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Press Office

Press release

European Medicines Agency starts review of Tredaptive, Pelzont and Trevaclyn

Agency issues interim advice

The European Medicines Agency has started a review of the safety and efficacy of Tredaptive, Pelzont and Trevaclyn, identical medicines that are used to treat adults with dyslipidaemia (abnormally high levels of fat in the blood), particularly combined mixed dyslipidaemia and primary hypercholesterolaemia.

The review was triggered because the Agency was informed by the pharmaceutical company Merck, Sharp & Dohme of the preliminary results of a large, long-term study comparing the clinical effects of adding these medicines to statins (standard medicines used to reduce cholesterol) with statin treatment alone. The study raises questions about the efficacy of the medicine when added to statins, as this did not reduce the risk of major vascular events (serious problems with the heart and blood vessels, including heart attack and stroke) compared with statin therapy alone. In addition, in the preliminary results a higher frequency of non-fatal but serious side effects was seen in patients taking the medicines than in patients only taking statins.

The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) will assess the data and make a recommendation to the Committee on Medicinal Products for Human Use (CHMP), which will issue an opinion on the regulatory action required. An opinion is expected in January 2013.

While the review is ongoing, the Agency recommends that no new patients should be started on treatment with these medicines or enrolled in clinical trials involving these medicines, pending the outcome of the Agency's assessment.

Patients currently using Tredaptive, Pelzont or Trevaclyn should not stop their treatment. Patients who have any questions should speak to their doctor at their next appointment.

Healthcare professionals in the European Union (EU) will receive a letter outlining the updated information on the use of these medicines.

This review of Tredaptive, Pelzont and Trevaclyn has been initiated by the European Commission and will be considered by the PRAC and CHMP at their January 2013 meetings. This is the first referral under Article 20 since the entry into force of the new pharmacovigilance legislation in July 2012. This type of procedure is triggered for medicines that have been authorised via the centralised procedure.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Tredaptive, Pelzont and Trevaclyn are identical medicines which were authorised throughout the EU on 3 July 2008. They contain the active substances laropiprant and nicotinic acid. They are marketed by the same company, Merck Sharp & Dohme Ltd.
3. The review 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.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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