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Questions and answers

Withdrawal of the marketing authorisation application for Megestrol Alkermes (megestrol)

On 6 March 2012, Alkermes Pharma Ireland Ltd. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Megestrol Alkermes, intended to treat weight loss and loss of appetite in patients with cancer or AIDS.

What is Megestrol Alkermes?

Megestrol Alkermes is a medicine that contains the active substance megestrol. It was to be available as an oral suspension (125 mg/ml).

Megestrol Alkermes was assessed as a 'hybrid generic medicine'. This means that it was intended to be similar to a 'reference medicine' called Megace which is already authorised in the European Union and contains the same active substance. Both medicines are oral suspensions but Megestrol Alkermes was formulated so that it could be given at a lower dose to obtain the same effect.

What was Megestrol Alkermes expected to be used for?

Megestrol Alkermes was expected to be used to treat weight loss and loss of appetite in patients with cancer or AIDS.

How is Megestrol Alkermes expected to work?

Megestrol Alkermes is expected to work in the same way as the reference medicine, Megace. The active substance in Megestrol Alkermes, megestrol, is similar to a naturally occurring hormone called progesterone and is used in the treatment of certain cancers. The exact way that megestrol works in the treatment of weight loss and appetite loss is not understood but megestrol may act on certain messenger substances and pathways that affect appetite.

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What did the company present to support its application?

Because Megestrol Alkermes was assessed as a hybrid generic medicine, the company presented the results of studies carried out to investigate whether it is bioequivalent to the reference medicine, Megace. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The company also presented a study investigating the effectiveness of Megestrol Alkermes in the treatment of weight loss and loss of appetite in patients with AIDS and data from the scientific literature supporting the use of megestrol in the treatment of weight loss and loss of appetite in patients with cancer and AIDS.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 180'. This means that the CHMP had evaluated the documentation provided by the company and formulated a list of questions. The company had not yet responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's responses to the CHMP lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Megestrol Alkermes could not have been approved. Based on the data submitted, the CHMP was of the opinion that the studies did not show that Megestrol Alkermes was bioequivalent to the reference medicine and therefore cannot be considered to have the same effectiveness as Megace in reversing weight loss and loss of appetite in patients with cancer and AIDS. 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 Megestrol Alkermes.

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 its withdrawal was due to the prioritisation of its activities.

The withdrawal letter is available here.