European Medicines Agency
Press office

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PRESS RELEASE
Novartis Vaccines and Diagnostics S.r.l. withdraws its marketing authorisation application for the pre-pandemic vaccine Aflunov

The European Medicines Agency (EMEA) has been formally notified by Novartis Vaccines and Diagnostics S.r.l. of its decision to withdraw the application for a centralised marketing authorisation for the pre-pandemic vaccine Aflunov (A/VietNam/1194/2004 (H5N1) virus surface inactivated antigen).

Aflunov was expected to be used for active pre-pandemic immunisation against H5N1 subtype of the influenza A virus.

The application for marketing authorisation for Aflunov was submitted to the EMEA on 6 November 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Aflunov was based on the fact that the CHMP's request for additional clinical data, as required by the pre-pandemic guideline, could not be met within the timeframe permitted by the centralised procedure. The CHMP had requested additional data because a good clinical practice (GCP) inspection showed that the main study had not been conducted in compliance with GCP, so that its results could not be considered reliable for use in the evaluation of the vaccine.

More information about Aflunov 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 EMEA website in due course following the CHMP meeting of 23-26 June 2008.

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Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. The 'Guideline on dossier structure and content of marketing authorisation applications for influenza vaccines derived from strains with a pandemic potential for use outside of the core dossier context' is available at: http://www.emea.europa.eu/pdfs/human/vwp/26349906en.pdf
3. Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.
4. 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