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

London, 24 September 2009
Doc.Ref. EMEA/582879/2009

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
LAMIVUDINE TEVA PHARMA B.V.

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

On 24 September 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Lamivudine Teva Pharma B.V., 150mg and 300mg, film-coated tablet, indicated as part of antiretroviral combination therapy for the treatment of HIV infected adults and children.

The applicant for this medicinal product is Teva Pharma B.V.

The active substance of Lamivudine Teva Pharma B.V. is lamivudine (J05AF05), an antiviral agent. It is a pyrimidine nucleoside analogue which is used as nucleoside reverse transcriptase inhibitor (NRTI) for the combination treatment of HIV infection.

Lamivudine Teva Pharma B.V. is a generic of Epivir, which has been authorised in the EU since 8 August 1996. Studies have demonstrated the satisfactory quality of Lamivudine Teva Pharma B.V., and its bioequivalence with Epivir. A question-and-answer document on generic medicines can be found here.

A pharmacovigilance plan for Lamivudine Teva Pharma B.V., as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Lamivudine Teva Pharma B.V. is indicated as part of antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infected adults and children. The therapy should be initiated by a physician experienced in the management of HIV infection.

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 Lamivudine Teva Pharma B.V. 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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