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

London, 25 June 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ZYLLT

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

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP), having considered new information, adopted a positive opinion,*** recommending to grant a marketing authorisation for the medicinal product Zyllt, 75 mg film-coated tablets intended for prevention of atherothrombotic events in patients suffering from myocardial infarction or from acute coronary syndrome. The Applicant for this medicinal product is KRKA, d.d., Novo mesto..

The active substance of Zyllt is clopidogrel (as hydrogen sulphate), a platelet aggregation inhibitor excl. heparin medicinal product (B01AC04). Zyllt selectively inhibits the binding of ADP to its platelet receptor, and the subsequent ADP-mediated activation of the GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Biotransformation of clopidogrel is necessary to produce inhibition of platelet aggregation.

Zyllt is a generic of Plavix, which has been authorised in the EU since 15 July 1998. Studies have demonstrated the satisfactory quality of Zyllt, and its bioequivalence with Plavix. A question-and-answer document on generic medicines can be found here.

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

The approved indication is: "Clopidogrel is indicated in adults 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".

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

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