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Withdrawal of the marketing authorisation application for Treprostinil SciPharm Sàrl (treprostinil)

On 5 September 2018, SciPharm Sàrl officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application for a marketing authorisation for Treprostinil SciPharm Sàrl, for the treatment of chronic thromboembolic pulmonary hypertension (high blood pressure in the lungs because of blocked blood vessels).

What is Treprostinil SciPharm Sàrl?

Treprostinil SciPharm Sàrl is a medicine that contains the active substance treprostinil. It was to be available as a solution for infusion (drip) into a vein.

What was Treprostinil SciPharm Sàrl expected to be used for?

Treprostinil SciPharm Sàrl was expected to be used to treat adults with chronic thromboembolic pulmonary hypertension (CTEPH) who cannot have surgery, and in patients whose CTEPH continues or has come back after surgery. In patients with CTEPH, scar tissue around a previous clot blocks the blood vessels that supply the lung and this causes high blood pressure. CTEPH can cause tiredness, chest pain and difficulty breathing, and it limits daily activities, such as walking.

Treprostinil SciPharm Sàrl was designated an 'orphan medicine' (a medicine to be used in rare diseases) on 8 February 2013 for the treatment of CTEPH. Further information on the orphan designation can be found here.

How does Treprostinil SciPharm Sàrl work?

Treprostinil is very similar to prostacyclin, a natural substance in the body that widens blood vessels and prevents blood clotting. In patients with CTEPH, treprostinil was expected to work in the same way as prostacyclin to widen the blood vessels supplying the lungs and prevent blood clots, so lowering the blood pressure in the lungs and improving the symptoms of the disease.

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Medicines containing treprostinil are authorised in the EU for the treatment of another type of high blood pressure in the lungs called pulmonary arterial hypertension.

What did the company present to support its application?

The company provided data from one main study in 105 patients with severe CTEPH who could not have surgery. The study compared the effects of 2 doses of Treprostinil SciPharm Sàrl on the patients' ability to walk for 6 minutes.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while the CHMP was still evaluating the initial documentation provided by the company.

What was the recommendation of the CHMP at that time?

As the CHMP was evaluating the initial documentation provided by the company, it had not yet made any recommendations.

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 its application because it could not provide the requested additional data from laboratory studies within the timetable for the medicine's assessment.

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 consequences for patients currently included in clinical trials.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.