WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

[HA593 trade name]*

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600mg/300mg/300mg Tablets

[HA593 trade name], manufactured at Cipla Limited, Maharashtra, India, was included in the WHO list of prequalified medicinal products for treatment of HIV, on 16 April 2015

[HA593 trade name] is indicated for HIV treatment. 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 [HA593 trade name] are efavirenz, lamivudine and tenofovir disoproxil fumarate.

The efficacy and safety of efavirenz, lamivudine and tenofovir disoproxil fumarate are well established based on extensive clinical experience in HIV treatment.

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 efavirenz, lamivudine and tenofovir disoproxil fumarate in HIV, the team of assessors advised that [HA593 trade name] is of acceptable quality, efficacy and safety to allow inclusion of [HA593 trade name] in the list of prequalified medicinal products.

Summary of prequalification status for [HA593 trade name]:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	16 April 2015	listed
Quality	01 April 2015	MR
Bioequivalence	08 April 2015	MR
Safety, efficacy	NA	NA
GMP (re-)inspection		
API	07 March 2014	MR*
API	22 August 2014	MR
API	18 September 2014	MR
FPP	21 February 2014	MR
GCP/GLP (re-)inspection	NA	NA

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.

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