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Questions and answers

Withdrawal of the marketing authorisation application for Docetaxel Sun (docetaxel)

On 6 June 2016, 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 Docetaxel Sun, for the treatment of various types of cancer.

What is Docetaxel Sun?

Docetaxel Sun is a medicine that contains the active substance docetaxel. It was to be available as a concentrate to make a solution for infusion (drip) into a vein.

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

What was Docetaxel Sun expected to be used for?

Docetaxel Sun was to be used to treat breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma (a type of stomach cancer) and cancer of the head and neck. It was intended to be used on its own or in combination with other cancer medicines, depending on the type of cancer and the response to previous treatments.

How is Docetaxel Sun expected to work?

Docetaxel Sun is expected to work in the same way as the reference medicine, Taxotere. The active substance in Docetaxel Sun and Taxotere, docetaxel, belongs to the group of cancer medicines known as taxanes. Docetaxel blocks the ability of cells to destroy the internal 'skeleton' that allows them to divide and multiply. With the skeleton still in place, the cells cannot divide and they eventually die.

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What did the company present to support its application?

Because Docetaxel Sun was developed as a generic medicine, the company presented the results of studies from the literature, and studies to show the quality of the medicine. No further studies were carried out because Docetaxel Sun is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Taxotere.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The CHMP was assessing the company's responses to the questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Docetaxel Sun could not have been approved for the treatment of cancer.

In particular, the CHMP noted that the docetaxel in Docetaxel Sun and in Taxotere is contained in tiny droplets (micelles) made with another substance, polysorbate 80, that helps the docetaxel to dissolve. The company had not carried out a study to demonstrate that Docetaxel Sun is bioequivalent to the reference medicine, because this is not required if the medicines are simple solutions that are given into a vein. (Two medicines are bioequivalent when they produce the same levels of the active substance in the body.) However, solutions containing micelles may behave differently from one another, and the CHMP considered that more information was needed to show that the Docetaxel Sun solution was similar enough in its composition and behaviour to Taxotere solution to allow a bioequivalence study to be omitted.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the company had not provided enough data to support the application for Docetaxel Sun.

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

In its letter notifying the Agency of the withdrawal of application, the company stated that it was withdrawing the application for Docetaxel Sun for commercial reasons.

The withdrawal letter is available here.