European Medicines Agency
Evaluation of Medicines for Human Use

London, 3 September 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Cozaar and associated names

International Non-Proprietary Name (INN): losartan

BACKGROUND INFORMATION

Cozaar and associated names, 12,5 mg, 25mg, 50 mg, 100 mg, film-coated tablets is an orally active angiotensin II (Ang- II) receptor antagonist, losartan, acting on the AT1 receptor subtype, thus blocking the effect of Ang-II in the renin angiotensin system (RAS) cascade. Losartan is indicated for the treatment of hypertension. Losartan may also delay progression of diabetic nephropathy and is also indicated for the reduction of renal disease progression in patients with type 2 diabetes, and microalbuminuria (>30 mg/24 hours) or proteinuria (>900 mg/24 hours).

On 23 February 2007, Denmark presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the nationally authorised summaries of product characteristics, package leaflet and labelling of the medicinal product Cozaar and associated names for the following indications: Treatment of essential hypertension; Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus with proteinuria > 0.5 g/day as part of an antihypertensive treatment; Reduction of risk of stroke in hypertensive patients with left ventricular hypertrophy documented by ECG; Treatment of chronic heart failure (in patients ≥ 60 years), when treatment with ACE inhibitors is not considered suitable due to incompatibility, especially cough, or contraindication.

The procedure started on 22 March 2007. The Marketing Authorisation Holder provided supplementary information on 23 July 2007.

During its 21 - 24 April 2008 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package leaflet was acceptable and that they should be amended.

The CHMP gave a positive opinion on 24 April 2008 recommending the harmonisation of the SPC, labelling and package leaflet for Cozaar 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, labelling and package leaflet in Annex III.

A Decision was issued by the European Commission on 3 September 2008.

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