EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency updates on pandemic influenza

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the granting of a conditional marketing authorisation for Humenza from Sanofi Pasteur SA. This is the fifth pandemic vaccine recommended for use by the Committee, and the second to be assessed using an emergency procedure which fast-tracks the evaluation of new vaccines developed during a pandemic influenza. Information on Humenza was evaluated in an accelerated timeframe using a rolling review which started with the submission of the first available data on 23 June 2009.

The Committee convened a group of vaccination experts to further analyse the variability seen in the serological tests used to measure the immune response following vaccination of children and adults with the centrally authorised pandemic vaccine Celvapan. Following discussion with the experts, the Committee concluded that the variability did not change the Committee's view that the vaccine is sufficiently immunogenic in all age groups when administered in accordance with the approved dosage recommendation of two doses at an interval of at least 3 weeks.

In addition, the Committee also reviewed further results from clinical studies and post-marketing experience for all three centrally authorised pandemic influenza vaccines, Celvapan, Focetria and Pandemrix. The data confirm the expected immunogenicity and safety profile for the vaccines. For Celvapan and Focetria the Committed recommended changes to the product information to include additional information on the vaccines' safety. The latest data on the safety show no unexpected serious safety issue. The most frequent adverse reactions that have been reported are non-serious and as expected.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary. The most recent weekly pandemic influenza pharmacovigilance update report was published on 17 February 2010.

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Notes

1. The recommended product information for Humenza is available here: http://www.ema.europa.eu/influenza/vaccines/humenza/humenza_pi.html and the summary of the European public assessment report is available here: http://www.ema.europa.eu/influenza/vaccines/humenza/humenza.html

2. A marketing authorisation under conditional approval means that further evidence on the medicinal product is awaited. In the case of Humenza this relates mainly to studies in children, adolescents and adults. The European Medicines Agency will review new information and update the product information as necessary.

3. For more information on the emergency procedure see here: http://www.ema.europa.eu/influenza/vaccines/authorisation_procedures.htm

4. The Committee has recommended in January 2010 the marketing authorisation for another pandemic vaccine via an emergency procedure, Arepanrix. A decision from the European Commission on this marketing authorisation is currently awaited. The product information for Arepanrix is available here: http://www.ema.europa.eu/influenza/vaccines/arepanrix/arepanrix_pi.html and the summary of the assessment report is available here http://www.ema.europa.eu/influenza/vaccines/arepanrix/arepanrix.html

5. For more details on the recommended changes for Celvapan, please refer to the updated product information: http://www.ema.europa.eu/influenza/vaccines/celvapan/celvapan_pi.html

6. For more details on the recommended changes for Focetria, please refer to the updated product information: http://www.ema.europa.eu/influenza/vaccines/focetria/focetria_pi.html

7. The latest approved product information for Pandemrix is available here: http://www.ema.europa.eu/influenza/vaccines/pandemrix/pandemrix_pi.html

8. More information on adverse reactions reported with centrally authorised pandemic medicines is provided in the weekly pandemic influenza pharmacovigilance update report: http://www.emea.europa.eu/influenza/updates.html

9. More information on the Agency's activities in relation to the influenza pandemic can be found on the Agency's pandemic influenza website: http://www.emea.europa.eu/influenza/home.htm

10. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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