WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA666 trade name][1]

Lamivudine/Tenofovir Disoproxil Fumarate 300 mg/300 mg Tablets

[HA666 trade name], manufactured at Cipla Limited, Maharashtra, India was included in the WHO list of prequalified products for the treatment of HIV/AIDS on 21 December 2016.

[HA666 trade name] is indicated in combination with at least one other antiretroviral medicinal product for the treatment of human immunodeficiency virus (HIV-1) infection in patients weighing at least 30 kg. 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 [HA666 trade name] are the nucleoside reverse transcriptase inhibitor 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 [HA666 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA666 trade name] in the list of prequalified medicinal products.

Summary of Prequalification Status for [HA666 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	21 December 2016	listed
Quality	08 December 2016	MR
Bioequivalence	23 July 2016	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 March 2014	MR
API	18 September 2014	MR
API	22 August 2016	MR
API	22 August 2016	MR
FPP	14 February 2014	MR
GCP/GLP (re-)inspection	NA	NA

MR: meets requirements
NA: not applicable, not available

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