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Human Medicines Development and Evaluation

Public statement on

Trevaclyn (nicotinic acid/laropiprant)

Withdrawal of the marketing authorisations in the European Union

On the 3 July 2008 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal products Trevaclyn (nicotinic acid/laropiprant), which had been approved for the treatment of dyslipidaemia, particularly in adult patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in adult patients with primary hypercholesterolaemia (heterozygous familial and non-familial).

The marketing authorisation holder (MAH) responsible for Trevaclyn was Merck Sharp & Dohme Ltd. The European Commission was notified by a letter dated 20 March 2013 of the MAH's decision to voluntarily withdraw the marketing authorisations. This followed the CHMP' recommendation to suspend the marketing authorisations of these products on 17 January 2013. None of the products are currently marketed in any EU country.

On 10 April 2013 the European Commission issued a decision to withdraw the marketing authorisations for Trevaclyn.

Pursuant to this decision the European Public Assessment Reports for Trevaclyn will be updated to reflect the fact that the marketing authorisations are no longer valid.

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