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Withdrawal of the marketing authorisation application for Rotigotine Mylan (rotigotine)

On 22 December 2017, Mylan SAS officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Rotigotine Mylan, for the treatment of Parkinson's disease and restless-leg syndrome.

What is Rotigotine Mylan?

Rotigotine Mylan is a medicine that contains the active substance rotigotine. It was to be available as transdermal patches (patches that deliver a medicine across the skin).

Rotigotine Mylan was developed as a 'generic medicine'. This means that Rotigotine Mylan contains the same active substance and was intended to work in the same way as a 'reference medicine' already authorised in the European Union called Neupro. For more information on generic medicines, see the question-and-answer document here.

What was Rotigotine Mylan expected to be used for?

Rotigotine Mylan was expected to be used to treat adults with Parkinson's disease and adults with restless-leg syndrome (a disorder where the patient has uncontrollable urges to move the legs to stop uncomfortable, painful or odd sensations in the body, usually at night).

How does Rotigotine Mylan work?

The active substance in Rotigotine Mylan, rotigotine, is a dopamine agonist, which means that it imitates the action of dopamine. Dopamine is a messenger substance in the parts of the brain that control movement and coordination. In patients with Parkinson's disease, the cells that produce dopamine die and the amount of dopamine in the brain decreases. Rotigotine stimulates the brain as dopamine would, so that patients can control their movement and have fewer of the signs and symptoms of Parkinson's disease, such as stiffness and slowness of movement.

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The way rotigotine works in restless-legs syndrome is not fully understood. The syndrome is thought to be caused by problems in the way dopamine works in the brain, which may be improved by rotigotine.

What did the company present to support its application?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Neupro, and did not need to be repeated for Rotigotine Mylan.

As for every medicine, the company provided studies on the quality of Rotigotine Mylan, including studies on how the patch sticks to the skin. The company also carried out studies to investigate whether Rotigotine Mylan is 'bioequivalent' to the reference medicine. 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 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 Rotigotine Mylan could not have been approved for the treatment Parkinson's disease and restless-leg syndrome.

The CHMP was concerned that insufficient data had been provided on the quality of the medicine and its manufacturing process. The Committee was also concerned that the studies on how the patch sticks to the skin had only been done in young adults. Since Parkinson's disease usually occurs in people over 60 years, studies in older people would be required because the skin structure changes due to aging.

Therefore, at the time of the withdrawal, the CHMP was of the opinion that the benefits of Rotigotine Mylan 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 would be unable to provide the required additional data in the time available.

The withdrawal letter is available here.

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that there are no ongoing clinical trials with Rotigotine Mylan.