

## Italy bans Novartis flu vaccine after suspicious deaths

November 27 2014

Italy suspended the use of a flu vaccine made by Swiss pharmaceuticals giant Novartis on Thursday amid fears it may have caused three deaths.

The Italian Pharmaceutical Agency (AIFA) banned the use of two batches of the Fluad vaccine after three people who had received it died and a fourth was taken seriously ill.

The victims were two women aged 87 and 79 and a 68-year old man, all of whom died between November 12 and 19 in southern Italy, according to Italian media reports. The fourth person, a 92-year old man, is in hospital in a serious condition.

"Novartis has been notified by AIFA of the precautionary suspension of two lots of Fluad in Italy following reports of the serious adverse effects events after vaccination. No causal relationship to the vaccine has been established," the Swiss company said.

A review of the two batches "have confirmed that they are in conformity with all production and quality standards," it said.

Health officials called for calm as news of the ban spread. Italian consumer association Codacons called on the health minister to suspend pro-vaccination campaigns, but AIFA insisted vaccines were "a precious resource and irreplaceable for the prevention of <u>seasonal flu</u>."

"We need to make sure that the number of people who get vaccinated



does not drop. We have to have faith in vaccines," said AIFA head Sergio Pecorelli, who added that "8,000 people die of seasonal flu" each year.

The suspected batches were produced at a Novartis plant in the Tuscan city of Siena.

The Swiss company said Fluad had been used since 1997, during which time over 65 million doses have been successfully administered throughout the world, "which confirms the data gathered during clinical studies which involved over 70,000 patients."

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