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

London, 18 December 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**SUMMARY OF POSITIVE OPINION***
**for**
**EFIENT**

International Nonproprietary Name (INN): ***prasugrel***

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Efient , 5 mg and 10 mg film-coated tablets intended for prophylaxis against atherothrombotic events in patients with acute coronary syndrome undergoing primary or delayed percutaneous coronary intervention. The applicant for this medicinal product is Eli Lilly.

The active substance of Efient is prasugrel; therapeutic class and ATC Code not assigned yet. Prasugrel is an inhibitor of platelet activation and aggregation through the irreversible binding of its active metabolite to the $P2Y_{12}$ class of ADP receptors on platelets. Since platelets participate in the initiation and/or evolution of thrombotic complications of atherosclerotic disease, inhibition of platelet function can result in the reduction of the rate of cardiovascular events such as death, myocardial infarction, or stroke.

The benefit of Efient, when administered with acetylsalicylic acid (75 mg to 325 mg), is the prevention of atherothrombotic events in patients with acute coronary syndrome who undergo primary or delayed percutaneous coronary intervention. Prasugrel is administered as a loading dose of 60 mg and a once daily maintenance dose of 10 mg. However, for patients at special risk ($\geq$75 years, < 60 kg), a dose reduction is strongly recommended. Following the administration of a loading dose of 60 mg, the 5 mg once daily maintenance dose is to be given. The most common side effects are bleeding, anaemia, haematoma and gastrointestinal haemorrhage.

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

The approved indication is: co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in patients with acute coronary syndrome (i.e. unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention (PCI).

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.

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

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* 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 EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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