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Withdrawal of the marketing authorisation application for Qizenday (biotin)

On 13 November 2017, Medday Pharmaceuticals officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Qizenday, for the treatment of progressive multiple sclerosis.

What is Qizenday?

Qizenday is a medicine that contains the active substance biotin. It was to be available as capsules to be taken by mouth.

What was Qizenday expected to be used for?

Qizenday was to be used to treat adults with the progressive form of multiple sclerosis, a disease in which the protective sheath around the nerve cells in the brain and spinal cord is damaged, and the nerves progressively degenerate. Symptoms include weakness, difficulty walking and problems with vision. Progressive means that symptoms get steadily worse over time.

How does Qizenday work?

The mechanism of action of Qizenday in multiple sclerosis is not well understood; however, it is thought that the medicine acts on enzymes (known as carboxylases) to increase energy production in the damaged nerves and to help repair the protective sheath around the nerve cells.

Three of these enzymes are involved in energy production, while a fourth is believed to be involved in the production of sheaths around the nerve cells.

What did the company present to support its application?

The company presented data from two main studies comparing Qizenday with placebo (a dummy treatment). The first study involved 154 patients with spinal progressive multiple sclerosis. The main

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measure of effectiveness was the number of patients whose overall disability decreased and whose ability to walk improved.

The second study involved 93 patients with multiple sclerosis who had visual loss due to inflammation of the optic nerve. The main measure of effectiveness was improvement in vision.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions.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 Qizenday could not have been approved for the treatment of progressive multiple sclerosis.

The CHMP considered that the data on the medicine's effectiveness were not robust enough, and that there were uncertainties regarding the medicine's safety given the small number of patients treated with Qizenday. In addition, the Committee was of the opinion that more information was needed about how the medicine is absorbed, modified and removed from the body.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Qizenday 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 the application, the company stated that the withdrawal is based on the CHMP's opinion that the clinical data presented do not allow the Committee to conclude on a positive benefit-risk balance for Qizenday.

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 Qizenday.

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.