EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2011
EMA/CHMP/795162/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Topotecan Eagle

topotecan

On 20 October 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Topotecan Eagle 3mg/ml concentrate for solution for infusion intended for *the treatment of* relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate. In combination with Cisplatin for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination. The applicant for this medicinal product is Eagle laboratories Ltd.

The active substance of Topotecan Eagle 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 Eagle is a hybrid of Hycamtin, which has been authorised in the EU since 12 November 1996. Studies have demonstrated the satisfactory quality of Topotecan Eagle. Topotecan Eagle *is administered 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.

A pharmacovigilance plan for Topotecan Eagle will be implemented as part of the marketing authorisation.

The approved indication is: "Topotecan monotherapy is indicated for the treatment of patients with relapsed small cell lung cancer (SCLC) for whom re-treatment with the first-line regimen is not considered appropriate.

Topotecan in combination with cisplatin is indicated for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination."

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), 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 there to be a favourable benefit to risk balance for *Topotecan Eagle* and therefore recommends the granting of the marketing authorisation.