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Human Medicines Development and Evaluation

Public statement on Riprazo

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 Riprazo, (aliskiren), which had been approved for treatment of essential hypertension.

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

On 24 January 2013, the European Commission issued a decision to withdraw the marketing authorisation for Riprazo, following its receipt of a letter dated 18 December 2012 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Riprazo was marketed in the following European countries: Spain (until 31 December 2012) and was not marketed in any other European country.

Pursuant to this decision, the European public assessment report for Riprazo will be updated to reflect that the marketing authorisation is no longer valid.

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