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Questions and answers

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

On 8 March 2010, Mylan S.A.S. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Docetaxel Mylan intended to be used to treat breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

What is Docetaxel Mylan?

Docetaxel Mylan is a medicine that contains the active substance docetaxel. It was to be available as a powder and solvent to be made up into a solution for infusion (drip into a vein).

Docetaxel Mylan was developed as a 'generic medicine'. This means that Docetaxel Mylan 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 Mylan expected to be used for?

Docetaxel Mylan was expected to be used to treat breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma (a type of stomach cancer) and head and neck cancer. It was to be used on its own or with other anticancer medicines.

How is Docetaxel Mylan expected to work?

The active substance in Docetaxel Mylan, docetaxel, belongs to the group of anticancer medicines known as the 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. Docetaxel also affects non-cancer cells such as blood cells, which can cause side effects.

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What did the company present to support its application?

The company provided data on docetaxel from the published literature. Because Docetaxel Mylan contains the same active substance as Taxotere and was to be given directly into a vein, the company did not consider additional studies on the Docetaxel Mylan to be necessary according to EU rules.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 120'. This means that the CHMP had evaluated the initial documentation provided by the company and formulated a list of questions. The company had not yet responded 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 Mylan could not have been approved.

Other substances are added to docetaxel to help it form small spherical structures called 'micelles' that are suitable for injection. However, the substances added in Docetaxel Mylan and Taxotere to form the micelles are not the same. Because of this and the complex nature of micelles themselves, the Committee had concluded that additional studies on Docetaxel Mylan were necessary, including studies on how the medicine would be treated by the body and its safety.

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 Mylan.

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 here.