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SCIENCE MEDICINES HEALTH

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Press release

No evidence that Fluad vaccine caused deaths in Italy

EMA Committee review reassures Member States over safety of flu vaccine

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) has concluded that there is no evidence that Fluad, a flu vaccine manufactured by Novartis, has caused serious events including deaths in Italy. These reports led the Italian Medicines Agency (AIFA) to suspend the use of two batches of Fluad as a precautionary measure on 27 November 2014.

Fluad is used in older people (65 years of age and older), especially in those 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, the PRAC concluded that there was no evidence for a causal relation between the reported fatal events and the administration of Fluad.

Fluad 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 Fluad have been distributed. The vaccine has also been used for the 2014/15 flu vaccination campaigns in Austria, Germany and Spain.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Fluad is authorised in Austria, Belgium, Germany, Denmark, Greece, Spain, France, Ireland, Luxembourg, Portugal, and Sweden.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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