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

London, 23 July 2009
Doc. Ref. EMEA/CHMP/456015/2009

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

International Nonproprietary Name (INN): ***irbesartan***

On 23 July 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 Teva, 75 mg, 150 mg and 300 mg, film-coated tablets intended for: "Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen". The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Irbesartan Teva is *irbesartan*, an angiotensin II antagonist, plain, medicinal product (C09CA04) acting as a selective angiotensin-II receptor (type AT1) antagonist.

Irbesartan Teva is a generic of Aprovel which has been authorised in the EU since 27 August 1997. Studies have demonstrated the satisfactory quality of Irbesartan Teva, and its bioequivalence with Aprovel. A question-and-answer document on generic medicines can be found here.

The approved indication is:
"Treatment of essential hypertension. Treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen".

A pharmacovigilance plan for Irbesartan Teva, as for all medicinal products, will be implemented as part of the marketing authorisation.

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 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.

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