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Human Medicines Development and Evaluation

Public statement

Sprimeo (aliskiren)

Withdrawal of the marketing authorisation in the European Union

On 22 August 2007 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Sprimeo (aliskiren). Sprimeo was approved for the treatment of essential hypertension.

The marketing authorisation holder (MAH) responsible for Sprimeo 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 for commercial reasons.

On 4 July 2012 the European Commission issued a decision to withdraw the marketing authorisation for Sprimeo. Pursuant to this decision the European Public Assessment Report for Sprimeo will be updated to reflect the fact that the marketing authorisation is no longer valid.

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