Novartis drug investigated after 11 deaths

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A multiple sclerosis drug made by industry giant Novartis is under investigation after at least 11 patients taking the medicine died.

The drug, Gilenya, was licensed last year in the European Union to treat patients with a severe type of multiple sclerosis.

The deaths raise concerns Gilenya could trigger heart problems after patients take their first dose, according to a statement issued Friday by the European Medicines Agency. The agency, which is now investigating the drug, said it isn't clear if it caused the deaths.

One of the deaths was in the U.S., where a patient died within 24 hours of taking the first dose.

The European agency said it didn't know where the other 10 deaths occurred, but that they were reported to its drug database, which monitors side effects from medicines in the European Union.

A spokeswoman at the U.S. Food and Drug Administration said it also is conducting a data analysis but has not made any definitive conclusions and does not know when its review will be complete.

More than 30,000 patients have taken Gilenya worldwide. The European Medicines Agency advised doctors to increase their monitoring of patients after the first dose of the medicine. The agency said the risk of a slow heart rate after the first dose of Gilenya was known when it was approved.

Novartis AG said it was advising doctors of new recommendations on using Gilenya. They had previously recommended all patients be monitored for six hours after their first dose, but are now tightening that to include continuous heart monitoring using electrocardiograms and measuring blood pressure and heart rate every hour. In certain patients, that monitoring should be extended, the drug maker said in a statement.

This new guidance applies only to patients taking their first dose, Novartis said in a statement.

The EU drug regulator hopes to finish its review of the drug by March.

More information: http://www.ema.europa.eu

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