European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

7 November 2005
CHMP/408150/2005

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
OPINION FOLLOWING AN ARTICLE 6 (12) REFERRAL

Perindopril tert-butylamine salt

International Non-Proprietary Name (INN): **Perindopril**

BACKGROUND INFORMATION*

Coversyl and associated names contain perindopril, a well-known, potent angiotensin converting enzyme inhibitor (ACE-I), currently indicated for the treatment of *hypertension* and *symptomatic heart failure.* It is licensed in the EU through the Mutual Recognition Procedure (MRP) and was first marketed in France in 1988 as Coversyl 2 and 4 mg. It is currently marketed in the entire European Union and world-wide in more than 10 countries, including USA and Japan.

This Referral procedure relates to a request for Arbritation concerning a type II variation for a new indication in the "*reduction of risk of cardiovascular events in patients with stable coronary artery disease"*. At the end of the MRP procedure there was a discrepancy between different MS regarding the wording of the indication that adequately reflects the clinical data submitted by the company, and an official referral for arbitration according to Article 6(12) of Commission Regulation EC No 1084/2003, as amended, was notified by the Netherlands to the CHMP on 17.03.2005.

The arbitration procedure was discussed and initiated by the CHMP at its plenary meeting in April 2005, and a Rapporteur (Dr Gonzalo Calvo Rojas) and Co-Rapporteur (Dr. Gottfried Kreutz) were appointed. The questions identified pertained to the inclusion of a specific group of revascularised patients in the proposed indication, the justification of the beneficial effect of perindopril beyond a mere reduction of myocardial infarction, and an overall justification of the claimed indication based on the results of relevant published literature on other ACE-Is in terms of patients to be included and goals of therapy. The company responded to these points on 20 May 2005.

Based on the evaluation of the currently available data and the (Co-)Rapporteurs' assessment reports, the CHMP adopted an opinion on 27 July 2005 recommending the variation of the Marketing Authorisations for the addition of the following new indication:
Stable coronary artery disease:
Reduction of risk of cardiac events in patients with a history of myocardial infarction and/or revascularisation.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II and the amended Summary of Product Characteristics in Annex III.
The final opinion was converted into a Decision by the European Commission on 7 November 2005.

Notes:
The information given in this document and Annexes reflect only the CHMP Opinion dated 27 July 2005.

The Member States competent authorities will continue to keep the product under regular review.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.eudra.org http://www.eudra.org/emea.html