



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Vanda Pharmaceuticals Ltd withdraws its marketing authorisation application for Fanaptum (iloperidone)

The European Medicines Agency has been formally notified by Vanda Pharmaceuticals Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Fanaptum (iloperidone) intended to be used for the treatment of schizophrenia.

The application for the marketing authorisation for Fanaptum was submitted to the Agency on 27 June 2011. On 13 December 2012 the Committee for Medicinal Products for Human Use (CHMP) recommended the refusal of a marketing authorisation for the medicinal product. The company has requested a re-examination of the opinion in February 2013. At the time of the withdrawal, the medicine was under review by the CHMP.

In its official letter, the company stated that it is withdrawing the application because the CHMP identified missing data which will not be available in a timeframe acceptable in the centralised procedure.

More information about Fanaptum and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document will be published on the Agency's website after the CHMP meeting of 18-21 March 2013.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information about the negative opinion for the marketing authorisation application for Fanaptum can be found here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002371/smop/s/Negative/human_smop_000459.jsp&mid=WC0b01ac058001d127
3. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
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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