14 October 2016
EMA/659373/2016
EMEA/H/C/004306

Questions and answers

Withdrawal of the marketing authorisation application for Pemetrexed (as ditromethamine) Hospira

On 22 September 2016, Hospira UK Limited officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Pemetrexed (as ditromethamine) Hospira, for the treatment of malignant pleural mesothelioma and non-small-cell lung cancer.

What is Pemetrexed (as ditromethamine) Hospira?

Pemetrexed (as ditromethamine) Hospira is a cancer medicine that contains the active substance pemetrexed. It was to be available as a powder to be made up into a solution for infusion (drip) into a vein.

Pemetrexed (as ditromethamine) Hospira was developed as a 'generic medicine'. This means that it was intended to be similar to a 'reference medicine' already authorised in the European Union called Alimta. For more information on generic medicines, see the question-and-answer document here.

What was Pemetrexed (as ditromethamine) Hospira expected to be used for?

Pemetrexed (as ditromethamine) Hospira was expected to be used to treat two types of lung cancer: malignant pleural mesothelioma (a cancer of the lining of the lungs usually caused by exposure to asbestos) and advanced non-small-cell lung cancer of the kind known as 'non-squamous'.

How does Pemetrexed (as ditromethamine) Hospira work?

Pemetrexed (as ditromethamine) Hospira is expected to work in the same way as the reference medicine, Alimta. The active substance in both medicines, pemetrexed, is changed in the body into an active form that blocks enzymes needed to make genetic material (DNA and RNA). The change into an

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

active form happens more readily in cancer cells than in normal cells. This prevents the cancer cells from growing and dividing, while normal cells are only slightly affected.

What did the company present to support its application?

Because Pemetrexed (as ditromethamine) Hospira was developed as a generic medicine, the company presented the results of studies to show the quality of the medicine. No further studies were carried out because Pemetrexed (as ditromethamine) Hospira is a generic medicine that is given by infusion into a vein and contains the same active substance as the reference medicine, Alimta.

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 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 asked the company to provide clarification on some aspects of manufacturing, storage and plans to monitor safety and effectiveness of the medicine after authorisation. The CHMP thought that the company could have addressed these questions and was of the provisional opinion that Pemetrexed (as ditromethamine) Hospira could have been approved for the treatment of malignant pleural mesothelioma and non-small-cell lung cancer.

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

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was withdrawing its application because of a change in commercial strategy.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials or compassionate use programmes?

The company informed the CHMP that there are no ongoing clinical trials or compassionate-use programmes for this product.