European Medicines Agency
Press office

London, 12 June 2009
Doc. Ref. EMEA/367042/2009

PRESS RELEASE
WHO declares influenza pandemic – European Medicines Agency initiates crisis-management plan

Following the declaration of an influenza pandemic by the World Health Organization (WHO) on 11 June 2009, the European Medicines Agency (EMEA) has initiated its pandemic crisis-management plan. The plan allows for the accelerated assessment of influenza vaccines and antivirals, as well as their intensive safety monitoring when used during a pandemic.

The Agency has been working towards the implementation of this plan since the outbreak of the A/H1N1 influenza virus in April 2009. Working closely with manufacturers of vaccines and antivirals, the EU Member States, the European Commission, the WHO, the United States Food and Drug Administration (FDA) and Health Canada, the Agency has initiated a series of activities to facilitate the availability of vaccines and antivirals for use in an influenza pandemic situation.

Vaccines
The Agency is in continuous dialogue with vaccine manufacturers and European and international regulators to discuss scientific and regulatory issues relating to the development and approval of vaccines. These include necessary requirements for clinical and non-clinical data to support the authorisation of influenza A/H1N1 vaccines, as well as strain recommendations for use in vaccine manufacture.

Before the current pandemic started, four mock-up influenza-pandemic vaccines were approved in the European Union. The Agency is continuing to work closely with vaccine manufacturers to identify the required data to allow for the modification of the marketing authorisation which would replace the current mock-up virus with one of the A/H1N1-derived pandemic-like strains as recommended by the WHO.
The Agency is of the opinion that companies using the mock-up approach would have to provide significantly less data, as important issues such as effectiveness and safety of adjuvants or dosing schedules in defined populations were already established at the time of authorisation.

The Agency is currently considering initial proposals from vaccine manufacturers for the development of A/H1N1 vaccines and will provide its advice for each of them in order to facilitate the earliest possible availability of authorised monovalent A/H1N1 vaccines.

Antivirals
Until a pandemic vaccine is available, antiviral medicines are available for treatment. Among the antiviral medicines that are authorised in the EU for use in an influenza outbreak, the neuraminidase inhibitors Tamiflu (oseltamivir) and Relenza (zanamivir) are two to which the A/H1N1 virus has shown susceptibility.

At the beginning of May 2009, the Agency gave guidance on the use of Tamiflu in children under one year of age and the use of Tamiflu and Relenza in pregnant and breastfeeding women following the official declaration of an influenza A/H1N1 pandemic, saying that Tamiflu could be used in children under one year and in pregnant and breastfeeding women. In addition, the Agency had also recommended extending the shelf life of Tamiflu from 5 to 7 years. A similar extension was approved for Relenza by the Member States at the end of May.

The Agency will issue updates on its activities during the pandemic.

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

-- ENDS --

Notes:

1. More information on the Agency's activities in relation to the A/H1N1 outbreak can be found here.
2. The EMEA Crisis Plan can be found here.
3. More information about mock-up vaccines is available here.
4. WHO information on A/H1N1 influenza can be found here.
5. Information about the European Centre for Disease Control and Prevention (ECDC) can be found here.
6. Information on the European Commission's influenza activities can be found here.
7. A link to EU Member States' national pandemic plans can be found here.
8. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: 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