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Withdrawal of application for the marketing authorisation of Asimtufii (aripiprazole)

Otsuka Pharmaceutical Netherlands B.V. withdrew its application for a marketing authorisation of Asimtufii for the maintenance treatment of schizophrenia.

The company withdrew the application on 2 May 2023.

What is Asimtufii and what was it intended to be used for?

Asimtufii was developed as a medicine for the maintenance treatment of schizophrenia in adults whose disease has already been stabilised with aripiprazole.

Asimtufii contains the active substance aripiprazole and was to be available as a prolonged-release suspension for injection in pre-filled syringes. 'Prolonged release' means that the active substance is released slowly over an extended period of time after being injected. The medicine was to be given once every two months by slow injection into the gluteal (buttock) or deltoid (shoulder) muscle by a doctor or nurse.

Asimtufii was developed as a 'hybrid medicine'. This means that it contained the same active substance as an authorised 'reference medicine', in this case Abilify Maintena, but it was to be available in a different pharmaceutical form and strength. Asimtufii was to be available as a ready-to-use medicine in contrast to Abilify Maintena, which requires pre-mixing before it can be given to the patient.

How does Asimtufii work?

The active substance in Asimtufii, aripiprazole, is an antipsychotic medicine. The exact way it works is not known but it attaches to receptors in the brain for two substances (neurotransmitters) called dopamine and serotonin, which are believed to play a role in schizophrenia. By attaching to these receptors, it is thought that aripiprazole helps normalise the activity of the brain, reducing psychotic symptoms and preventing them from returning.

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What did the company present to support its application?

As for every medicine, the company provided studies on the quality of Asimtufii. It also provided results from a main study comparing the levels of the active substance in the body after treatment with Asimtufii and a comparator medicine.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Asimtufii could not have been authorised for the maintenance treatment of schizophrenia.

The Agency noted that in the main study the company should have compared Asimtufii with the reference medicine (Abilify Maintena) available in the EU. As the company had not done so, the study presented by the company did not provide enough evidence to support the application.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Asimtufii 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 a change in the company's strategy.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Asimtufii.