The European Agency for the Evaluation of Medicinal Products

London, 2 March 2004
EMEA/CPMP/6214/03/Final

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

SUMMARY INFORMATION ON REFERRAL OPINION

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

Pravachol and associated names (See Annex I)

International Non-Proprietary Name (INN): Pravastatin

BACKGROUND INFORMATION

Pravastatin is a hydrophilic inhibitor of the hydroxy-methyl-glutaryl conenzyme A reductase (HMG-CoA reductase). This enzyme catalyses the initial rate-limiting step in cholesterol biosynthesis (the reduction of 3-hydroxy-3-methyl-glutaryl-Coenzyme A into mevalonic acid). Pravastatin is a serum lipid-lowering agent.

Different Summaries of Product Characteristics (SPC) had been authorised, based on national, divergent decisions from the authorisations in the EU Member States. On 8 November 2002, 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 Pravachol and associated names.

The referral procedure started on 21 November 2002. 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 pravastatin is considered to be favourable in the following indications:

Hypercholesterolemia

Treatment of primary hypercholesterolemia or mixed dyslipidaemia, as an adjunct to diet, when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.

Primary prevention

Reduction of cardiovascular mortality and morbidity in patients with moderate or severe hypercholesterolemia and at high risk of a first cardiovascular event, as an adjunct to diet (see section 5.1).

Secondary prevention

Reduction of cardiovascular mortality and morbidity in patients with a history of myocardial infarction or unstable angina pectoris and with either normal or increased cholesterol levels, as an adjunct to correction of other risk factors (see section 5.1).

Post transplantation

Reduction of post transplantation hyperlipidaemia in patients receiving immunossupressive therapy following solid organ transplantation. (see sections 4.2, 4.5 and 5.1).

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The CPMP gave a positive opinion on 20 November 2003 recommending the harmonisation of the SPC for Pravachol 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 **2 March 2004.**

