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

London, 23 July 2009
Doc.Ref. EMEA/CHMP/436960/2009

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

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

On 23 July 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, 100mg, film-coated tablet, intended for treatment of adult patients with chronic hepatitis B and evidence of viral replication with decompensated liver disease or with histologically documented active liver inflammation and/or fibrosis.

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

The active substance of Lamivudine Teva is lamivudine (J05AF05), an antiviral agent with a pyrimidine nucleoside analogue structure which suppresses HBV viral replication by terminating HBV DNA chain elongation.

Lamivudine Teva is a generic of Zeffix, which is part of the global marketing authorisation of the lamivudine containing reference medicinal product Epivir which has been authorised in the EU since 8 August 1996. Studies have demonstrated the satisfactory quality of Lamivudine Teva, and its bioequivalence with Epivir. A question-and-answer document on generic medicines can be found here.

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

The approved indication is: for the treatment of chronic hepatitis B in adults with:
- Compensated liver disease with evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active liver inflammation and / or fibrosis.
- Decompensated liver disease.

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 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.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu