European Medicines Agency
Press office

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PRESS RELEASE
Teva Pharma B.V. withdraws its marketing authorisation application for Clopidogrel Teva Pharma (clopidogrel hydrobromide)

The European Medicines Agency has been formally notified by Teva Pharma B.V. of its decision to withdraw its application for a centralised marketing authorisation for Clopidogrel Teva Pharma (clopidogrel hydrobromide) 75 mg film-coated tablets.

Clopidogrel Teva Pharma was developed as a generic medicine to be used for the prevention of atherothrombotic events in patients who have myocardial infarction, ischaemic stroke or established peripheral arterial disease. The reference medicine for Clopidogrel Teva Pharma is Plavix (clopidogrel hydrogensuphate), which has been authorised in the European Union since July 1998.

The application for Clopidogrel Teva Pharma was submitted to the Agency on 15 July 2008. At the time of withdrawal it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that they decided not to continue this application due to their marketing strategy.

More information about Clopidogrel Teva Pharma 75 mg film-coated tablets and the state of the scientific assessment at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website after the next CHMP meeting of 26-29 May 2009.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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