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Vanda Pharma withdraws application for Fanaptum

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Singapore: Vanda Pharmaceuticals has withdrawn its application from European Medicines Agency for a centralized marketing authorization for the medicine Fanaptum (iloperidone) intended to be used for the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 June 27, 2011. On December 13, 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.