



European Medicines Agency
Press office

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Press release
European Medicines Agency update on the safety of Tamiflu

A potential influenza pandemic remains currently of high public interest and the European Medicines Agency wants to provide the following update on Tamiflu (oseltamivir). Tamiflu is an antiviral approved in the European Union for the treatment of influenza in children between 1 and 13 years of age and for the prevention and treatment of influenza in adolescents over 13 years and adults.

Two cases of alleged 'suicide' associated with treatment of influenza (involving a 17-year-old boy in February 2004 and a 14-year-old boy in February 2005) were reported to the EMEA. In both cases the adolescents exhibited abnormal/disturbed behaviour, which led to their deaths. So far, no causal relationship has been identified between the use of Tamiflu and psychiatric symptoms (such as hallucination and abnormal behaviour). The EMEA stresses that the assessment of psychiatric events during Tamiflu treatment is difficult because:

- Other medicines are often taken at the same time as Tamiflu
- Patients with influenza and a high fever can show psychiatric symptoms. This is particularly relevant for children and elderly patients.

All adverse reactions are monitored and assessed by the Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP) on a continuous basis.

The CHMP, at its meeting of 14-17 November 2005, decided to request the Marketing Authorisation Holder (Roche) of Tamiflu to provide a cumulative safety review of all available data on serious psychiatric disorders, including all case reports with a fatal outcome where Tamiflu was involved. The EMEA will make a statement on the outcome of this evaluation.

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NOTES:

1. More information on Tamiflu is available in the European Public Assessment Report on the EMEA website, which can be found [here](#).
2. The EMEA has produced a summary report on the use of antivirals in case of pandemic influenza, which is available on the EMEA website [here](#).
3. This press release, together with other information on the work of the EMEA is available on the EMEA website: <http://www.emea.eu.int>.

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