17 February 2011
EMA/124454/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Sprimeo HCT

aliskiren / hydrochlorothiazide

On 17 February 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 Sprimeo HCT, 150 mg/12.5 mg, 150 mg/25 mg, 300 mg/12.5 mg and 300 mg/25 mg, film-coated tablet, intended for the treatment of essential hypertension (high blood pressure) in adults. The applicant for this medicinal product is Novartis Europharm Ltd. 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 substances of Sprimeo HCT (ATC code: C09XA52) are aliskiren hemifumarate, a renin inhibitor, and hydrochlorothiazide, a diuretic. Sprimeo HCT is effective in lowering blood pressure in patients with essential hypertension, especially in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone. Aliskiren inhibits human renin, the enzyme responsible for the conversion of angiotensinogen to angiotensin I. Therefore the final production of the potent vasoconstrictor angiotensin II is inhibited by blocking the renin system at its very origin. Hydrochlorothiazide is a thiazide diuretic acting on the renal distal convoluted tubule. Thiazides affect the electrolyte re-absorption mechanisms directly by increasing sodium and chloride excretion to an approximately equal extent, and indirectly by this diuretic action reducing plasma volume.

Sprimeo HCT is the same medicinal product as Rasilez HCT, which is already authorised in the European Union. The marketing authorisation holder for Rasilez HCT has agreed that its scientific data on Rasilez HCT can be used to assess Sprimeo HCT.

The benefit with Sprimeo HCT is its blood pressure lowering effect achieved by combination of two antihypertensive compounds in a single tablet formulation to control blood pressure in patients with essential hypertension. The combination of the two active substances has an additive effect, reducing the blood pressure more than either medicine alone. The most common side effect of Sprimeo HCT is diarrhoea. When aliskiren is taken as monotherapy, side effects included diarrhoea, rush, angioedema

[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.

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and cough. Furthermore, the adverse events for the hydrochlorothiazide may include: gastrointestinal irritations, weakness or headache.

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

The approved indication is:

"Treatment of essential hypertension in adults.

Sprimeo HCT is indicated in patients whose blood pressure is not adequately controlled on aliskiren or hydrochlorothiazide used alone.

Sprimeo HCT is indicated as substitution therapy in patients adequately controlled with aliskiren and hydrochlorothiazide, given concurrently, at the same dose level as in the combination."

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 Sprimeo HCT and therefore recommends the granting of the marketing authorisation.