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

London, 24 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
OLANZAPINE MYLAN

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

On 24 July 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion**, recommending the granting of a marketing authorisation for the medicinal product Olanzapine Mylan 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg film-coated tablets intended for the treatment of schizophrenia. The applicant for this medicinal product is Generics (UK) Ltd.

The active substance of Olanzapine Mylan is olanzapine which is an atypical antipsychotic (N05AH03).
Olanzapine Mylan is a generic of Zyprexa, which has been authorised in the EU since 27 September 1996. Studies have demonstrated the satisfactory quality of Olanzapine Mylan, and its bioequivalence with Zyprexa. A question-and-answer document on generic medicines can be found here.

The approved indication is: "Olanzapine is indicated for the treatment of schizophrenia. Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response. Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder".

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 the data submitted, considers that there is a favourable benefit risk balance for Olanzapine Mylan, and therefore recommends the granting of the marketing authorisation.

* 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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