European Medicines Agency

London, 16 January 2004
CPMP/423/04

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

SUMMARY INFORMATION ON REFERRAL OPINION

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

Zestril and associated names (See Annex I)

International Non-Proprietary Name (INN): lisinopril

BACKGROUND INFORMATION

Zestril contains an active substance named lisinopril, an angiotensin converting enzyme inhibitor. The mechanism through which lisinopril lowers blood pressure is believed to be primarily via the suppression of the renin-angiotensin-aldosterone system. Zestril (a medicinal product containing lisinopril) was first authorised in 1984 in the treatment of essential hypertension and renovascular hypertension and in the treatment of congestive heart failure as adjunctive treatment with diuretics and, where appropriate, digitalis.

Different Summaries of Product Characteristics (SPC) had been authorised, based on national, divergent decisions from the authorisations in the EU Member States. On 18 July 2002, The Netherlands presented to the EMEA (See Annex I) a referral under Article 30 of Directive 2001/83/EEC.

The referral procedure started on 24 July 2002 in order to resolve divergences amongst the nationally authorised SPCs and to harmonise the SPCs within the Member States and Norway.

During its September 2003 meeting, 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 lisinopril is considered to be favourable in the following indications:

Treatment of hypertension, symptomatic heart failure, acute myocardial infarction (for the short-term 6 weeks), treatment of haemodynamically stable patients within 24 hours of an acute myocardial infarction) and for the renal complications of diabetes mellitus (treatment of renal disease in hypertensive patients with type 2 diabetes mellitus and incipient nephropathy).

A positive opinion was therefore adopted on 25 September 2003, recommending the harmonisation of the SPC for Zestril 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.

The European Commission issued a Decision on 16 January 2004.

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