13 March 2012
EMA/174944/2012
Press Office

Press release

Alkermes Pharma Ireland Limited withdraws its marketing authorisation application for Megestrol Alkermes (megestrol)

The European Medicines Agency has been formally notified by Alkermes Pharma Ireland Limited of its decision to withdraw its application for a centralised marketing authorisation for the medicine Megestrol Alkermes (megestrol), 125 mg/ml oral suspension. Megestrol Alkermes was intended to be used for the treatment of anorexia, cachexia or an unexplained significant weight loss in adult AIDS and oncology patients.

The application for the marketing authorisation for Megestrol Acetate was submitted to the Agency on 11 December 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 they decided to withdraw the application as a consequence of portfolio prioritisation.

More information about Megestrol Alkermes 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 CHMP meeting of 12-15 March 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

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