



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2011
EMA/134567/2011
Press Office

Press release

Sun Pharmaceutical Industries Europe B.V. withdraws its marketing authorisation application for Topotecan SUN (topotecan)

The European Medicines Agency has been formally notified by Sun Pharmaceutical Industries B.V. of its decision to withdraw its application for a centralised marketing authorisation for the medicinal product Topotecan SUN (topotecan) 1 mg and 4 mg powder for concentrate for solution for infusion.

The medicine was developed as a generic medicine to be used for the treatment of metastatic cancer of the ovary, small cell lung cancer and cervical cancer. The reference medicinal product for Topotecan SUN is Hycamtin, which has been authorised in the European Union since 1996.

The application for the marketing authorisation for Topotecan SUN was submitted to the Agency on 1 November 2010. 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 it decided to discontinue the application because due to the number of competitors it no longer had a commercial interest in the product.

More information about Topotecan SUN 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 CHMP meeting on 14 - 17 February 2011.

Notes

1. This press release is available on the Agency's website.
2. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.



3. A generic medicine is a medicine which is similar to a medicine that has already been authorised (the 'reference medicine'). Generic and reference medicines are used at the same dose to treat the same disease, and they are equally safe and effective.
4. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu