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Human Medicines Development and Evaluation

Public statement

Clopidogrel Sandoz (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 Sandoz (clopidogrel). Clopidogrel Sandoz 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 Sandoz was Acino Pharma GmbH.

The European Commission was notified by letter dated 9 March 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for Clopidogrel Sandoz for commercial reasons.

On 31 March 2011 the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel Sandoz. Pursuant to this decision the European Public Assessment Report for Clopidogrel Sandoz will be updated to reflect the fact that the marketing authorisation is no longer valid.

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