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

London, 25 June 2009
Doc. Ref. EMEA/CHMP/379470/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for

ZOPYA

International Non-proprietary Name (INN): ***clopidogrel***

On 25 June 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Zopya, 75 mg, film-coated tablets intended for use 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. The applicant for this medicinal product is Norpharm Regulatory Services Ltd.

The active substance of Zopya is clopidogrel (as hydrochloride), a platelet aggregation inhibitor excl. heparin medicinal product (B01AC04). Clopidogrel 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.

Zopya is a generic of Plavix. Studies have demonstrated the satisfactory quality of Zopya, and its bioequivalence with the reference product Plavix. A question-and-answer document on generic medicines can be found here.

The approved indication is as follows:
"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."

A pharmacovigilance plan for Zopya, 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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Zopya 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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