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Questions and answers

Withdrawal of the marketing authorisation application for Topotecan SUN (topotecan)

On 3 January 2011, Sun Pharmaceutical Industries Europe B.V. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Topotecan SUN for the treatment metastatic cancer of the ovary, small cell lung cancer and cervical cancer.

What is Topotecan SUN?

Topotecan SUN is a powder to be made up into a solution for infusion (drip into a vein). It contains the active substance topotecan.

Topotecan SUN was developed as a 'generic medicine'. This means that Topotecan SUN was intended to be similar to a 'reference medicine' already authorised in the European Union called Hycamtin. For more information on generic medicines, see the question-and-answer document here.

What was Topotecan SUN expected to be used for?

Topotecan SUN was to be used on its own to treat patients with:

- metastatic cancer of the ovary (when the cancer has spread to other parts of the body) after at least one other treatment has failed;
- small cell lung cancer, when the cancer has relapsed (come back).

It was also to be used together with cisplatin (another anticancer medicine) to treat women with cervical cancer (cancer of the cervix), when the cancer had come back after radiotherapy, or when the disease was at an advanced stage (stage IVB: the cancer has spread beyond the cervix).

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How is Topotecan SUN expected to work?

The active substance in Topotecan SUN, topotecan, is an anticancer medicine that belongs to the group 'topoisomerase inhibitors'. It blocks an enzyme called topoisomerase I, which is involved in the division of DNA. When the enzyme is blocked, the DNA strands break. This prevents the cancer cells from dividing and they eventually die. Topotecan SUN also affects non-cancer cells, which causes side effects.

What did the company present to support its application?

The company provided data from the published literature on topotecan. No additional studies were needed as Topotecan SUN is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Hycamtin.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn before 'day 120'. This means that the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

The letter from the company notifying the Agency of the withdrawal of the application is available under the tab 'All documents'.