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Human Medicines Development and Evaluation

Public statement

Enviage (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 Enviage (aliskiren). Enviage is approved for the treatment of essential hypertension.

The marketing authorisation holder (MAH) responsible for Enviage was Novartis Europharm Ltd.
The European Commission was notified by letter dated 4 May 2010 of the MAH's decision to voluntarily withdraw the marketing authorisation for Enviage for commercial reasons.

As of 4 May 2010, Enviage has not been marketed anywhere in the European Union and there is no intention to market Enviage in the future. Enviage was an additional application to Rasilez, intended for co-marketing purposes.

The MAH will maintain the Marketing Authorisations for the three other medicinal products containing aliskiren, i.e. Rasilez, Riprazo and Sprimeo.

On 27 September 2010 the European Commission issued a decision to withdraw the marketing authorisation for Enviage. Pursuant to this decision the European Public Assessment Report for Enviage will be updated to reflect that the marketing authorisation is no longer valid.

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