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Human Medicines Development and Evaluation

Public statement on

Clopidogrel 1A Pharma (clopidogrel)

Withdrawal of the marketing authorisation in the European Union

On the 28 July 2009 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Clopidogrel 1A Pharma, a medicine that contains the active substance clopidogrel, which had been approved 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.
- Patients suffering from acute coronary syndrome:

- Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA).

- ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy.

For further information please refer to section 5.1.

The marketing authorisation holder (MAH) responsible for Clopidogrel 1A Pharma was Acino Pharma GmBH. The European Commission was notified by a letter dated 20 December 2010 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Clopidogrel 1A Pharma for commercial reasons. Clopidogrel 1A Pharma was not marketed in any European country.

On 1 February 2011 the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel 1A Pharma.

Pursuant to this decision the European Public Assessment Report for Clopidogrel 1A Pharma will be updated to reflect that the marketing authorisation is no longer valid.

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