16 February 2012
EMA/112567/2012
Press Office

Press release

Novartis Vaccines and Diagnostics S.r.l. withdraws its application for paediatric-use marketing authorisation for Fluad Paediatric (influenza vaccine)

The European Medicines Agency has been formally notified by Novartis Vaccines and Diagnostics S.r.l. of its decision to withdraw its application for a paediatric-use marketing authorisation (PUMA) for the medicine Fluad Paediatric (influenza vaccine, surface antigen, inactivated, adjuvanted with MF59C.1).

Fluad Paediatric was intended to be used for the active immunisation against influenza in infants and young children.

The application for the paediatric-use marketing authorisation for Fluad Paediatric was initially submitted to the Agency on 13 December 2010. At the time of the withdrawal it was under evaluation by the Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that their decision to withdraw the application is based on the fact that they are unable to address the questions of the Committee within the required timelines.

More information about Fluad Paediatric and the stage of the scientific assessment procedure 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 CHMP meeting on 13-16 February 2012.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu