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Human Medicines Development and Evaluation

Public statement

Clopidogrel Hexal (clopidogrel)

Withdrawal of the marketing authorisation in the European Union

On 28 July 2009 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Clopidogrel Hexal (clopidogrel). Clopidogrel Hexal was approved for the prevention of atherothrombotic events in patients with peripherial vascular diseases or who have had a stroke or myocardial infarction.

The marketing authorisation holder (MAH) responsible for Clopidogrel Hexal was Acino Pharma GmbH.

The European Commission was notified by letter dated 11 January 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Clopidogrel Hexal for commercial reasons.

On 09 February 2012 the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel Hexal. Pursuant to this decision the European Public Assessment Report for Clopidogrel Hexal will be updated to reflect the fact that the marketing authorisation is no longer valid.

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