European Medicines Agency
Press office

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Press release
European Medicines Agency review of pandemic vaccines underway

The European Medicines Agency has started to receive data on H1N1 pandemic vaccines and the review began in July, with the commitment from the Committee for Medicinal Products for Human Use, to fast-track the review of data as vaccine manufacturers make them available.

Given the public health threat posed by the current pandemic, the Agency's goal is to ensure data submitted to support marketing authorisations for vaccines are reviewed as early as possible, before the beginning of the Northern hemisphere flu season, expected in September. At present the Committee (or CHMP) is reviewing data relating to manufacture of vaccines. Additional clinical trials in adults and children are currently being initiated by the vaccine manufacturers and the results will be reviewed in the coming months as they become available.

Four 'mock-up' vaccines developed by Baxter, GlaxoSmithKline and Novartis have already been approved in the European Union based on earlier data generated with the H5N1 virus strain, which is similar to H1N1. These vaccines were developed in the knowledge that the virus strain would be changed in the event of a declared pandemic, to include the strain causing the pandemic. Altogether, they have been tested in more than 8,000 subjects. Decades of experience with seasonal influenza vaccines indicate that insertion of a new strain in a vaccine, as will apply with the change from H5N1 to H1N1 in the mock-up vaccines, should not substantially affect the safety or level of protection offered.

Data relating to the change in strain are currently being reviewed by the CHMP on a rolling basis as soon as they become available. Approval of the H1N1 vaccine is expected to be given after satisfactory review of these data. Clinical trials with the H1N1 strain are currently being initiated or are ongoing. Initial results on the efficacy, immunogenicity and safety of the vaccine from these trials are expected from September 2009 onwards, and will also be reviewed as soon as they become available.

As with all medicines, rare adverse reactions can only be detected during the wider use of the vaccine. Regulatory authorities and vaccine manufacturers will implement plans to actively investigate and monitor the safety of these vaccines and take swift action if safety issues emerge.

In addition to the mock-up vaccines, a number of other pandemic influenza vaccines are currently under development, and preliminary data from GlaxoSmithKline and Sanofi Pasteur are also being assessed by the Committee on an accelerated basis.

For each of these vaccines, the Committee will make a recommendation to the European Commission for final authorisation. Following this, the use of the vaccines in each Member State will depend on national recommendations and the availability of the vaccines in each country.

The Agency has undertaken to provide regular updates on its influenza pandemic preparedness through its website and the issuing of press releases as appropriate.

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 27 Fax (44-20) 74 18 84 09
E-mail: press@emea.europa.eu http://www.emea.europa.eu

NOTES

1. More information is available in a question and answer document.
2. More information on the Agency's activities in relation to the A/H1N1 outbreak can be found here.
3. More information about mock-up vaccines is available here.
4. More information about pharmacovigilance of pandemic vaccines is available here.
5. The EMEA pandemic influenza Crisis Plan can be found here.
6. WHO information on A/H1N1 influenza can be found here.
7. Information about the European Centre for Disease Control and Prevention (ECDC) can be found here.
8. Information on the European Commission's influenza activities can be found here.
9. A link to EU Member States' national pandemic plans can be found here.
10. 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