Variation(s) requested		Type
C.I.4	Variations related to significant modifications of the Summary of Product Characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	II
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- Update of the current paragraph in section 5.1 of the SmPC that provides information on the relative efficacy of valsartan/amlodipine 80/5 mg compared to amlodipine 10 mg in relation to the incidence of oedema. In addition, the MAH took the opportunity to update the SmPC in line with the latest QRD template and to update the contact details of the local representatives in the Package Leaflet.

- Update of section 5.1 of the SmPC with information on efficacy in obese patients based on studies VAA 2401, VAA 2402, VAA 2403, VAA 2404 and VAA US02 (as well as original dossier studies VAA 2201, VAA 2305, VAA 2306, VAA 2307 and VAA 2308).

And the following variation for the following medicinal products was considered not to be acceptable by the CHMP on the following grounds:

This application concerns the following medicinal products:

Medicinal product:	International non-proprietary name:	Presentations:
Dafiro	amlodipine / valsartan	See Annex A
Copalia	amlodipine / valsartan	See Annex A
Exforge	amlodipine / valsartan	See Annex A
Imprida	amlodipine / valsartan	See Annex A

Variation(s) requested		Type
C.I.4	Variations related to significant modifications of the Summary of Product Characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	II

- (*Scope as applied for by the MAH*): Update of section 5.1 of the SmPC with information on efficacy in patients with stage 2 hypertension and black patients based on studies VAA 2402 and VAA 2403.

Grounds for refusal:

Whereas

- The studies submitted by the MAH in support of the variation are not sufficiently robust;
- The studies submitted by the MAH in support of the variation are not in line with the authorised indication;

the CHMP has recommended the refusal of the variation to the terms of the Marketing Authorisation