7 March 2013
EMA/PRAC/138313/2013

PRAC List of questions

To be addressed by the marketing authorisation holders for nicotinic acid and related substances indicated for the treatment of lipid disorders

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1366

INN: Nicotinic acid, acipimox and xantinol nicotinate

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The marketing authorisation holders (MAHs) for medicinal products containing nicotinic acid and related substances indicated for the treatment of lipid disorders are requested to provide the following:

1. Please provide information on how your product is used, including:

    - Information on the current marketing status of your product, including information on approved indications(s), recommended doses, treatment duration, contraindications, warnings and precautions included in the summary of product characteristics;

    - Information on sales figures and estimated patient exposure for your product. This should include a yearly breakdown of sales and exposure over the last 10 years for each EU Member State;

    - An analysis of usage patterns for your product in the EU, and data on the way your product is used in clinical practice, including information on patient populations, daily doses, duration of treatment and concomitant treatments.

2. In light of the recent data from the HPS2-THRIVE study that lead to the suspension of the centrally-authorised products Tredaptive, Trevaclyn and Pelzont containing a fixed combination of nicotinic acid and laropiprant, due to an unfavourable benefit-risk balance, please submit a detailed benefit-risk analysis of your product.

    The analysis should take into account all available data including the new data from the HPS2-THRIVE study as well as other relevant data from clinical and epidemiological studies, PSUR data and other sources providing information on the safety profile of your product and evidence of benefit including effects on mortality and cardiovascular outcomes.

    The analysis should include a discussion on patient populations at special risk, patient populations that might specifically benefit from the drug and patient populations for which the benefit-risk balance of your product is considered positive.