EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Refusal of a change to the marketing authorisation for Temybric Ellipta (fluticasone furoate / umeclidinium / vilanterol)

The European Medicines Agency has recommended the refusal of a change to the marketing authorisation for Temybric Ellipta. The change concerned an extension of indication to add treatment of patients with asthma.

The Agency issued this opinion on 25 February 2021.

The company that applied for the change to the authorisation, GlaxoSmithKline Trading Services Limited, may ask for re-examination of the opinion within 15 days of receiving the opinion.

What is Temybric Ellipta and what is it used for?

Temybric Ellipta is a medicine for relieving the symptoms of moderate to severe chronic obstructive pulmonary disease (COPD). COPD is a long-term disease in which the airways and air sacs inside the lungs become damaged or blocked, leading to difficulty breathing.

Temybric Ellipta has been authorised in the EU since June 2019.

It contains the active substances fluticasone furoate, umeclidinium and vilanterol. It is available as an inhalation powder, which the patient inhales through the mouth using an inhaler device.

Further information on Temybric Ellipta's uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/temybric-ellipta

What change had the company applied for?

The company applied for an extension of indication to add the maintenance treatment in adult patients with asthma whose symptoms could not be controlled well enough with a combination of inhaled corticosteroid and a long-acting beta-2 agonist.

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How does Temybric Ellipta work?

Temybric Ellipta contains three active substances, which work in different ways to widen the airways and improve breathing.

Fluticasone furoate is a corticosteroid. It works in a similar way to naturally occurring corticosteroid hormones, reducing the activity of the immune system by attaching to receptors (targets) in various types of immune cells. This reduces the release of substances involved in the inflammation process, such as histamine, thereby reducing inflammation and helping to keep the airways clear and allowing the patient to breathe more easily.

Umeclidinium is a muscarinic receptor antagonist. It works by blocking muscarinic receptors, which are involved in the contraction of muscles. When umeclidinium is inhaled, it causes the muscles of the airways to relax.

Vilanterol is a long-acting beta-2 agonist. It works by attaching to beta-2 receptors in some types of muscle cells. When inhaled, vilanterol activates the beta-2 receptors in the airways. This causes the muscles of the airways to relax, helping to keep the airways open and allowing the patient to breathe more easily.

What did the company present to support its application?

The company presented one main study comparing Temybric Ellipta with a combination of only fluticasone furoate and vilanterol in 2,436 patients. These patients all had asthma that was not well controlled despite treatment with inhaled corticosteroids and a long-acting beta-2 agonist. The study looked at the change in FEV_1 (the maximum volume of air they could breathe out in one second) after 24 weeks of treatment.

What were the main reasons for refusing the change to the marketing authorisation?

The European Medicines Agency considered that an improvement in lung function alone is not enough to show that a medicine is suitable for treating asthma. The main study did not clearly show that the medicine was effective at reducing asthma attacks or controlling symptoms.

Therefore, the Agency's opinion was that the benefits of Temybric Ellipta in the treatment of asthma did not outweigh its risks. Hence, the Agency recommended refusing the change to the marketing authorisation.

Does this refusal affect patients in clinical trials?

The company informed the Agency that there are no ongoing studies with Temybric Ellipta in asthma patients in the EU.

What is happening with Temybric Ellipta for treatment of COPD?

There are no consequences for Temybric Ellipta in COPD.