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Withdrawal of application for the marketing authorisation of Abilify MyCite (aripiprazole)

Otsuka Pharmaceutical Netherlands B.V. withdrew its application for a marketing authorisation of Abilify MyCite for the treatment of schizophrenia and bipolar I disorder.

The company withdrew the application on 17 July 2020.

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

Abilify MyCite was developed as a combination of a medicine and a medical device for:

- the treatment of schizophrenia;
- the prevention of a manic episode in adults who had predominantly manic episodes and whose manic episodes responded to aripiprazole treatment;
- the treatment of moderate to severe manic episodes in bipolar I disorder.

Abilify MyCite contains aripiprazole and was to be available as a tablet with an ingestible sensor for monitoring the medication ingestion.

Abilify MyCite was developed as a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substance, in this case Abilify, but Abilify MyCite is available in a different formulation (tablets containing an integrated ingestible sensor).

How does Abilify MyCite work?

The active substance in Abilify MyCite is aripiprazole. The exact way it works is not known but it attaches in the brain to receptors for two substances (neurotransmitters) called dopamine and serotonin (5HT), which are believed to play a role in schizophrenia and bipolar disorder. By attaching to these receptors, it is thought that aripiprazole helps normalise the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.

Abilify MyCite contains aripiprazole and was to be available as an aripiprazole tablet containing an ingestible sensor. Once ingested, the sensor is activated in the stomach and transmits data on the date and time of ingestion to a personal monitor (wearable sensor, also called patch). The patch then transmits the data to a medical software application (the App) and to a web-based portal for

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healthcare professionals and caregivers. Having these data available to the patient, doctors and caregivers was expected to help monitor if and when the medicine is ingested.

What did the company present to support its application?

Studies on the benefits and risks of the active substance are not needed for a hybrid medicine because they have already been carried out with the reference medicine. As for every medicine, the company provided studies on the quality of Abilify MyCite.

The company also submitted two clinical studies to explore certain aspects of how the digital medicine system worked in selected patients who received specific training.

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, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Abilify MyCite could not have been authorised in patients with schizophrenia and bipolar I disorder.

The Agency could not assess how well the tablet with the integrated sensor, the patch and the App work together as only limited aspects of usability and technical performance were investigated. There was not sufficient evidence that Abilify MyCite is able to reliably measure intake of the medicine in the target population.

From a safety point of view, there is a risk the patient could take too many doses because the digital medicine system may not work reliably. In addition, the patch can cause skin and subcutaneous tissue reactions.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Abilify MyCite 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 it withdrew its application because the Agency's concerns could not currently be resolved.

Does this withdrawal affect patients in clinical trials?

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

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.