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 Comp and associated names

International Non-Proprietary Name (INN): losartan + hydrochlorothiazide

BACKGROUND INFORMATION

Cozaar Comp and associated names, 50/12.5 mg; 100/12.5 mg; 100/25 mg, film coated tablets is a fixed dose combination of losartan and hydrochlorothiazide. Losartan is an orally active angiotensin II (Ang- II) receptor antagonist acting on the AT1 receptor subtype, thus blocking the effect of Ang-II in the renin angiotensin system (RAS) cascade. Hydrochlorothiazide (HCTZ) is a thiazide diuretic which has also been used as an antihypertensive agent. The losartan/hydrochlorothiazide combination is indicated for the treatment of hypertension in patients whose blood pressure is not adequately controlled on losartan or hydrochlorothiazide.

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 Comp. and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Cozaar Comp. and associated names approved across EU Member States, with respect to the following indications: Treatment of hypertension in patients whose blood pressure is not adequately controlled on losartan or hydrochlorothiazide; As first step treatment in patients with moderate to severe hypertension and in patients with high or very high cardiovascular risk; Reduction of cardiovascular morbidity and mortality in hypertensive patients with left ventricular hypertrophy.

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 Comp. 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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