EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 November 2010
EMA/700091/2010
Press Office

Press release

Schering-Plough Europe withdraws its marketing authorisation application for Zenhale (mometasone furoate/formoterol fumarate)

The European Medicines Agency has been formally notified by Schering-Plough Europe of its decision to withdraw its application for a centralised marketing authorisation for the medicine Zenhale (mometasone furoate/formoterol fumarate) 50/5, 100/5 or 200/5 mg, pressurised inhalation.

This medicine was intended to be used for long-term, twice-daily maintenance treatment of asthma, including reduction of asthma exacerbations, in adults and children aged 12 years or older.

The application for the marketing authorisation for Zenhale was submitted to the Agency on 3 August 2009. 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 its decision to withdraw the application was based on its inability to address the CHMP's requests to provide additional data within the timeframe allowed in the centralised procedure.

More information about Zenhale 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 15-18 November 2010.

Notes

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. 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

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

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

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu