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Withdrawal of application for the marketing authorisation of Dimherity (dimethyl fumarate)

Sandoz GmbH withdrew its application for a marketing authorisation of Dimherity for the treatment of adults with relapsing remitting multiple sclerosis (MS).

The company withdrew the application on 22 February 2022.

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

Dimherity was developed as a medicine to treat MS, a disease in which inflammation damages the protective insulation around nerves (demyelination) as well as the nerves themselves. It was to be used in adults with a type of MS known as relapsing-remitting MS, where the patient has flare-ups of symptoms (relapses) followed by periods of recovery (remissions).

Dimherity contains the active substance dimethyl fumarate and was to be available as gastro-resistant capsules (capsules that can pass through the stomach intact).

Dimherity was developed as a 'generic medicine'. This means that Dimherity contained the same active substance as an authorised 'reference medicine', Tecfidera, and was intended to work in the same way. For more information on generic medicines, see the question-and-answer document here.

How does Dimherity work?

In MS, the immune system (the body's natural defences) malfunctions and attacks parts of the central nervous system (the brain, spinal cord and the optic nerve of the eye), causing inflammation that damages the nerves and the insulation around them. The active substance in Dimherity, dimethyl fumarate, is thought to work by activating a protein called Nrf2 that regulates certain genes that produce antioxidants involved in protecting cells from damage. Dimethyl fumarate has been shown to reduce inflammation and modulate the activity of the immune system.

What did the company present to support its application?

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

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investigate whether Dimherity is 'bioequivalent' to the reference medicine Tecfidera. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

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. At the time of withdrawal, the company had responded to the last round of questions.

What did the Agency recommend at that time?

The marketing authorisation application for Dimherity was a duplicate of an original application for another medicine, Dimethyl fumarate Polpharma, which the Agency had recommended for authorisation.

The Agency initially had concerns about the information provided in the application for Dimherity as it was not aligned with the information in the original application. The company addressed the concerns in its response to the last round of questions but decided to withdraw the application.

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 was withdrawing the application for commercial reasons.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Dimherity.