European Medicines Agency

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PUBLIC STATEMENT ON

Clopidogrel BMS
(clopidogrel)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 16 July 2008 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Clopidogrel BMS, clopidogrel, which had been approved 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.

The marketing authorisation holder (MAH) responsible for Clopidogrel BMS was Bristol Myers Squibb Pharma EEIG. The European Commission was notified by letter dated 20 October 2009 of the MAH's decision to voluntarily withdraw the marketing authorisation for Clopidogrel BMS for commercial reasons.

On 12 November 2009 the European Commission issued a decision to withdraw the marketing authorisation for Clopidogrel BMS. Pursuant to this decision the European Public Assessment Report for Clopidogrel BMS will be updated to reflect that the marketing authorisation is no longer valid.

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