EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Sanofi Pasteur withdraws its marketing authorisation application for Emerflu, pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)

The European Medicines Agency has been formally notified by Sanofi Pasteur of its decision to withdraw its application for a centralised marketing authorisation for Emerflu, a pandemic influenza vaccine (split virion, inactivated, adjuvanted) A/Vietnam/1194/2004 NIBRG-14, 30 µg of haemagglutinin + aluminium hydroxide adjuvant, suspension for injection.

This medicine was intended to be used for prophylaxis of influenza in an officially declared pandemic situation. A core pandemic dossier was submitted in the context of prevention of influenza in an officially declared pandemic situation, according to the mock-up vaccine procedure.

The application for the marketing authorisation for Emerflu was submitted to the Agency on 27 April 2007. Emerflu received a negative opinion from the Committee for Medicinal Products for Human Use (CHMP) on 19 March 2009 and at the time of withdrawal a European Commission decision was pending.

In its official letter, the company stated that its decision to withdraw the application was based on the CHMP's consideration that the data provided do not allow the Committee to conclude on a positive benefit/risk balance.

More information about Emerflu and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the Agency's website after the next CHMP meeting on 13 – 16 December 2010.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The question-and-answer document on the negative opinion is available on the Agency's website.
3. Withdrawal of an application does not prejudice the possibility of the company making a new application at a later stage.

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4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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