EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Development and Evaluation

Public statement

Clopidogrel Acino Pharma (clopidogrel)

Withdrawal of the marketing authorisation in the European Union

On 21 September 2009 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Clopidogrel Acino Pharma (clopidogrel). Clopidogrel Acino Pharma 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 Acino Pharma 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 Acino Pharma for commercial reasons.

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Assessment Report for Clopidogrel Acino Pharma will be updated to reflect the fact that the marketing authorisation is no longer valid.

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