

European drug regulator: Novartis flu vaccine OK

December 3 2014

Europe's drug regulator says there is no proof that a flu vaccine for the elderly was linked to side effects, including deaths in Italy.

Last week, Italy pulled two batches of Flud, made by Switzerland's Novartis AG, after reports that people died after getting immunized. Flud is typically given to people 65 and older who often have other health problems like heart disease and are at higher risk of complications.

After reviewing available evidence, the European Medicines Agency said in a statement Wednesday that "there was no evidence for a causal relation between the reported fatal events and the administration of Flud."

Novartis said on its website this week the vaccine was linked to 13 deaths in Italy. It said all its batches of Flud had passed safety and other testing.

About 4 million doses of Flud have been distributed this year in Italy and have been used in flu vaccination campaigns in Austria, Germany and Spain. It is also licensed in Belgium, Denmark, Greece, France, Ireland, Luxembourg, Portugal and Sweden. Flud is not authorized for use in the U.S.

Shots for the seasonal flu are adjusted each year to include what scientists think will be the three to four most prevalent strains of the

virus that year. According to the World Health Organization, flu shots may be less effective in preventing sickness in the elderly but they can still reduce the severity of disease and the likelihood of complications including death.

WHO estimates flu infects 3 to 5 million people every year and kills up to 500,000 worldwide.

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Citation: European drug regulator: Novartis flu vaccine OK (2014, December 3) retrieved 25 April 2024 from

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