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Public statement

Topotecan Eagle

Withdrawal of the marketing authorisation in the European Union

On 2 October 2014, the European Commission withdrew the marketing authorisation for Topotecan Eagle (topotecan) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Eagle Laboratories Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Topotecan Eagle was granted marketing authorisation in the EU on 22 December 2011 for the treatment of patients with relapsed small cell lung cancer when re-treatment with the first-line regimen is not considered appropriate. It was also approved for the treatment of women with cancer of the cervix in combination with cisplatin when the cancer has come back after radiotherapy, or when the disease is at an advanced stage (stage IVB: the cancer has spread beyond the cervix).

The marketing authorisation was initially valid for a 5-year period.

Topotecan Eagle is a 'hybrid generic medicine' of Hycamtin. There are other generic medicinal products of Hycamtin authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Topotecan Eagle will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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