European Medicines Agency
Press office

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PRESS RELEASE
Sanofi Pharma Bristol-Myers Squibb SNC withdraws its marketing authorisation application for DuoPlavin

The European Medicines Agency (EMEA) has been formally notified by Sanofi Pharma Bristol-Myers Squibb SNC of its decision to withdraw its application for a centralised marketing authorisation for the medicine DuoPlavin (fixed-dose combination tablets of 75 mg clopidogrel/75 mg acetylsalicylic acid and 75 mg clopidogrel/100 mg acetylsalicylic acid). DuoPlavin was expected to be used by patients already taking clopidogrel and acetylsalicylic acid for the approved indication of prevention of atherothrombotic events in acute coronary syndrome.

The application for marketing authorisation for DuoPlavin was submitted to the EMEA on 30 May 2007. At the time of the 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 the withdrawal of DuoPlavin was based on the request of the CHMP regarding the need to document bioequivalence based on the current guideline on bioavailability and bioequivalence. The company informed in the letter that it intends to perform a new bioequivalence study measuring plasma levels of clopidogrel parent compound to address the CHMP's request but the results of that study will not be available in the timelines defined by the centralised procedure.

More information about DuoPlavin 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 shortly.

-- 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

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu