



MYLAN PHARMACEUTICALS INC

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September 12, 2003

RECEIVED
SEP 15 2003
BY: *dyo*

Charles Ganley, MD
Division of Over-the-Counter Drug Products, HFD-540
Center for Drug Evaluation and Research
Food and Drug Administration
CRP2, Room S205
9201 Corporate Boulevard
Rockville, MD 20850

Dear Dr. Ganley:

Mylan has received and references the Citizen's Petition filed with FDA on August 12, 2003 regarding Prilosec OTC ("Petition"). The Petition raises concerns regarding anticipated confusion between the Rx Prilosec product and the OTC version. Mylan has just received several pieces of information which substantiate the concerns raised in the Petition (attached for your reference). Additionally, the information we have reviewed evidences that the problems caused by the launch of this product are much more extensive than those addressed in the Petition. We believe these issues present great cause for healthcare provider concern regarding adverse health consequences to consumers. The consumer is at risk because of actions by formularies and other leading health insurers, related to the launch of Prilosec OTC, planned for September 15, 2003.

The following are quotes from an article in today's Wall Street Journal, and highlights the extreme measures being enacted as a result of this OTC launch.

"The product will get another edge from Aetna Inc. and other big insurers eager to reduce a major source of drug outlays. As of next week, Aetna will stop covering Prilosec (and any other prescription omeprazole sold in a 20-milligram dose, as Prilosec OTC is) for the majority of members in its drug plans, steering them instead to Prilosec OTC. Patients filling prescriptions for competing PPIs will pay a co-payment ranging from \$20 to \$35, making Prilosec OTC a good deal. In part because of the insurance advantage, many doctors anticipate that about 25% of PPI users will switch to Prilosec OTC."

"Wellpoint Health Networks, a big insurer that helped Claritin make the OTC switch, is going further. It is sending many of its PPI users one coupon for a free 14-pill box of Prilosec OTC and two coupons for \$10 discounts. Dr. Robert Seidman, Wellpoint's chief pharmacy officer, says the goal is to sway more than half of PPI users to switch to Prilosec OTC. Roughly 8% of Wellpoint's annual \$1.5 billion prescription drug costs are for PPIs."

OSP-D366

LET 1

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Dr. Ganley
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As you know, the indications included in the labeling for Prilosec OTC are very narrow compared to the Rx version. However, as feared, it is being treated as identical not only to Rx Prilosec, but other Rx medications in the proton-pump inhibitor class of drugs. Formularies and other plans are directing patients to take the OTC Prilosec product, in place of current prescription products on which patients are maintained. This OTC product was not approved nor intended to encompass this far-reaching impact on Rx Prilosec and other products in this class. The outcome will lead to improper patient self-diagnosis and consumption of a product for unapproved uses. The magnitude of the misleading and incorrect action of substitution is illustrated by the marketer of the product, AstraZeneca.

"AstraZeneca has insisted that the launch of Prilosec OTC is not important for the company, as it is only indicated for heartburn and those patients requiring chronic use (more than 14 days) are likely to keep seeing their physicians to fill prescriptions." (PJB Publications Ltd 2003, August 27th/29th 2003) *emphasis added*

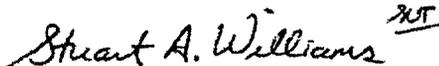
The inconsistencies between the Aetna and AstraZeneca comments show a disconnect between the FDA's approval for use, and the insurers' intent for broad and non-restrictive uses.

Based upon the health risk to consumers, Mylan requests that FDA immediately and urgently review the issues surrounding not only the labeling and name change of the product, but the manner in which this country's private healthcare system is treating the class of drugs referenced. This problem will continue to exacerbate, as historically, state and federal government programs mimic the private system's plan structures.

We would like the Agency's view on this matter at your earliest convenience.

If you should have any questions regarding this correspondence, please do not hesitate to contact me at (304) 599-2595.

Sincerely,

 ST

Stuart A. Williams
Chief Legal Officer

SAW/dn

cc: Janet Woodcock, MD, Center Director
Robert J. Temple, MD, Director ODE I
Robert Justice, MD, Director, Division of GI
Daniel E. Troy, Chief Counsel



Over the counter (OTC) Prilosec OTC® covered in Tier 1 effective September 15th

Based on the recommendations of the Independent Health Pharmacy and Therapeutics Committee, the OTC version of omeprazole 20mg (Prilosec OTC®) will be covered as formulary – tier 1 as long as a prescription for this product is written.

- **Quantity limits for Prilosec OTC® will be a maximum of 42 tablets for a 42 day supply (based on available package size) for a single tier 1 copayment.**
- **Aciphex® and Protonix® will maintain their current tier 2 status.**
- **Also effective September 15th, prior authorization will be required for new patient starts on the prescription versions of omeprazole (10 mg and 20 mg). On-line step therapy confirming the use of formulary proton pump inhibitors will also be added to Nexium®, Prilosec®, and Prevacid® (except for patients < 16 years of age) for new patient starts.**
- **Existing prescriptions for omeprazole will be honored through December 31, 2003. Beginning January 1, 2004, all prescription versions of omeprazole will be non-formulary or tier 3.**

If you have any questions regarding the coverage of proton pump inhibitors, please contact our pharmacy help desk at (716) 631-2927 or 1-800-993-9898. Our pharmacy assistants are available to assist you Monday – Friday from 8:30 a.m. to 8:00 p.m., Saturdays from 9:00 a.m. to 3:00 p.m. and Sundays from 10:00 a.m. to 2:00 p.m. You may also e-mail us at script@independenthealth.com.

Usted puede solicitar una traducción oral de todos los materiales escritos si la necesita
(Oral translation of written materials available upon request)

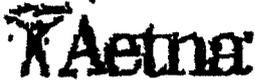


100 Parsons Pond Drive
 Franklin Lakes, NJ 07417
www.medcohealth.com/rph

Medco Health announcement

Plan sponsor:	Book of Business	Geographic area:	Nationwide
Effective date	September 1, 2003		
For Information Only:	<p>Based on the approval of Prilosec OTC by the FDA, please be aware that while many Medco Health clients will continue to cover <i>Prilosec</i>[®] and generic omeprazole, some clients may choose to implement benefit management programs for the proton pump inhibitor (PPI) category. These programs may require their members (your customers) to pay a higher co-payment for prescription PPIs or to obtain prior authorization. Some clients may choose to exclude PPIs from coverage altogether.</p>		
Note:	<p>Clients may continue coverage for prescription PPIs by offering coverage programs for prescription omeprazole in both its brand-name and generic forms.</p>		
For more information:	<p>Contact the Medco Health Pharmacy Services Help Desk at 1 800 922-1557 or visit the Pharmacist Resource Center at www.medcohealth.com/rph.</p>		

Medco Health is the pharmacy benefit manager of many of your customers at the request of their health plans



P.O. Box 10000
Hartford, CT 06186-0000

August 11, 2003

Dear Member:

Aetna is committed to offering a pharmacy benefit that balances choice, quality and affordability for members and their employees. For that reason, we want to let you know about the introduction of the over-the-counter medication, Fildena, to your pharmacy benefit.

On June 20, 2003, the Food and Drug Administration (FDA) approved the over-the-counter sale of Fildena (sildenafil) 50-20 mg strength. The introduction of Fildena OTC will make this product available around September 23, 2003. Aetna's standard pharmacy benefit plans do not cover over-the-counter medications or their prescription equivalents. Therefore, when Fildena OTC is available for sale without a prescription, the 20 mg strength of prescription Fildena and equivalent will no longer be covered under your Aetna pharmacy benefit.

If you currently take prescription Fildena or equivalent in a 20 mg strength, talk to your doctor. If using an over-the-counter medication is right for you, over-the-counter medications may offer you greater convenience and may cost you less than prescription medications, depending on your pharmacy plan.

If you have any questions about your pharmacy benefit, please call the Member Services number on your member ID card. As always, thank you for choosing Aetna.

Sincerely,

Mark Rubin, R.Ph., M.H.A.
Chief Pharmacy Officer

Aetna is the brand name used by members and service providers for the Aetna member health plan. Aetna is a registered service mark of Aetna Health Inc., Aetna Health of California Inc., Aetna Health of the Columbia River, Aetna Health of Florida Inc., Aetna Health of Washington Inc., Aetna Health Insurance Company of Connecticut, Aetna Health Insurance Company of New York, Corporate Health Insurance Company, Aetna Life Insurance Company.

Prilosec OTC Blitz by P&G Represents New Drug Foray

By SARAH ELLISON
Staff Reporter of THE WALL STREET JOURNAL

Procter & Gamble Co. has identified the ideal customer for its latest product. Her name is Joanne. She is a mother over 35. She shops for her entire household. And she has heartburn.

P&G is gearing up for what it hopes will be crowds of Joannes to rush to stores Monday and snap up purple packages of Prilosec OTC, its over-the-counter version of AstraZeneca PLC's blockbuster prescription heartburn drug. P&G says Prilosec OTC will sell for well under \$1 a pill.

P&G will bring its compulsive consumer research -- and a \$100 million marketing campaign, including a former soap-opera star -- to one of its most important product launches ever. The company has stumbled in the drug business before, including a failed attempt in 2000 to make a big pharmaceutical acquisition. Since then, P&G has pursued less risky pharmaceutical strategies.

Despite some successes -- P&G led the over-the-counter launch of the pain-reliever Aleve, and its osteoporosis drug Actonel is a solid seller -- the company has been unable to come up with blockbuster drugs. Now, it is making a big push to establish marketing partnerships with big drug companies as they take prescription drugs over-the-counter.

Prilosec OTC will test this ambition. P&G is hoping the product will generate \$200 million to \$400 million in retail sales in its first year. For P&G, which already sells Metamucil, Vicks and Pepto-Bismol, Prilosec OTC is its biggest drug launch by far. The results will say much about whether pharmaceutical products can be sold like detergent and diapers.

The market for "proton-pump inhibitors," or PPIs -- which stop the acid-producing pumps that cause heartburn -- stands at \$13 billion. But the field is as crowded as a pepperoni-and-sausage pizza. Prilosec was once the best-selling drug in the world, with sales that peaked in 2000 at \$6.3 billion. Last year, AstraZeneca's patent ran out and sales dropped to \$4.6 billion amid competition from cheaper generic versions. AstraZeneca tried switching people to a similar

P&G has created a 24-hour "command center." A fleet of 1,200 trucks is delivering Prilosec OTC to retailers so that the product hits many shelves at one minute past midnight Monday morning. P&G drove a purple van through 24 cities in a "Burntown Challenge" to help promote Prilosec OTC directly to consumers. The company has made an unprecedented effort with retailers like Wal-Mart Stores Inc. to teach pharmacists how to push Prilosec on shoppers. Commercials are already running on TV and in stores, featuring a former (male) star of "Guiding Light" and "As the World Turns." The slogan: "One pill, 24 hours, zero heartburn. It's possible with Prilosec OTC."

Guiding the campaign is P&G's vaunted research. "We know Joanne," says Joseph A. Arcuri, the executive heading up the Prilosec initiative. "We know what she feels. We know what she eats. We know what else she likes to buy in the store." Joanne, a composite of the army of consumers P&G interviewed, isn't like the stereotypical heartburn sufferer, a late-night pizza-eating, beer-guzzling guy. Joanne's heartburn can be triggered by something as seemingly innocuous as a cup of coffee, says Mr. Arcuri.

In other words: you don't have to stuff yourself on chili dogs to have heartburn.