European Medicines Agency
Press office

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PRESS RELEASE
Sepracor Pharmaceuticals Ltd withdraws its marketing authorisation application for Lunivia (eszopiclone)

The European Medicines Agency has been formally notified by Sepracor Pharmaceuticals Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Lunivia (eszopiclone), 2 and 3 mg tablets.

Lunivia was expected to be used for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening in adults, usually for short-term duration.

The application for the marketing authorisation for Lunivia was submitted to the Agency on 23 July 2007. In October 2008, Lunivia received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), recommending that the medicine be granted a marketing authorisation. However, the CHMP recommended that the medicine should not be granted 'new active substance' status.

Following a re-examination procedure at the request of the applicant, the CHMP confirmed its previous opinion in February 2009. At the time of withdrawal, the application was pending the adoption of a marketing authorisation decision by the European Commission.

In its official letter, the company stated that the withdrawal of the application was based on the CHMP's recommendation that Lunivia should not be regarded as containing a new active substance, and that the commercial viability of launching the product in the European Union was compromised.

More information about Lunivia 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 26-29 May 2009.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. The press release from the October 2008 meeting can be found here: http://www.emea.europa.eu/pdfs/human/press/pr/55020608en.pdf
3. The summary of the positive opinion from October 2008 can be found here: http://www.emea.europa.eu/pdfs/human/opinion/Lunivia_54602208en.pdf
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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