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

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
TOPOTECAN TEVA

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

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Topotecan Teva 1mg/ml concentrate for solution for infusion intended for Topotecan monotherapy is indicated for the treatment of patients with metastatic carcinoma of the ovary therapy and patients with relapsed small cell lung cancer. The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Topotecan Teva is topotecan, (as hydrochloride), an antineoplastic and immunomodulating agent (L01XX17). Topotecan is a cytotoxic anti-cancer agent and acts by inhibition of the nuclear enzyme topoisomerase I that is involved in DNA replication. As a result, DNA damage induces apoptotic cell death predominantly in replicating cells such as tumour cells.

Topotecan Teva is a generic of Hycamtin, which has been authorised in the EU since 12 November 1996. Studies have demonstrated the satisfactory quality of Topotecan Teva. Topotecan Teva is administrated intravenously and is 100% bioavailable. Therefore, a bioequivalence study versus the reference medicinal product was not required. A question-and-answer document on generic medicines can be found here

The approved indication is:

"Topotecan monotherapy is indicated for the treatment of:

- Patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy.
- Patients with relapsed small cell lung cancer [SCLC] for whom re-treatment with the first-line regimen is not considered appropriate (see section 5.1)."

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

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 Topotecan Teva 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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