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

Procedure No: EMEA/H/A-31/1366

Substances related to nicotinic acid (acipimox) indicated for the treatment of lipid disorders

Divergent statement

The undersigned member of CMDh did not agree with the CMDh's position recommending that the marketing authorisations of acipimox-containing products should be varied as stated by the CMDh.

The reasons for this divergent opinion were as follows:

For most patients with dyslipidaemia, the therapeutic needs are theoretically covered by the use of statins. For patients who are insufficiently controlled by statins or who cannot tolerate them, there are treatment alternatives.

Before the HPS2-THRIVE results, in the absence of morbidity/mortality data, nicotinic acid was to be considered under the category of symptomatic treatment for dyslipidaemia.

The HPS2-THRIVE trial results were very awaited especially as the AIM-HIGH trial, which compared the combined nicotinic acid/simvastatin with simvastatin alone, failed to demonstrate additional cardiovascular benefit of nicotinic acid among patients with ischemic heart disease.

In the light of HPS2-THRIVE results, the role of nicotinic acid in prevention of cardiovascular disease appears strongly questionable and could not be raised in the absence of data from cardiovascular prevention trials documenting adequately the safety and the efficacy of nicotinic acid.

Taking all these aspects and the safety profile of the product into account, the member considered that the benefit/risk of acipimox-containing products is negative, even in a restricted indication.

CMDh member expressing a divergent position:

Virginie Bacquet (FR)	18 December 2013	Signature: ……