European Medicines Agency
Press office

London, 8 May 2009
Doc. Ref. EMEA/285148/2009

PRESS RELEASE

European Medicines Agency gives guidance for use of antiviral medicines in case of a novel influenza A/H1N1 pandemic

The European Medicines Agency has given guidance on the use of Tamiflu (oseltamivir) in children under one year of age and the use of Tamiflu and Relenza (zanamivir) in pregnant and breastfeeding women in the case of a declared influenza A/H1N1 pandemic.

Children under the age of one
The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that during an officially declared influenza A/H1N1 pandemic the benefits of the use of Tamiflu outweigh its risks in the treatment of children under the age of one. Because there is less evidence to support the use of Tamiflu for the prevention of influenza, doctors should carefully consider the benefits and risks for each patient.

During a pandemic, if Tamiflu is prescribed to children under the age of one, the recommended dosage is 2 to 3 mg per kg body weight.

Pregnant and breastfeeding women
Following a review of the available data for Tamiflu and Relenza, the CHMP concluded that the benefits of using these medicines in pregnant or breastfeeding women outweigh the risks in case of an 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).

Unless a pandemic has been announced, Tamiflu and Relenza should be used according to the currently approved product information.

—Ends—

Notes
1. More information is available in a question-and-answer document.
2. Tamiflu is a centrally authorised medicine (i.e. authorised for use in all countries of the European Union, as well as in Iceland, Liechtenstein and Norway) 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 here.
3. Relenza is authorised in all 27 EU Member States for the treatment of influenza. The reference Member State for Relenza is Sweden. Further information on Relenza is available in the summary of product characteristics and the patient information leaflet. The assessment report of the CHMP with recommendations on the use of Tamiflu and Relenza in children under one year of age and pregnant and breastfeeding women in the event of a pandemic is available here.
4. A separate press release with information on the Agency's recommendation to extend the shelf life of Tamiflu is available here.
5. More information on the work of the European Medicines Agency in relation to pandemic influenza vaccines is available here.
6. An EMEA review of influenza antiviral medicinal products for use in pandemics is available here.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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: http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_en.htm
   Information about the work of the ECDC can be found at: http://ecdc.europa.eu/
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: http://www.emea.europa.eu/

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu