European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency statement on safety of Tamiflu

The European Medicines Agency (EMEA) has been made aware of new reports of neuro-psychiatric adverse events occurring with the use of Tamiflu originating from Japan. These cases have been detected through the routine safety monitoring.

The Agency's Committee for Medicinal Products for Human Use (CHMP) has monitored closely all adverse drug reactions reported in connection with the use of Tamiflu since it was introduced in the European Union in 2003.

During its 19-22 February 2007 meeting, the CHMP recommended an update of the product information to inform healthcare professionals and patients about neuro-psychiatric side effects. The recommended wording for patients is that, *"Convulsion, depressed level of consciousness, abnormal behaviour, hallucinations and delirium have been reported during Tamiflu administration, leading in rare cases to accidental injury. Patients, especially children and adolescents should be closely monitored and their healthcare professional should be contacted immediately if the patient shows any signs of unusual behaviour."*

The EMEA and CHMP will continue to closely monitor any emerging safety information on Tamiflu, including neuro-psychiatric disorders. If any concerns emerge, further action will be taken. With these measures in place, the CHMP maintains its opinion that the benefits of Tamiflu outweigh its risks when the product is used according to the adopted recommendations.

Patients who are concerned about their treatment should consult their doctor.

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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 previously issued statements on the safety of Tamiflu in December 2005 and November 2006.
3. This press release, together with other information on the work of the EMEA is available on the EMEA website: http://www.emea.europa.eu

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