8 December 2009
EMA/796337/2009
Press Office

**Press release**

# Amarin Neuroscience Ltd withdraws its marketing authorisation application for Ethyl Eicosapent Soft Capsules (ethyl eicosapent)

The European Medicines Agency has been formally notified by Amarin Neuroscience Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ethyl Eicosapent (ethyl eicosapent), 500 mg soft gelatine capsules.

Ethyl Eicosapent was expected to be used for the long-term stabilisation of symptoms in patients with Huntington's disease, a hereditary neurological disorder of the central nervous system that causes progressive degeneration of cells in the brain,

The application for the marketing authorisation for Ethyl Eicosapent was submitted to the Agency on 6 March 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 the withdrawal of the application was based on the preliminary comments of rapporteur and co-rapporteur which indicate that the CHMP is unlikely to conclude a favourable opinion without additional efficacy information.

More information about Ethyl Eicosapent Soft Gelatin Capsules 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 of 14-17 December 2009.

## Notes

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8416
**E-mail** press@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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

Martin Harvey Allchurch or Monika Benstetter

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu