European Medicines Agency
Evaluation of Medicines for Human Use

London, 20 March 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION[*]
for
VIREAD

International Nonproprietary Name (INN): ***tenofovir disoproxil fumarate***

On 19 March 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion[**] to recommend the variation to the terms of the marketing authorisation for the medicinal product Viread. The Marketing Authorisation Holder for this medicinal product is Gilead Sciences International Ltd.

The CHMP adopted a new indication as follows:

> "Hepatitis B infection: Viread is indicated 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 inflammation and/or fibrosis.
>
> This indication is based on histological, virological, biochemical and serological responses mainly in adult nucleoside-naïve patients with HBeAg positive and HBeAg negative chronic hepatitis B with compensated liver function."

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication(s) for Viread will be as follows[***]:

"HIV-1 infection: Viread is indicated in combination with other antiretroviral medicinal products for the treatment of HIV-1 infected adults over 18 years of age.

The demonstration of benefit of Viread in HIV-1 infection is based on results of one study in treatment-naïve patients, including patients with a high viral load (> 100,000 copies/ml) and studies in which Viread was added to stable background therapy (mainly tritherapy) in antiretroviral pre-treated patients experiencing early virological failure (< 10,000 copies/ml, with the majority of patients having < 5,000 copies/ml).

The choice of Viread to treat antiretroviral experienced patients with HIV-1 infection should be based on individual viral resistance testing and/or treatment history of patients.

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This indication is based on histological, virological, biochemical and serological responses mainly in adult nucleoside-naïve patients with HBeAg positive and HBeAg negative chronic hepatitis B with compensated liver function."

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[*] Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

[**] Marketing Authorisation Holders 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.

[***] The text in bold represents the new or the amended indication.

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