European Medicines Agency

London, 29 July 2004
EMEA/CHMP/1268/04/Final

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION

PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Lopid and associated names (See Annex I)

International Non-Proprietary Name (INN): Gemfibrozil

BACKGROUND INFORMATION

Gemfibrozil is a serum-lipid lowering agent belonging to the family of the non-halogenated phenoxypentanoic acid derivatives.

Different Summaries of Product Characteristics (SPC) had been authorised, based on national, divergent decisions from the authorisations in the EU Member States. On 6 January 2003, the European Commission presented to the EMEA (see Annex 1) a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the national SPCs of the medicinal product Lopid and associated names.

The referral procedure started on 23 January 2003. The CPMP having considered the Rapporteur and the Co-Rapporteur assessment reports, the scientific discussion within the Committee and the comments from the Marketing Authorisation Holders (MAH), was of the opinion that the benefit/risk ratio of Lopid is considered to be positive in the following indications:

Lopid is indicated as an adjunct to diet and other non-pharmacological treatment (e.g. exercise, weight reduction) for the following:

Treatment of dyslipidemia
Mixed dyslipidaemia characterised by hypertriglyceridaemia and/or low HDL-cholesterol. Primary hypercholesterolaemia, particularly when a statin is considered inappropriate or is not tolerated.

Primary prevention
Reduction of cardiovascular morbidity in males with increased non-HDL cholesterol and at high risk for a first cardiovascular event, particularly when a statin is considered inappropriate or is not tolerated (see section 5.1).

The CPMP gave a positive opinion on 24 March 2004 recommending the harmonisation of the SPC for Lopid and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC in Annex III.

A Decision was issued by the European Commission on **29 July 2004.**

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