Roche probed for not reporting side effects

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In this June 6, 2011 file picture, the logo of Swiss drugmaker Roche is photographed in Rotkreuz, Switzerland. The European Medicines Agency has started an infringement procedure against pharmaceutical giant Roche for allegedly failing to properly report side effects in patients in the U.S. (AP Photo/Keystone/Urs Flueeler, File)

(AP)—Europe's top drug regulator announced Tuesday it is taking action against pharmaceutical giant Roche for allegedly failing to properly report the side effects of 19 drugs being used by U.S. patients.

It is the first time the European Medicines Agency has begun a so-called 'infringement proceeding' against a drug maker. European regulations lay out numerous requirements for pharmaceuticals, including reporting suspected side effects and submitting such cases to officials.

Eight of the drugs involved are used for the treatment of cancer, including breast cancer. They include Avastin, Herceptin, Tarceba, and

Xeloda. The flu drug Tamiflu was also included in the list.

British authorities brought the problem to the attention of the European authorities in May after noticing "serious shortcomings" in how Roche AG reported potential side effects.

Regulators said about 80,000 reports by consumers of possible adverse effects to drugs sold in the U.S. had not been properly analyzed. Among those reports were over 15,000 deaths, though it was unclear if those deaths were caused by Roche medicines.

The regulator said there was no evidence that users of Roche's drugs were at risk.

The European Medicines Agency did not state what the side effects were but said it was more concerned that these potential reactions were not properly reported.

"It could have been anything like a rash on your hand to something more serious," including death, said Monika Benstetter, an agency spokeswoman. "There was a failure in the system," she said, noting officials didn't have information on how many of the side effects may have been reported.

If Roche is found to have violated its reporting requirements, it could be fined up to five percent of its sales revenue in the European Union from the preceding year. Shares in the company fell 2 percent on Tuesday.

The European Commission, the executive body for the 27-country EU, asked the European Medicines Agency to begin the infringement process. In a statement, the European Medicines Agency said it will further investigate the allegations against Roche.

The agency sent Roche a detailed letter listing the allegations against them and is now awaiting the company's response. Officials have 18 months to finish their investigation. After that, it will be up to the European Commission to decide whether Roche should be penalized.

Daniel Grotzky, a Roche spokesman, said the company was working with the EMA to provide more information and it did not want to speculate on the outcome of the investigation. Roche said patient safety was "of paramount importance" and that it was possible some of the potential side effects may have been reported to European officials in other ways, such as reports from doctors.

"Both the EMA and other health authorities have consistently said there is no change to the safety profile of our drugs," Grotzky said.

He said Roche recognized that some adverse events had not properly been reported in the past.

"We are taking measures within the company...to make sure this does not happen again," he said.