European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
DUOPLAVIN

International Nonproprietary Name (INN): ***clopidogrel / acetylsalicylic acid***

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product DuoPlavin, 75 mg clopidogrel/75 mg acetylsalicylic acid, 75mg clopidogrel/100 mg acetylsalicylic acid, film coated tablets intended for prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and acetylsalicylic acid (ASA).

The applicant for this medicinal product is Sanofi Pharma Bristol-Myers Squibb SNC.
DuoPlavin is a new fixed combination and its active substances are clopidogrel hydrogen sulphate and acetylsalicylic acid. It is a medicinal product belonging to the group of Platelet aggregation inhibitors excl. heparin (ATC Code B01AC30). Clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. ASA inhibits platelet aggregation by irreversible inhibition of prostaglandin cyclo-oxygenase and thus inhibits the generation of thromboxane A2, an inducer of platelet aggregation and vasoconstriction; this effect lasts for the life of the platelet.

The benefit with DuoPlavin is its simplification of treatment, i.e. patients need to take one instead of two tablets. The most common side effect is bleeding.

A pharmacovigilance plan for DuoPlavin as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Prevention of atherothrombotic events in adult patients already taking both clopidogrel and acetylsalicylic acid (ASA). DuoPlavin is a fixed-dose combination product for continuation of therapy in:

- 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
- ST segment elevation acute myocardial infarction in medically treated patients eligible for thrombolytic therapy."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for DuoPlavin and therefore recommends the granting of the marketing authorisation.