01 September 2014
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Human Medicines Development and Evaluation

Public statement on Clopidogrel Qualimed

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 medicinal product Clopidogrel Qualimed, generic of Plavix, which had been approved for adults 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 Qualimed was Qualimed.

On 01 September 2014, the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel Qualimed, following its receipt of a letter dated 10 August 2014 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for marketing reason.

Clopidogrel Qualimed was not marketed in any European country.

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public assessment report for Clopidogrel Qualimed will be updated to reflect that the marketing authorisation is no longer valid.

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