The European Agency for the Evaluation of Medicinal Products

London, 4 December 2003
CPMP/32703/03

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS (CPMP)

SUMMARY INFORMATION ON REFERRAL OPINION PERSUANT TO ARTICLE 30 OF COUNCIL DERECTIVE 2001/83/EC FOR

Coversyl and associated names (See Annex I)

International Non-Proprietary Name (INN): perindopril

BACKGROUND INFORMATION

Perindopril is a specific, competitive inhibitor of Angiotensin I-Converting Enzyme (ACE), belonging to the category of ACE-inhibitors. The beneficial effects of ACE-inhibitors appear to result primarily from the suppression of the plasma renin-angiotensin-aldosteron system.

Perindopril was initially approved in 1988, for the treatment of hypertension throughout the European Union, Iceland and Norway. From the authorisations in Member States, different Summaries of Product Characteristics (SPC) had been issued, based on national, divergent decisions.

On 6 January 2003, the European Commission referred the matter to the EMEA under Article 30 of Directive 2001/83/EC[1]. The referral procedure started on 23 January 2003 in order to resolve divergencies amongst the nationally authorised SPCs and to harmonise the SPCs within the Member States, Norway and Iceland.

The Rapporteur and Co-Rapporteur appointed were: Dr E. Abadie and Pharm. M. Avgerinos, respectively. Written explanations were provided by the Marketing Authorisation Holder on 18 March 2003 and 5 June 2003.

During its July 2003 meeting, the CPMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio of perindopril is considered favourable for treatment of hypertension and symptomatic heart failure and that the SPC should be amended. A positive opinion was therefore adopted on 24 July 2003, recommending the harmonisation of the SPC for Coversyl 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 final opinion was converted into a Decision by the European Commission on 4 December 2003.

[1] Corresponding to Article 11 of Directive 75/319/EEC, for referrals presented before 18 December 2001

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