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Questions and answers on the withdrawal of the marketing authorisation application for Ethyl Eicosapent soft gelatin capsules (ethyl eicosapent)

On 1 December 2009, Amarin Neuroscience Ltd officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Ethyl Eicosapent soft gelatin capsules, for the long-term stabilisation of symptoms in patients with Huntington's disease.

What is Ethyl Eicosapent soft gelatin capsules?

Ethyl Eicosapent soft gelatin capsules is a medicine containing the active substance ethyl eicosapent. It was to be available as capsules (500 mg).

What was Ethyl Eicosapent soft gelatin capsules expected to be used for?

Ethyl Eicosapent soft gelatin capsules was expected to be used to stop the symptoms of patients with Huntington's disease from worsening. Huntington's disease is a hereditary disease that causes brain cells to die, leading to symptoms such as involuntary jerky movements and dementia (loss of intellectual function).

Ethyl Eicosapent soft gelatin capsules was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 29 December 2000 for Huntington's disease.

How was Ethyl Eicosapent soft gelatin capsules expected to work?

The active substance in the medicine, ethyl eicosapent is broken down in the body to form eicosapentaenoic acid (EPA). EPA is an omega-3 fatty acid which is obtained from fish oil. It is also found in dietary supplements.

The exact way in which the medicine was supposed to work in Huntington's disease is not clear, but it was thought that higher amounts of EPA in the membranes of brain cells could help prevent the cells from being damaged.

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What documentation did the company present to support its application to the Agency?

The effects of Ethyl Eicosapent soft gelatin capsules were first tested in experimental models before being studied in humans. The company also presented data on experimental models from the scientific literature.

In three main studies involving 741 patients with Huntington's disease, the medicine was compared with placebo (a dummy medicine). The main measure of effectiveness was the reduction in symptoms affecting patients' movements after six months or one year.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn at 'day 120'.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 Ethyl Eicosapent soft gelatin capsules could not have been approved for the long-term stabilisation of symptoms in patients with Huntington's disease. The CHMP noted that results from the three main studies failed to show that the medicine is effective. There was also insufficient information provided on what would happen to the medicine in the body. Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Ethyl Eicosapent soft gelatin capsules did not outweigh its risks.

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

The letter from the company notifying the CHMP of the withdrawal of the application is available here.

What are the consequences of the withdrawal for patients in clinical trials or compassionate use programmes using Ethyl Eicosapent soft gelatin capsules?

The company informed the CHMP that there are currently no patients in clinical trials or compassionate use programmes with Ethyl Eicosapent soft gelatin capsules.

The summary of opinion of the Committee for Orphan Medicinal Products for Ethyl Eicosapent soft gelatin capsules is available here.