



DRUGS THAT LOST PATENT PROTECTION

January 2009		
BRAND NAME	GENERIC NAME	INDICATION
GLYSET	miglitol	Diabetes
KEPPRA	levetiracetam	Seizures
KEPPRA XR	levetiracetam	
TRICOR	fenofibrate	Lowers blood fat
TRICOR (MICRONIZED)	fenofibrate	

COMMENTS: Check your formularies to ensure that patients are paying generic copays for these drugs.

FEWER DTC DRUG ADS

Spending on Direct-To-Consumer (DTC) drug ads fell 6% in the first 8 months of 2008 to \$3.2 billion, according to TNS Media Intelligence, and that followed a decline of 3 % for all of 2007 to \$5.3 billion, Dow Jones reports.

Much of the decline came from a downturn in so-called non-branded advertising, including corporate promotion messages and disease-awareness spots. Another factor appears to be the drop in FDA approvals of new drugs resulting in a decline in spending on new brands (a fall of 7% in 2007) while spending on established brands rose 5% for the same period. (Compare this with prior years when DTC advertising was generally increasing and peaked at \$5.4 billion in 2006.)

There is a growing backlash to drug advertising, particularly after Merck removed Vioxx painkiller four years ago over links to heart attacks and strokes. Meanwhile, Congressman Henry Waxman wants to renew the call for a ban on DTC ads for new meds. In response, PhRMA is expected to unveil restrictions that include a specified minimum period of time before advertising can start for a newly approved drug. New measures will update guidelines PhRMA adopted in 2005 that were designed to ensure ads provided accurate and balanced information about safety and effectiveness.

MERCK WANTS TO DEVELOP FOLLOW-ON BIOLOGICS

Merck is hosting its annual R&D briefing for Wall Street analysts and fund managers where the drug company will establish a new unit to make generic biotech, which some call biogenerics, biosimilars or follow-on biologics, although there are subtle differences between these terms. The move represents “significant opportunity” since so many patents on so many big-selling biologicals are scheduled to expire through 2017.

The effort is based on Merck’s acquisition of GlycoFi, a biotech acquired two years ago for its proprietary glyco-engineering technology. Merck’s first follow-on biologic is for an anemia product, with release planned in 2012. In addition, another five candidates are hoped to be in late-stage development in the same period.

Of course, the possibility that Congress will finally give the FDA a green light to create a so-called pathway for developing follow-on biologics is more likely, since President Barack Obama made a point of saying he supports such a move as a way to lower health care costs.

COMMENT: Merck plans to push for expanded use of its ISENTRESS (AIDS med) and the Gardasil (HPV vaccine) next year. In particular, the drugmaker will seek FDA approval to market the Gardasil HPV vaccine for women up to 45 years old as well as for ...men. **Consider this information as you set up your pharmacy and drug benefits for 2010 and beyond.**

CHECK YOUR PHARMACY INVOICE LIKE YOU CHECK YOUR SUPPLY INVOICES

Invoices for payments to PBMs and Health Plans for prescriptions filled by their network pharmacies (both retail and mail), should be checked -- the same way one would check a grocery or restaurant receipt.

The assumption that electronic claim adjudication is without errors can be dangerous for both medical and pharmacy claims. Pro Pharma’s experience indicates that at least 5-7% of all paid drug claims are incorrect. Prime areas for errors are eligibility, pricing, claim validity, payments for benefit exclusions, etc.

Pro Pharma screens pharmacy invoices within 72 hours to validate invoices prior to payment.

COMMENT: The reduction in DTC may decrease some of your drug spend. However, increased utilization of highly advertised drugs may still wipe out any savings. Check your utilization of highly advertised drugs like Lipitor, Crestor, Allegra, etc. Does utilization of these drugs increase, decrease or stay the same? This will be a gauge of what is happening in your population.

CONTACT: Carol Stern at: (888) 701-5438 or carol.stern@propharmaconsultants.com to order.

www.propharmaconsultants.com

**Pro Pharma Pharmaceutical Consultants, Inc. has assisted Payers and Providers
for over 23 years to Maintain Quality while Controlling Costs.**

Copyright © 2009 Pro Pharma Pharmaceutical Consultants, Inc.