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US probes Sanofi over blockbuster drug Plavix (Update 2)

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The U.S. Justice Department is investigating drug maker Sanofi's disclosures to the Food and Drug Administration about different responses to its blockbuster blood thinner Plavix.

The French company said in a filing with the Securities and Exchange Commission last week that it learned in June about the investigation.

It did not provide details, saying only that the investigation centered on "the variability of response to Plavix." The company did not immediately respond to requests to give more details on the investigation.

Plavix is prescribed to heart disease patients to prevent dangerous blood clots, which can cause heart attack, stroke and death. In 2010, the FDA added a black box—its strongest form of warning—to the drug's label. At the time, the watchdog said certain patients with a genetic variation cannot metabolize the drug, putting them at increased risk for heart attack and stroke.

Before it got U.S. generic competition last May, Plavix was the No. 2 drug in the world by revenue, with annual sales of around $9 billion in 2011.

Sanofi says it is cooperating with the investigation into Plavix, which is jointly marketed with U.S.-based Bristol-Myers Squibb. Bristol-Myers Squibb spokeswoman Jennifer Fron Mauer said the company had no comment on the investigation.

Experts were divided over the potential impact of the investigations, partly because few details are known.

"If the company knew about it in June, why did it delay disclosure?" said Erik Gordon, professor and analyst at University of Michigan's Ross School of Business. "Investors are likely to bring lawsuits over the delay."

He noted that the DoJ's involvement raised the stakes: "The DoJ has people who carry badges. It can pursue criminal penalties. It could indicate that the FDA thinks the companies deliberately misled the agency. "

But Les Funtleyder, healthcare strategist at private equity fund Poliwogg, said the probe was likely not a big deal as it is retrospective.

"These issues seem to crop up a lot with pharmaceuticals," he said. "This is the type of event that investors tend to look around, as the occurrence is fairly common."

Shares in Sanofi ended the day 0.5 percent lower on Monday, slightly worse than the broader market.

In order to work effectively, Plavix must be broken down by a particular liver enzyme. But the FDA says 2 to 14 percent of people in the U.S. have low levels of the enzyme, preventing them from successfully processing Plavix. The likelihood of being a non-responder varies by race, according to the FDA.