16 October 2012
EMA/670070/2012
Press Office

Public Statement

Imprida HCT (amlodipine/valsartan/hydrochlorothiazide)

Cessation of validity of the marketing authorisation in the European Union

On 15 October 2009, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Imprida HCT (amlodipine/valsartan/hydrochlorothiazide), indicated for the treatment of essential hypertension. The marketing authorisation holder was notified on the 19 October 2009.

Imprida HCT (amlodipine/valsartan/hydrochlorothiazide) had not been marketed in Europe since this initial marketing authorisation. In accordance with article 14(4) of Regulation (EC) No 726/2004 ('sunset clause'), the marketing authorisation of a medicinal product lapses if the product has never been marketed in one of the Member States within three years of its initial authorisation.

Because of this, from 20 October 2012, the marketing authorisation for Imprida HCT is no longer valid.

Pursuant to the expiry of the marketing authorisation, the European Assessment Report (EPAR) for Imprida HCT will be updated to reflect that the marketing authorisation is no longer valid.

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