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Withdrawal of application for the marketing authorisation of Apremilast Viatris (apremilast)

Viatris Limited withdrew its application for a marketing authorisation of Apremilast Viatris for the treatment of plaque psoriasis, active psoriatic arthritis and mouth ulcers caused by Behçet's disease.

The company withdrew the application on 17 September 2024.

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

Apremilast Viatris was developed as a medicine used in adults to treat:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin) in patients who have not responded to or cannot use other systemic (affecting the whole body) treatments for psoriasis, such as ciclosporin, methotrexate or PUVA (psoralen plus ultraviolet-A).
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in patients who cannot take or who have not responded well enough to other treatments called disease-modifying antirheumatic drugs (DMARDs);
- mouth ulcers caused by Behçet's disease, an inflammatory disease that may affect many parts of the body.

Apremilast Viatris contains the active substance apremilast and was to be available as tablets taken by mouth.

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

How does Apremilast Viatris work?

The active substance in Apremilast Viatris and Otezla, apremilast, blocks the action of an enzyme inside cells called phosphodiesterase 4 (PDE4). This enzyme plays a role in triggering the production of messenger molecules in the immune system (the body's natural defences) called cytokines, which are involved in the inflammation and other processes that cause psoriasis, psoriatic arthritis and Behçet's

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disease. By blocking PDE4, apremilast reduces the level of these cytokines in the body, and so reduces the inflammation and other symptoms of psoriasis, psoriatic arthritis and Behçet's disease.

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 Apremilast Viatris. The company also provided studies to investigate whether Apremilast Viatris is 'bioequivalent' to the reference medicine Otezla. 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. 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 Apremilast Viatris could not have been authorised for the treatment of plaque psoriasis, active psoriatic arthritis and mouth ulcers caused by Behçet's disease.

The Agency considered that bioequivalence with the reference medicine was not demonstrated as the study results showed differences in the extent and rate of absorption (how much of a medicine is absorbed into the blood after it is taken and how quickly this occurs).

Therefore, at the time of the withdrawal, the Agency's opinion was that the medicine could not have been authorised based on the data from the company.

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 as EMA considered that the data provided did not allow it to draw conclusions on the bioequivalence of the medicine.

Does this withdrawal affect patients in clinical trials?

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

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