European Medicines Agency

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Questions and answers on the withdrawal of the marketing authorisation application for Lunivia
eszopiclone

On 13 May 2009, Sepracor Ltd. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Lunivia, for the treatment of insomnia.

What is Lunivia?
Lunivia is a medicine that contains the active substance eszopiclone. It was to be available as tablets.

What was Lunivia expected to be used for?
Lunivia was expected to be used to treat adults with insomnia, including difficulty falling asleep, waking up during the night and waking up early, usually for short periods.

How does Lunivia work?
The active substance in Lunivia, eszopiclone, belongs to a group of medicines that are related to the benzodiazepines. It is a purified form of one of the two 'enantiomers' (mirror-image forms) of the substance zopiclone. Zopiclone has been available in the European Union (EU) as a treatment for insomnia since the mid-1980s.
Although it is chemically different from the benzodiazepines, eszopiclone acts on the same receptors in the brain. It activates receptors in the brain called gamma-aminobutyric acid A (GABA-A) receptors, which are involved in bringing about sleep. By activating these receptors, eszopiclone can help patients with insomnia to sleep.

What documentation did the company present to support its application to the CHMP?
The effects of Lunivia were first tested in experimental models before being studied in humans.
The company presented the results of eight main studies involving over 4,000 adults to support its application. The studies looked at 'transient' insomnia (in this case, insomnia caused by spending a night in an unfamiliar setting), at primary insomnia (insomnia with no other cause) and at insomnia caused by other conditions (major depression, generalised anxiety disorder, the menopause and rheumatoid arthritis).
All of the studies compared Lunivia with placebo (a dummy treatment). The main measures of effectiveness were how long it took for the patients to fall asleep or how long the patients were awake during the night after first falling asleep.

How far into the evaluation was the application when it was withdrawn?
The evaluation had finished and the CHMP had given a positive opinion. The company withdrew before the European Commission had issued a decision on this opinion.

What was the recommendation of the CHMP at that time?
Based on the review of the data and the company's response to the CHMP's lists of questions, at the time of the withdrawal, the CHMP had given a positive opinion, recommending that a marketing authorisation be granted for Lunivia for the treatment of insomnia.

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However, the Committee had also concluded that eszopiclone could not be considered to be a new active substance. As a consequence, Lunivia would not have been able to benefit from 10 years of 'market exclusivity'. This is the period during which other companies would have been prevented from marketing 'generic medicines' of Lunivia (medicines that contain the same active substance at the same dose as Lunivia and that are used for the same conditions).
The company had requested a re-examination of the CHMP's opinion, but after re-examining the opinion, the Committee had confirmed its earlier opinion.

What were the main concerns of the CHMP?
The CHMP had no major concerns and the application could have been approved.

What were the reasons given by the company for withdrawing the application?
The letter from the company notifying the Agency of the withdrawal of the application is available here.

What are the consequences of the withdrawal for patients in clinical trials using Lunivia?
The company informed the CHMP that there are no consequences for patients currently included in clinical trials using Lunivia. If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.