WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA448 trade name]*

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

[HA448 trade name], manufactured at Hetero Labs Limited, Hyderabad, Telangana, India was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 01 September 2011.

[HA448 trade name] is indicated in combination with other antiretroviral medicinal product for the treatment of human immunodeficiency virus (HIV-1) infection in patients weighing at least 30 kg or more .Detailed information on the use of this product is described in the Summary of Product Characteristics (SmPC), which can be found in this WHOPAR.

The active pharmaceutical ingredients (APIs) of [HA448 trade name] are the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine and the nucleotide reverse transcriptase inhibitor tenofovir disoproxil fumarate.
The efficacy and safety profile of lamivudine 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 lamivudine and tenofovir disoproxil fumarate in HIV/AIDS, the team of assessors advised that [HA448 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA448 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA448 trade name]:

	Initial Acceptance	
	Date	**Outcome**
Status on PQ list	01 September 2011	listed
Quality	25 July 2011	MR
Bioequivalence	14 June 2011	MR
Safety, Efficacy	NA	MR
Inspection Status		
GMP(re-)inspection		
API	27 January 2011	MR
FPP	28 August 2009	MR
GCP (re-)inspection	NA	MR
Batch Analysis	NA	NA

MR: meets requirements
NA: not applicable, not available

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.