



LATEST NEWS [RUSSIA'S MEDVEDEV BACKS PUTIN TO BECOME PM](#)



Were you there?

Share the news **you capture** with Reuters and the world.

[Submit your photos](#)

Broker Center sponsored links

FREE \$50,000

¥ € \$ - Learn. Practice. Trade.

Learn to Trade with a FREE Guide.

\$0 stock tra

You are here: [Home](#) > [News](#) > [Health](#) > Article

[HOME](#)

[BUSINESS](#)

[INVESTING](#)

[NEWS](#)

[U.S.](#)

[Politics](#)

[International](#)

[Technology](#)

[Entertainment](#)

[Sports](#)

[Lifestyle](#)

[Oddly Enough](#)

[Environment](#)

[Health](#)

[Science](#)

[Special Coverage](#)

[Video](#)

[Pictures](#)

[You Witness](#)

[Blogs](#)

[Weather](#)

[Reader Feedback](#)

[Do More With Reuters](#)

[RSS](#)

[Mobile](#)

[Podcasts](#)

[Newsletters](#)

[My Headlines](#)

[You Witness News](#)

[Partner Services](#)

[CareerBuilder](#)

[Affiliate Network](#)

[Professional Products](#)

FDA Expected To Comment On Its Safety Evaluation Of Nexium And Prilosec In December 2007

powered by BlogBurst

POSTED: Friday, December 07, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

Agency's Follow-Up On Its August 2007 "Early Communication" About These Heartburn Drugs Is Late, But Just In Time For Christmas Dinner

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

As reported previously, [in early August 2007 the FDA and Health Canada raised concerns about possible serious cardiac events in patients using Nexium and Prilosec](#), made by AstraZeneca (AZN), which are used for the treatment of gastroesophageal reflux disease (GERD) and esophageal erosions, as well as for maintenance of healing erosions of the esophagus.

At that time the FDA had said it should have further guidance for doctors and patients concerning these two popular heartburn, or stomach-acid, drugs in approximately 90 days.

Now, almost four months after the FDA released this so-called "early communication" about Nexium (esomeprazole) and Prilosec (omeprazole), we finally get an indication that the FDA may be getting close to providing its more definitive advice on these two drugs, which are reportedly taken by more than one billion people worldwide.

As previewed by *Reuters* reporter Kim Dixon in her December 6, 2007 article, "[FDA update on AstraZeneca heartburn drugs seen](#)", what the FDA will say about the safety of Nexium and Prilosec remains uncertain but, for sure, whatever is said by the FDA will be of great significance to AstraZeneca.

On the medical side, according to the December 6 *Reuters* article, the stage is set as follows:

In early August, the U.S. Food and Drug Administration and Health Canada said they were studying the cardiac impact of Prilosec and Nexium.

The agencies at the time cited two studies suggesting an association with greater risk of heart attacks, heart failure and heart-related sudden death when compared with surgery. However, the FDA's own initial analyses did not show a higher heart risk, and both agencies told

[Support \(Customer Zone\)](#)[Reuters Media](#)[Financial Products](#)[Find a financial adviser](#)

About Reuters

doctors not to change prescribing practices....

The FDA has said both studies in question may have been skewed, in part because surgical patients tended to be younger and less likely to have risk factors for heart problems.

Fourteen other studies of patients treated for up to two years did not suggest a higher risk of heart problems with Prilosec, the FDA said.

On the business aspect of this matter, however, things are more straightforward. According to this same *Reuters* article:

Nexium is AstraZeneca's top-selling product and was the world's No. 2 best-selling drug in the world in 2006, according to pharmaceutical information firm IMS Health. AstraZeneca reported \$5.2 billion in Nexium sales for last year.

Presuming the FDA renders its opinion about the safety of Nexium and Prilosec in the next couple of weeks, AstraZeneca will soon know whether the FDA is its Santa or its Grinch this holiday season.

Update: From a December 10, 2007 article by Jennifer Corbett Dooren, "[No Increased Heart-Attack Risk With Nexium, Prilosec, FDA Says](#)". (12/10/07)

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

Reuters.com: [Help and Contact Us](#) | [Advertise With Us](#) | [Mobile](#) | [Newsletters](#) | [RSS](#)  | [Interactive TV](#) | [Labs](#) | [Reuters in S](#)

Reuters Corporate: [Copyright](#) | [Disclaimer](#) | [Privacy](#) | [Professional Products](#) | [Professional Products Support](#) | [About Reuters](#) |

International Editions: [Africa](#) | [Arabic](#) | [Argentina](#) | [Brazil](#) | [Canada](#) | [Chinese Simplified](#) | [Chinese Traditional](#) | [France](#) | [Gerr](#)
[Russia](#) | [Spain](#) | [United Kingdom](#) | [United States](#)

Reuters is the world's largest international multimedia news agency, providing investing news, world news, business news, technology news, headline market, and mutual funds information available on Reuters.com, video, mobile, and interactive television platforms. Reuters journalists are subject to the disclosure of relevant interests.

NYSE and AMEX quotes delayed by at least 20 minutes. Nasdaq delayed by at least 15 minutes. For a complete list of exchanges and delays, please