WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)[HA414 trade name][*]

Lamivudine/Tenofovir Disoproxil Fumarate 300mg/300 mg film coated tablets

[HA414 trade name], manufactured at [†]Mylan Laboratories Limited, Nashik, Maharashtra, India, was included in the WHO list of prequalified medicinal products for the treatment of HIV/AIDS on 30 June 2010.

[HA414 trade name] is indicated for the treatment of HIV/AIDS. 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 of [HA414 trade name] are lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg.

The efficacy and safety 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 [HA414 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA414 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA414 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	30 June 2010	listed
Quality	19 May 2010	MR
Bioequivalence	24 Sept 2009	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	28 May 2009	MR
FPP	11 Aug 2009	MR
GCP/GLP (re-)inspection	21 July 2009	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	30 September 2019	MR

[*] Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility.
[†] Formerly known as Matrix Laboratories at time of prequalification