21 July 2011
EMA/CHMP/522766/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Telmisartan Teva Pharma

telmisartan

On 21 July 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Telmisartan Teva Pharma, 20 mg, 40 mg and 80 mg, tablets intended for the treatment of essential hypertension in adults. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Telmisartan Teva Pharma 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 Pharma 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 Pharma, 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 (SmPC), 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 there to be a favourable benefit to risk balance for Telmisartan Teva Pharma and therefore recommends the granting of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu