WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA525 trade name]*

Lamivudine/tenofovir disoproxil fumarate 300 mg/300 mg film-coated tablets

[HA525 trade name], manufactured at Sun Pharmaceutical Industries Limited, Himachal Pradesh, India was accepted for the WHO list of prequalified products for the treatment of HIV/AIDS on 11 September 2012.

[HA525 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 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 [HA525 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 are 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 [HA525 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA525 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

Summary of Prequalification Status for [HA525 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	11 September 2012	
Quality	30 July 2012	MR
Bioequivalence	15 August 2012	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	27 January 2011	MR
API2	18 March 2011	MR
FPP	16 March 2012	MR
GCP/GLP (re-)inspection*	NA	MR
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard]	GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification	

The table represents the status of relevant completed activities only.

Requalification	13 May 2019	MR