

Novartis' flu drug is not the cause of 13 deaths in Italy: EU regulatory

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Singapore: Novartis influenza vaccine, Flud, was taken off the shelf in Italy and its safety was questioned after 13 deaths were reported, allegedly due to the drug administration. However, European Medicines Agency (EMA), Europe's drug watchdog, has cleared Flud as safe with no connection to the deaths that occurred in Italy.

Flud, indicated for patients age 65 and older, comprising of approximately 500,000 doses solely distributed in Italy were put on a precautionary hold following reports of 13 deaths in the country.

Flud is indicated for people who have a number of illnesses at the same time and are at an increased risk of health complications. After the review of the cases reported, EMA concluded that there was no evidence for a causal relation between the reported fatal events and the administration of Flud.

Flud is authorised in the European Union (EU) in a number of Member States. For the current vaccination campaign in Italy, about 4 million doses of Flud have been distributed. The vaccine has also been used for the 2014/15 flu vaccination campaigns in Austria, Germany and Spain.