

European Medicines Agency *Press office*

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PRESS RELEASE

European Medicines Agency recommendations on extension of shelf life for Tamiflu

The European Medicines Agency has recommended that the shelf life of Tamiflu capsules should be extended from five to seven years. Once formally approved by the European Commission, this will apply to all newly manufactured Tamiflu capsules.

In view of the recent outbreak of the novel influenza A/H1N1 virus, the European Medicines Agency has also reviewed ways to use Tamiflu capsules in case of a shortage. The Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that Tamiflu capsules that are already on the market may be used for up to two more years after their current five-year expiry date during a declared pandemic. Patients who have Tamiflu capsules that have recently expired should not dispose of them because they might be needed during a novel influenza A/H1N1 pandemic.

The recommendations are made by the Committee as part of a wider request from Agency's Executive Director Thomas Lönngren to look into ways to prevent shortages of antiviral medicines and to ensure that the medicines are available to those who might need them. These recommendations will only apply if a pandemic has been declared by the World Health Organization (WHO).

Antiviral medicines such as Tamiflu play an important role in the management of an influenza pandemic. Unlike vaccines, which are normally not available during the early stages of a pandemic, antivirals can be used right from the onset of the pandemic. Governments worldwide have been stockpiling these medicines, including Tamiflu, to make them available to the public, in accordance with national preparedness plans.

Notes

-Ends-

- 1. More information is available in a <u>question-and-answer document</u>.
- 2. Tamiflu is a centrally authorised medicine for the treatment and prevention of influenza in adults and children over the age of one year. The European public assessment report for Tamiflu is available <u>here</u>.
- 3. The assessment report of the CHMP with recommendations on the usability of expired Tamiflu in the event of a pandemic is available <u>here.</u>
- 4. A separate press release with information on the Agency's guidance on use of antiviral medicines in case of a novel influenza A/H1N1 pandemic is available <u>here</u>.
- 5. An EMEA review of influenza antiviral medicinal products for use in pandemics is available <u>here</u>.
- 6. More information on the work of the European Medicines Agency in relation to pandemic influenza vaccines is available <u>here</u>.
- 7. The European Commission and the European Centre for Disease Prevention and Control (ECDC) are responsible for the coordination of the European response to the public health threats posed by the influenza outbreak. The European Medicines Agency is working closely with them to support their work. An overview of the activities of the European Commission can be found at:

An overview of the activities of the European Commission can be found at: <u>http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_en.htm</u> Information about the work of the ECDC can be found at: <u>http://ecdc.europa.eu/</u>

- 8. Information about the work of the WHO can be found at: http://www.who.int/en/
- 9. This press release, together with other information about the work of the EMEA, is available on the EMEA website: <u>http://www.emea.europa.eu/</u>

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