



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Questions and answers

Withdrawal of the marketing authorisation application for Belviq (lorcaserin)

On 3 May 2013, Arena Pharmaceuticals officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Belviq, a medicine intended for helping to achieve weight control in obese and overweight patients.

What is Belviq?

Belviq is a medicine that contains the active substance lorcaserin. It was to be available as tablets (8.4 mg).

What was Belviq expected to be used for?

Belviq was expected to be used together with diet and exercise to achieve weight control in obese patients, people with a body mass index (BMI, a measure of weight relative to height) of at least 30 kg/m². It was also to be used in overweight patients (people with a BMI of over 27 kg/m²) with health problems such as hypertension (high blood pressure), dyslipidaemia (abnormal levels of fat in the blood), cardiovascular disease (heart and circulatory problems), type 2 diabetes or sleep apnoea (frequent interruption of breathing during sleep).

How is Belviq expected to work?

The active substance in Belviq, lorcaserin, stimulates the activity of a certain type of receptor called serotonin receptor 2C (5-HT_{2C}), which is normally activated by serotonin, a chemical messenger. Lorcaserin is expected to imitate the effects of serotonin on 5-HT_{2C} receptors, which include an increased sense of fullness after a meal and reduced hunger before meals, thereby reducing food consumption.



What did the company present to support its application?

The company presented the results of three main studies involving more than 7,500 overweight and obese patients, comparing the effects of Belviq with placebo (a dummy treatment). In one of the studies all the patients had type 2 diabetes. In all the studies, the main measure of effectiveness was based on the amount of weight the patients lost after one year of treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. After the CHMP had assessed the company's responses to the last round of questions, there were still some unresolved issues.

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 Belviq could not have been approved for weight control in obese and overweight patients. Although a modest benefit in terms of weight loss was seen in the main studies, the Committee was concerned about the potential risk of tumours, particularly with long-term use, based on the results of laboratory tests. The CHMP also had other safety concerns, including the potential risk of psychiatric disorders (such as depression) and valvulopathy (problems with the heart valves), which were seen in some patients during the studies. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Belviq 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 would not be able to address all of the CHMP's concerns within the timetable for the application.

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 Belviq.

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.