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Press Office

Press release

Sanofi Aventis withdraws its marketing authorisation application for Sliwens (eplivanserin)

The European Medicines Agency has been formally notified by Sanofi Aventis of its decision to withdraw its application for a centralised marketing authorisation for the medicine Sliwens (eplivanserin), 5 mg, film-coated tablets.

Sliwens was intended to be used for the treatment of chronic insomnia.

The application for the marketing authorisation for Sliwens was submitted to the Agency on 3 December 2008. 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 their decision to withdraw the application was based on feedback from regulatory agencies.

More information about Sliwens 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 on 18-21 January 2010.

Notes

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

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