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Human Medicines Development and Evaluation

Public statement on Clopidogrel ratiopharm

Withdrawal of the marketing authorisation in the European Union

On 23 September 2009, the European Commission issued a marketing authorisation valid throughout the European Union for the generic medicinal product Clopidogrel ratiopharm, which had been approved for:

Clopidogrel is indicated in adults for the prevention of atherothrombotic events in:

- Patients suffering from myocardial infarction (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.

The marketing authorisation holder (MAH) responsible for Clopidogrel ratiopharm was Archie Samuel s.r.o..

On 25 October 2013, the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel ratiopharm, following its receipt of a letter dated 10 September 2013 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Clopidogrel ratiopharm was not marketed in any European country.

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public assessment report for Clopidogrel ratiopharm will be updated to reflect that the marketing authorisation is no longer valid.

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