IRISH MEDICINES BOARD

Notice Information: - 3rd Party Publications 18 January 2013

Part 1. Product Information

a)	Title:	European Medicines Agency confirms recommendation to suspend Tredaptive, Pelzont and Trevaclyn
b)	Product Name/Type:	Tredaptive, Pelzont, Trevaclyn
c)	Active Substance:	Nicotinic acid/laropiprant

Part 2. Problem/Issue

a)	Problem/Issue:	The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has confirmed the recommendation to suspend the marketing authorisations of Tredaptive, Pelzont and Trevaclyn (nicotinic acid/laropiprant) used to treat adults with dyslipidaemia (abnormally high levels of fats such as triglycerides and cholesterol). The CHMP decision follows the recent recommendation by the Pharmacovigilance Risk Assessment Committee (PRAC) to suspend these medicines. The marketing authorisation holder, Merck Sharp and Dohme Ltd, has, in the meantime, announced that it is taking steps to suspend availability of the medicines across the European Union.

Part 3. Action to be taken

a)	Action to be taken:	The CHMP encourages patients currently taking these medicines to make a non-urgent appointment with their doctor to discuss their treatment. Doctors should no loonger prescribe Tredaptive, Pelzont and Trevaclyn and should review patients' treatment options.

Part 4. Enquiries

a)	All enquiries should be made to:	For full EMA statment please refer to link below: European Medicines Agency confirms recommendation to suspend Tredaptive, Pelzont and Trevaclyn - press release Please see previous publications regarding this matter: European Medicines Agency (EMA) announces a review of Tredaptive, Pelzont and Trevaclyn European Medicines Agency - press release Tredaptive (nicotinic acid/laropiprant) - Letter to healthcare professionals Irish Medicines Board communication on PRAC recommendation on Tredaptive