European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 September 2009
Doc. Ref. EMEA/592212/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
IRBESARTAN/HYDROCHLOROTHIAZIDE TEVA

International Nonproprietary Names (INN): ***irbesartan / hydrochlorothiazide***

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Irbesartan/Hydrochlorothiazide Teva 150/12.5, 150/25 and 300/25 mg film-coated tablets, intended for: "Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone". The applicant for this medicinal product is Teva Pharma B.V.

The active substances of Irbesartan/Hydrochlorothiazide Teva are *irbesartan*, an angiotensin II antagonist, plain, medicinal product acting as a selective angiotensin II receptor (type AT_1) antagonist and *hydrochlorothiazide*, a thiazide diuretic (C09CA04).

Irbesartan/Hydrochlorothiazide Teva is a generic of CoAprovel which has been authorised in the EU since 15 October 1998. Studies have demonstrated the satisfactory quality of Irbesartan/Hydrochlorothiazide Teva, and its bioequivalence with CoAprovel. A question-and-answer document on generic medicines can be found here.

The approved indication is: "Treatment of essential hypertension. This fixed dose combination is indicated in patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone".

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Irbesartan/Hydrochlorothiazide Teva and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu