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Human Medicines Development and Evaluation

Public statement

Sprimeo HCT (aliskiren/hydrochlorothiazide)

Withdrawal of the marketing authorisation in the European Union

On 23 June 2011 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Sprimeo HCT (aliskiren/hydrochlorothiazide). Sprimeo HCT was approved for the treatment of essential hypertension.

The marketing authorisation holder (MAH) responsible for Sprimeo HCT was Novartis Europharm Ltd.

The European Commission was notified by letter dated 10 June 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Sprimeo HCT for commercial reasons.

On 6 July 2012 the European Commission issued a decision to withdraw the marketing authorisation for Sprimeo HCT. Pursuant to this decision the European Public Assessment Report for Sprimeo HCT will be updated to reflect the fact that the marketing authorisation is no longer valid.

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