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

London, 19 November 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
TELMISARTAN TEVA

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

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP), having considered new information, adopted a positive opinion,*** recommending to grant a marketing authorisation for the medicinal product Telmisartan Teva 20 mg, 40 mg, 80 mg tablets intended for use in treatment of essential hypertension in adults. The Applicant for this medicinal product is Teva Pharma B.V

The active substance of Telmisartan Teva is *telmisartan*, an Angiotensin II-antagonists medicinal product *(ATC Code*: C09CA07) that displaces angiotensin II from its binding site at the AT_1 receptor subtype, which is responsible for the known actions of angiotensin II.

Telmisartan Teva is a generic of Micardis, which has been authorised in the EU since 16 December 1998. Studies have demonstrated the satisfactory quality of Telmisartan Teva, and its bioequivalence with Micardis. A question-and-answer document on generic medicines can be found here.

The approved indication is: Treatment of essential hypertension in adults

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 Telmisartan 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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