WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA417 trade name]*

emtricitabine/tenofovir disoproxil fumarate 200mg/300mg film-coated tablets

[HA417 trade name], manufactured at Mylan Laboratories Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 20 August 2010.

[HA417 trade name] is indicated in combination with at least one other antiretroviral product for the treatment of HIV-1 infection in adults and adolescents over 10 years of age and weighing at least 30 kg. [HA417 trade name] may be used for pre-exposure prophylaxis in adults and adolescents (weighing at least 35 kg) at substantial risk of HIV infection.

The active pharmaceutical ingredients (APIs) of [HA417 trade name] are the nucleoside reverse transcriptase inhibitor emtricitabine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate. The APIs have been investigated in combination therapy in several clinical trials for pre-exposure prophylaxis and in combination therapy with other antiretrovirals for the treatment of HIV, in both treatment-naïve and treatment-experienced patients.

The efficacy and safety profile of emtricitabine and tenofovir disoproxil fumarate is well established based on extensive clinical experience in the treatment of HIV/AIDS.

For details on the uses of this product and for side effects and warnings, see Part 4 of this WHOPAR (summary of product characteristics).

On the basis of data submitted and public information on the use of emtricitabine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA417 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA417 trade name] in the list of prequalified medicinal products.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
† Formerly Matrix Laboratories Limited.

Summary of Prequalification Status for [HA417 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	**20 Aug 2010**	**listed**
Quality	**20 July 2010**	**MR**
Bioequivalence	**13 Aug 2010**	**MR**
Safety, efficacy	**NA**	**NA**
GMP (re-)inspection		
API (1)	**28 May 2009**	**MR**
API (2)	**NA**	**NA**
FPP	**11 Aug 2009**	**MR**
GCP/GLP (re-)inspection	**29 May 2009**	**MR**

MR: meets requirements
NA: not applicable, not available

The table represents the status of relevant completed activities only.