



European Medicines Agency
Press office

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Press release

Skye Pharma PLC withdraws its application to extend the marketing authorisation for DepoCyte

The European Medicines Agency has been formally notified by Skye Pharma PLC of its decision to withdraw its application for an extension of the marketing authorisation for the medicinal product DepoCyte (cytarabine).

DepoCyte was first authorised in the European Union on 11 July 2001. It is currently indicated for the intrathecal treatment (injection into the space between the lining of the spinal cord and brain) of lymphomatous meningitis, a complication of lymphoma when tumour cells spread to the membranes that surround the nervous system.

On 5 August 2005, Skye Pharma PLC submitted an application for the extension of the marketing authorisation to include the treatment of solid tumour neoplastic meningitis.

In its official withdrawal letter, the company stated that it decided to withdraw the application for DepoCyte because the Committee for Medicinal Products for Human Use (CHMP) considered that the data provided would not allow a conclusion to be drawn on a positive benefit-risk balance.

More information about DepoCyte and the current 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 EMEA website, after the next meeting of the CHMP on 24-27 July 2006.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company to making a new application at a later stage.
2. Information about DepoCyte in its currently approved indication can be found [here](#).
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.eu.int>

Media enquiries only to:
Martin Harvey Allchurch
Tel: (44-20) 74 18 84 27, E-mail: press@emea.eu.int