European Medicines Agency

London, 15 December 2006
Doc. Ref. EMEA/501557/2006

QUESTIONS AND ANSWERS ON 'MOCK-UP' PANDEMIC FLU VACCINES

To prepare for a potential influenza (flu) pandemic in the European Union, the European Commission, together with the European Medicines Agency (EMEA), developed a novel European procedure in 2003. This procedure allows manufacturers to gain an authorisation for a 'mock-up' vaccine before a flu pandemic has occurred.

What is a flu pandemic?
A flu pandemic is a rare but recurrent event. It occurs when a new type (strain) of flu virus emerges that can spread easily from person to person. It is different from the normal 'seasonal' flu, because the strain is new, and because people have no protection (immunity) against it. Because of the lack of immunity, the virus can spread widely. The consequences of a flu pandemic can be serious, in terms of public health and economic costs.

Three pandemics occurred during the 20th century: 'Spanish influenza' in 1918, 'Asian influenza' in 1957 and 'Hong Kong influenza' in 1968.

Can flu vaccines be used during a flu pandemic?
The spread of infection during a pandemic can be controlled using a number of measures, including the use of vaccines and antiviral medicines. However, normal flu vaccines, which are prepared to protect against seasonal flu, are not effective during a flu pandemic. Instead, special pandemic flu vaccines would need to be used, in order to build up some protection against the pandemic virus in people who have not yet been exposed to it. This can help to slow down the spread of the pandemic.

Until the pandemic starts, however, the strain of flu virus that will be involved is not known. Therefore, pandemic flu vaccines can only be prepared once a pandemic has started and the strain of flu virus responsible is identified.

Is there a way to speed up the availability of pandemic flu vaccines?
Yes, there is. The new European procedure, which was established by the Commission and implemented by the EMEA, allows manufacturers to gain an authorisation for a 'mock-up' vaccine before a pandemic has occurred.

A mock-up pandemic influenza vaccine is a vaccine that mimics the future pandemic influenza vaccine in terms of its composition and manufacturing method. However, because the virus strain causing the pandemic is not known, the mock-up vaccine contains another flu strain instead. This is a strain that is not circulating in humans, and to which humans have not been exposed in the past. This enables the company to test its vaccine in preparation for any flu pandemic that may occur in the future, by carrying out studies with the mock-up vaccine that predict how people will react to the vaccine when the strain causing a pandemic is included.

What documentation does the company need to present to the EMEA to support an application for a mock-up vaccine?
The EMEA's scientific committee, the Committee for Medicinal Products for Human Use (CHMP), looks at data on the methods used to make and test the mock-up vaccine, as well as the results from studies of the vaccine tested in healthy people. This information covers the immunogenicity of the vaccine (its ability to make the immune system, the body's defence mechanism, produce antibodies against the virus strain), as well as its safety (side effects). The documentation also contains a 'risk management plan' that details what will be done to monitor the safe use of the vaccine in a pandemic.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What are the next steps?
The objective behind a mock-up vaccine is to have a marketing authorisation (licence) in place, which can be changed quickly in the event of a pandemic to include the responsible virus strain, once it has been identified. The mock-up vaccine itself is not expected to be used or stockpiled (stored for use in the future) before the outbreak of a pandemic.

Once a pandemic has started, the company will first include the pandemic flu strain in the vaccine. It will then apply for a variation (a change to the vaccine's marketing authorisation) by supplying full information to the CHMP on the vaccine including the new pandemic flu strain. Once the variation has been approved and been granted a marketing authorisation by the European Commission, the vaccine will be available for use. This variation will be processed quickly - normally within a few days - as most of the data on the pandemic flu vaccine will already have been reviewed during the assessment of the mock-up vaccine.

When will the pandemic vaccine be available?
Once the flu strain causing a pandemic is known, it takes about 12 weeks to prepare a suitable vaccine, as the viruses need to be grown in live cells, such as hens' eggs.

After the final vaccine is ready, decisions on who should receive the vaccine, and when they should receive it, will be made by the government in each European Union Member State.