European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 October 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
LUNIVIA

International Nonproprietary Name (INN): ***eszopiclone***

On 23rd October 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Lunivia 2mg and 3 mg, film-coated tablets intended for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening, in adults. The applicant for this medicinal product is Sepracor Pharmaceuticals, Ltd.

The active substance of Lunivia is eszopiclone, a Benzodiazepine related drugs medicinal product (ATC code: N05CF04*)*, a positive allosteric agonist at gamma-aminobutyric acid type A receptors (GABAA). It is believed to increase GABA-evoked chloride conductance resulting in neuronal hyperpolarisation and thereby inhibiting neuronal transmission and causing sleep.

The benefit with Lunivia is its improvement of primary insomnia as demonstrated by the effect on sleep latency in clinical studies. Lunivia in adults (3 mg) and elderly (2 mg) reduced time to sleep onset by 19 minutes (range 15.8 – 28.5) as compared to placebo in short-term trials and, at a dose of 3 mg in adults, Lunivia reduced time to sleep onset by 19.2 minutes (range 18 – 20.5) as compared to placebo in long-term trials in non-elderly adults.

The most common side effects are unpleasant taste (dysgeusia); other common adverse events include dizziness, somnolence, and dry mouth, consistent with the known pharmacology of non-benzodiazepines. Headache, dyspepsia, and pain including back pain, have also been frequently observed, however, the incidence of these have not been as notably different from placebo treatment groups in clinical trials.

A pharmacovigilance plan for Lunivia, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "LUNIVIA is indicated for the treatment of insomnia, including difficulty falling asleep, nocturnal awakening or early awakening, in adults, usually for short term duration."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Lunivia and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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