

# Shire agrees to settle ADHD drug inquiry

The Associated Press

Shire PLC said Friday it agreed to pay about \$57.5 million to resolve a federal investigation into the marketing of its drugs for treating attention deficit hyperactivity disorder.

The Irish company makes several ADHD drugs, including the former blockbuster Adderall XR, which was its top-selling product before generic competition began to erode its price and sales. Shire's new best-seller is Vyvanse, a newer ADHD drug that does not have any generic competition. Government agencies have been investigating the way the company market Vyvanse and both brand-name and generic Adderall XR.

Shire said it reached an agreement to settle civil investigations into its marketing practices related to both drugs and Daytrana, an ADHD patch. The company says it will take a \$57.5 million charge to cover the costs of the settlement as well as interest and other items. The charge will be included in Shire's fourth-quarter results.

Shire said the proposed settlement would also address sales practices for its ulcerative colitis drugs Lialda and Pentasa.

In September 2009, Shire received a subpoena from the U.S. Department of Health and Human Services and the U.S. Attorney's Office for the Eastern District of Pennsylvania. It said the agency wanted documents related to the sales of Adderall XR, Vyvanse, and Daytrana.

The U.S. attorney's office had no comment on the announced settlement Friday.

In the third quarter of 2012, sales of Vyvanse climbed 24 percent to about \$247 million and shares of Adderall XR fell 32 percent to \$102 million.

Authorized generic versions of Adderall XR are made by Impax Laboratories Inc. and Teva Pharmaceutical Industries Ltd. Shire gets a portion of revenue from those sales, but the generics cost less than the brand-name version originally did.

Shire started supplying the authorized generic version of Adderall XR to Teva in April 2009. In October of that year, Teva sued Shire and said it was in breach of a contract between the companies. The lawsuit was settled less than two months later.

In April 2012, the company said the Federal Trade Commission had asked it for information about Adderall XR and Vyvanse. Shire said it believed the request was related to reported shortages in 2011 of brand-name Adderall XR and its authorized generic versions of the drug. The FTC asked about the marketing of both products

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as well as its marketing of Vyvanse.

Actavis Inc. started selling its own generic version of Adderall XR in 2012, further reducing the price of the drug.

Shire licensed Daytrana to Noven Pharmaceuticals Inc., and it sold the rights to the drug to Noven in 2010.

U.S.-traded shares of Shire rose \$1.03 cents to \$101.17 in afternoon trading.

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