
Carvedilol tablets/Taro	Antihypertensive (beta-blocker)	Coreg®	Approved	09/05/07	09/11/07	
Cetirizine tablets and syrup/multiple manufacturers	Nonsedating antihistamine	Zyrtec®	Approved	12/27/07	January 2008	• Cetirizine now available OTC. • Brand Zyrtec OTC products, marketed by Johnson & Johnson, became available in January 2008. • Liquid formulation is available as brand Zyrtec, generic, and OTC. • All other formulations available OTC.
Clopidogrel tablets/ Apotex	Platelet inhibitor	Plavix®	Approved	01/20/06	August 2006, then withdrawn	• Patent litigation upheld. • Patent expires in 2011.
Dexmethylphenidate extended-release (ER) capsules/Barr	Attention deficit hyperactivity disorder agent	Focalin® XR	Early	TBD	TBD	Patent litigation is ongoing.
Diltiazem extended-release tablets/Andrx	Blood pressure agent	Cardizem® LA	Early	TBD	TBD	Andrx will not market until April 1, 2009, per agreement with Biovail.
Escitalopram tablets/IVAX	Antidepressant agent	Lexapro®	Approved	02/06/07	TBD	• Patent litigation upheld. • Patent expires in 2012.
Esomeprazole capsules/**Ranbaxy**	Gastric acid secretion reducer	Nexium®	Late	Tentative	TBD	• Patent litigation pending. • Ranbaxy could launch at risk in April 2008.

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Ezetimibe/ simvastatin tablets	Cholesterol agent	Vytorin®	Early	TBD	TBD	Patent expires September 2013.
Famciclovir tablets/Teva	Antiviral agent	Famvir®	Approved	08/24/07	Teva was allowed by court order to resume marketing in late September 2007.	Litigation ongoing.
Fluticasone/ salmeterol powder for inhalation	Antiasthmatic agent	Advair Diskus®	Early	TBD	TBD	Patent expires September 2010.
Fluvastatin capsules and **fluvastatin** extended-release tablets	Cholesterol agent	Lescol® and Lescol® XL	Early	TBD	TBD	Patent expires April 2012.
Formoterol powder for inhalation	Antiasthmatic agent	Foradil® Aerolizer®	Early	TBD	TBD	Patent expires December 2016.
Granisetron tablets/ Barr	Anti-emetic agent	Kytril®	Approved	12/28/07	January 2008	Patent expired December 28, 2007.
Lansoprazole delayed-release capsules/Teva	Gastric acid secretion reducer	Prevacid®	Late	Tentative	TBD	Teva is in patent litigation concerning the generic, and a court decision is expected before June 2008.

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Losartan tablets/Lek	Antihypertensive (angiotensin receptor blocker)	Cozaar®	Late	Tentative	TBD	Patent protection ends August 2009.
Metoprolol extended-release tablets/KV Pharm and Sandoz	Antihypertensive (beta-blocker)	Toprol XL®	Approved	05/18/07	Available	
Modafinil tablets/multiple manufacturers	Narcolepsy agent	Provigil®	Late	Tentative	TBD	Patent protection ends November 2007.
Ofloxacin 0.3% otic solution/Apotex	Antibiotic	Floxin® Otic	Approved		Available	Apotex will have a 180-day marketing exclusivity.
Olmesartan tablets/Mylan	Antihypertensive (angiotensin receptor blocker)	Benicar®	Late	Tentative	TBD	Patent protection ends April 2016.
Omeprazole delayed-release tablets/Dexcel	Anti-ulcer agent	Prilosec OTC®	Late	Tentative	TBD	Litigation is ongoing.

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Pantoprazole delayed-release tablets/Teva	Anti-ulcer agent	Protonix®	Approved	08/02/07	Caraco launched its generic on January 30, 2008 and is currently involved in patent litigation with Wyeth.	• Wyeth launched its generic Protonix, distributed by Prasco, on January 29, 2008. • Teva began initial shipment on 12/24/07 but agreed to halt until 1/30/08 to resume settlement talks with Wyeth. However, Teva did not relaunch and does not plan to do so. • Teva will share 180-day marketing exclusivity with Caraco. • With Wyeth supplying its own generic product, the supply is expected to meet demand. • Wyeth will continue to pursue patent infringement claims against Teva and Caraco. • Protonix patent will expire in July 2010 but may be extended to January 2011 with pediatric exclusivity.
Paroxetine extended-release tablets/Mylan	Antidepressant agent	Paxil CR®	Approved	06/29/07	TBD	
Pramipexole tablets/Barr	Antiparkinsonism agent	Mirapex®	Approved	02/19/08	TBD	
Propranolol extended-release capsules/Par	Antihypertensive – beta-blocker	Inderal® LA	Approved	01/26/07	02/02/07	

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Ramipril tablets/TBD	Antihypertensive – ACE-inhibitor	Altace®	Approved	10/24/2005	01/09/08	Generic ramipril was launched by Cobalt.
Repaglinide tablets/ Caraco	Antidiabetic agent	Prandin®	Late	Tentative	TBD	
Risperidone tablets and solution/Pliva	Antipsychotic agent	Risperdal®	Late	Tentative	TBD	Pediatric exclusivity expires June 2008.
Rivastigmine capsules/Dr. Reddy's Laboratories (DRL)	Alzheimer's agent	Exelon®	Approved	10/31/07	Launch suspended until 2014.	
Rosiglitazone tablets/Teva	Antidiabetic agent	Avandia®	Early	Tentative	TBD	Under the settlement reached between Teva and GlaxoSmithKline, Teva is allowed to launch the generic in the first quarter of 2012.
Rosiglitazone/ metformin tablets/Teva	Antidiabetic agent	Avandamet®	Early	Tentative	TBD	Under the settlement reached between Teva and GlaxoSmithKline, Teva is allowed to launch the generic in the first quarter of 2012.
Rosiglitazone/ glimepiride tablets/Teva	Antidiabetic agent	Avandaryl®	Early	TBD	TBD	Under the settlement reached between Teva and GlaxoSmithKline, Teva is allowed to launch the generic in the first quarter of 2012.
Rosuvastatin tablets	Cholesterol agent	Crestor®	Early	TBD	TBD	Patent expires January 2016.
Salmeterol powder for inhalation	Antiasthmatic agent	Serevent® Diskus®	Early	TBD	TBD	Patent expires September 2010.
Sildenafil tablets/Teva	Erectile dysfunction agent	Viagra®	Late	Tentative	TBD	

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Sumatriptan injection/ Wockhardt	Migraine agent	Imitrex® injection	Approved	04/22/08	TBD	
Sumatriptan tablets/multiple manufacturers	Migraine agent	Imitrex® tablets	Late	Tentative	TBD	Ranbaxy settled all matters with GlaxoSmithKline, and generic launch is anticipated in December 2008.
Tamsulosin capsules/ multiple manufacturers	Urologic agent	Flomax®	Late	Tentative	TBD	Patent expires October 27, 2009.
Telmisartan tablets/Watson	Antihypertensive (angiotensin receptor blocker)	Micardis®	Late	Tentative	TBD	Patent protection ends January 2014.
Terbinafine tablets and topical cream/multiple manufacturers	Antifungal agent	Lamisil®	Approved	7/2/07	7/10/07	
Valacyclovir tablets/Ranbaxy	Antiviral agent	Valtrex®	Approved	01/31/07	TBD	Litigation dismissed; product to be marketed late 2009.
Valsartan tablets/Ranbaxy	Antihypertensive (angiotensin receptor blocker)	Diovan®	Late	Tentative	TBD	Patent protection ends September 2012.
Venlafaxine extended-release capsules/Sun Pharmaceuticals	Antidepressant	Effexor XR®	Early	TBD	TBD	Sun Pharmaceuticals obtained permission from Wyeth, the innovator of Effexor XR, and will submit an abbreviated new drug application.
Zaleplon capsules/ multiple manufacturers	Insomnia agent	Sonata®	Mid	Tentative	TBD	Anticipated availability in 2008.

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Zolpidem tablets/Ranbaxy	Insomnia agent	Ambien®	Approved	04/23/07	04/23/07	

*Release date refers to the availability of NDCs for use in Walgreens' system. Actual availability may occur after NDCs are released.

Information for *Mortar & Pestle* is obtained from the following sources (with secondary-source links provided):
Food and Drug Administration (www.fda.gov)
American Society of Health-Systems Pharmacists® (www.ashp.org)
P&T Community (www.ptcommunity.com)
Pharmaceutical News Harvest™ (www.internetdrugnews.com)
Drugs.com™ (www.drugs.com)
Pharmacy OneSource® (www.pharmacyonesource.com)

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