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Review started of Tredaptive, Pelzont and Trevaclyn (nicotinic acid/laropiprant)

The European Medicines Agency has started a review of Tredaptive, Pelzont and Trevaclyn, identical medicines which contain the active substances laropiprant and nicotinic acid. These medicines are used to treat adults with dyslipidaemia (abnormally high levels of fat in the blood), particularly 'combined mixed dyslipidaemia' and 'primary hypercholesterolaemia'. Patients with combined mixed dyslipidaemia have high levels of low-density-lipoprotein (LDL) cholesterol (also known as 'bad cholesterol') and triglycerides (a type of fat), and low levels of high-density-lipoprotein (HDL) cholesterol (also known as 'good cholesterol'). Patients with primary hypercholesterolaemia have high blood cholesterol levels with no identifiable cause.

The review is being carried out following the preliminary results of a large long-term study involving over 25,000 patients, looking at the effects of adding this medicine to statins (standard medicines used to reduce cholesterol) compared with statin treatment alone. The preliminary results indicate that giving the medicine together with statin treatment did not further reduce the risk of major vascular events (serious problems with the heart and blood vessels, including heart attack and stroke) compared with statins alone. In the preliminary results, a higher frequency of non-fatal but serious side effects of various kinds was also seen in patients taking the medicine than in patients only taking statins.

The European Medicines Agency will assess the data in relation to these safety concerns and their impact on the benefit-risk balance of Tredaptive, Pelzont and Trevaclyn, and will issue an opinion on whether the marketing authorisations for these medicines should be maintained, varied, suspended or withdrawn across the EU. An opinion is expected in January 2013.

More about the medicine

Tredaptive, Pelzont and Trevaclyn are identical medicines which were authorised throughout the EU on 3 July 2008. They are marketed by the same company, Merck Sharp & Dohme Ltd. They are available

as modified release tablets (meaning that the two active substances are released at different rates over a few hours), containing 1000 mg nicotinic acid and 20 mg laropiprant.

The medicine is normally given in combination with a statin when the effectiveness of a statin alone is inadequate. It may be used alone only in patients who cannot take statins.

The two active substances, nicotinic acid and laropiprant, work in different ways. Nicotinic acid is a naturally occurring substance used in low doses as a vitamin (known as niacin or vitamin B₃). In higher doses, it reduces the levels of fat in the blood via a mechanism that is not fully understood. It was first used as a medicine to modify blood fat levels in the mid-1950s, but its use has been limited because of its side effects, particularly flushing (reddening of the skin). Laropiprant has no effect on cholesterol but it reduces flushing, by blocking the receptors for a substance called 'prostaglandin D2' which is released when nicotinic acid is taken and which dilates (widens) the blood vessels in the skin.

More about the procedure

The review of Tredaptive, Pelzont and Trevaclyn has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004. It will follow the procedural steps laid out in Article 107i of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendation will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for all questions concerning medicines for human use, which will adopt a final opinion. An opinion is expected to be adopted in January 2013.