EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

News item

Investigation into reports of serious adverse events following use of Fluad

EU regulatory authorities following up on suspension of two batches of flu vaccine in Italy

The European Medicines Agency (EMA) is working with the Italian medicines authority AIFA and other EU medicines regulatory authorities to investigate the cause of serious adverse events, including deaths, in a small number of elderly patients who had received Fluad flu vaccine. There is so far no evidence to suggest a causal link between the vaccine and the reported adverse events. The suspension is a precautionary measure.

AIFA has suspended the use of two batches of the flu vaccine produced by Novartis. Testing of the batches is underway, as well as a detailed analysis of the case reports from Italy. This includes examining all available information on the affected patients' age, health condition and medication regime.

The issue will be discussed by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), a scientific body that brings together Europe's best experts on the safety of medicines, at their meeting starting on Monday, 1 December 2014.

Member States across the European Union continue with their annual flu vaccination campaigns as influenza can cause severe illness or death especially in the elderly and in people with long-term conditions. WHO estimates that annual influenza epidemics result in about 3 to 5 million cases of severe illness worldwide, and about 250 000 to 500 000 deaths. Influenza vaccines are the most effective way to prevent the disease and/or the serious complications it can cause.

Fluad is authorised in the EU in a number of EU Member States. For the current vaccination campaign, 4 million doses of Fluad have been distributed in Italy. In the EU, the vaccine has also been distributed for the 2014-15 flu vaccination campaign in Austria, Germany and Spain.

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