European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency prepares for approval of pandemic vaccines

The European Medicines Agency, together with its partners in the EU Member States, the European Commission, the European Centre for Disease Prevention and Control (ECDC), the World Health Organization (WHO) and the European Directorate for the Quality of medicines and healthcare (EDQM) met today with vaccine manufacturers. The purpose of the meeting was to share information on the novel influenza virus and discuss regulatory and scientific issues concerning the development and eventual approval of vaccines for use in a pandemic situation. Any decision on a strategy for development of pandemic vaccines will depend on recommendations from the WHO.

The Agency has been preparing for a pandemic scenario since 2004. Working closely with its partners in the European Union, it has established a scientific and regulatory framework that can accommodate a range of different vaccine approval strategies.

There are currently six centrally approved marketing authorisations for vaccines, four of them specifically designed to be modified rapidly to incorporate a new pandemic strain, once it has been recommended by the WHO. However, it may take four to six months before initial doses of vaccine are available.

Until a vaccine becomes available, antiviral medicines can be used for the treatment of pandemic influenza cases. Member States have prepared emergency plans, which also include how antivirals will be made available to citizens. The neuraminidase inhibitors Tamiflu (oseltamivir) and Relenza (zanamivir) have shown effectiveness against the novel flu virus.

While the European Medicines Agency, together with the European Commission, is responsible for the authorisation and supervision of centrally authorised medicines, decisions on availability and distribution of medicines within their territories are taken by each European Member State in accordance with their national pandemic plans.

—Ends—

Notes

1. More information on the work of the European Medicines Agency in relation to pandemic influenza vaccines is available here.
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. The European public assessment report for Tamiflu is available here.
3. Relenza (zanamivir) 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.
4. An EMEA review of influenza antiviral medicinal products for use in pandemics is available here.
5. 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.

* The information on Relenza in Note 3 has been updated.

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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/

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

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