25 July 2014
EMEA/H/C/002418

Questions and answers

Withdrawal of the marketing authorisation application for Neofordex (dexamethasone)

On 17 July 2014, Laboratories CTRS officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Neofordex, for the treatment of multiple myeloma.

What is Neofordex?

Neofordex is a corticosteroid medicine that contains the active substance dexamethasone. It was to be available as 40 mg tablets.

What was Neofordex expected to be used for?

Neofordex was to be used in combination with other medicines to treat adult patients with multiple myeloma who have developed symptoms. Multiple myeloma is a cancer of the plasma cells in the bone marrow.

Neofordex was developed as a 'hybrid medicine'. This means that it was intended to be similar to a 'reference medicine' containing the same active substance, but in a higher strength. While the reference medicine Dectancyl is available as 0.5 mg tablets, Neofordex was to be available as 40 mg tablets.

Neofordex was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 6 June 2010 for the treatment of multiple myeloma. More information on the orphan designation can be found here: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

How is Neofordex expected to work?

The active substance in Neofordex and Dectancyl, dexamethasone, belongs to a group of medicines known as corticosteroids, which reduce the activity of the immune system (the body's natural defences) by attaching to receptors in various types of immune cells. In multiple myeloma, high-dose

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7129
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

dexamethasone is used together with chemotherapy to make chemotherapy more effective and to reduce certain side effects of cancer treatment, such as nausea (feeling sick) and vomiting. In addition, by providing a high dose in a single tablet Neofordex was expected to simplify dosing.

What did the company present to support its application?

Because Neofordex was assessed as a hybrid medicine, and the effects of high-dose dexamethasone in multiple myeloma are well established, the company presented the results of a study carried out to investigate whether it is bioequivalent to the reference medicine, Dectancyl. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The company also presented studies from the literature on the use of dexamethasone for the treatment of multiple myeloma.

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

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists 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 response to the CHMP lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Neofordex could not have been approved for the treatment of multiple myeloma. The Committee considered that controls to ensure suitable and consistent quality of the medicine have not been shown to be adequate. Therefore, up to the time of the withdrawal, the CHMP was of the opinion that due to the concerns about quality the benefits of Neofordex did not outweigh its risks.

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 since it would not be possible to provide the additional data regarding the quality of the medicine within the timetable required by the procedure.

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 consequences for patients currently included in clinical trials or compassionate use programmes using Neofordex.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, contact the doctor who is giving it to you.