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

London, 23 July 2009
Doc.Ref. EMEA/CHMP/471511/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION [*]
for
DAFIRO HCT

International Nonproprietary Name (INN): ***amlodipine besylate / valsartan / hydrochlorothiazide***

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 Dafiro HCT, amlodipine/valsartan/hydrochlorothiazide, 5 mg/160 mg/12.5 mg, 10 mg/160 mg/12.5 mg, 5 mg/160 mg/25 mg, 10 mg/160 mg/25 mg and 10 mg/320 mg/25 mg, film-coated tablet, intended for the treatment of essential hypertension in adults. The applicant for this medicinal product is Novartis Europharm Limited.

The active substances of Dafiro HCT (ATC code: C09DX01) are amlodipine besylate, valsartan and hydrochlorothiazide**.** Dafiro HCT combines three antihypertensive compounds with complementary mechanisms to control blood pressure in patients with essential hypertension: amlodipine belongs to the calcium antagonist class, valsartan to the angiotensin II antagonist class and hydrochlorothiazide belongs to the thiazide diuretics. Dafiro HCT is effective in lowering blood pressure in the treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide, taken either as three single-component formulations or as a dual-component and a single-component formulation. Patients should be controlled on stable doses of the monocomponents taken at the same time and the dose of Dafiro HCT should be based on the doses of the individual components of the combination at the time of switching.

The benefits with Dafiro HCT are its blood pressure lowering effect achieved by combination of three antihypertensive compounds in a single formulation to control blood pressure in patients with essential hypertension. The most common side effects of Dafiro HCT are dizziness, peripheral oedema, and headache. When amlodipine is taken as monotherapy, dizziness, headache or oedema can occur. Furthermore, adverse events of valsartan may include fatigue and abdominal discomfort, and adverse events of hydrochlorothiazide may include gastrointestinal irritations, weakness or headache.

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

The approved indication is: "Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation."

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

[*] 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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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 Dafiro HCT and therefore recommends the granting of the marketing authorisation